



# 科妍生物科技股份有限公司

## SciVision Biotech Inc.

### 107年度法人說明會

研發部 專案經理  
陳俊彰 博士

## 免責聲明

本簡報及同時發佈之相關訊息所提及之預測性資訊包括營運展望、財務狀況以及業務預測等內容，乃是建立在本公司從內部與外部來源所取得的資訊基礎。本公司未來實際所可能發生的營運結果、財務狀況以及業務成果，可能與這些明示或暗示的預測性資訊有所差異。其原因可能來自於各種因素，包括但不限於價格波動、競爭情勢、國際經濟狀況、匯率波動、市場需求以及其他本公司無法掌控之風險等因素。

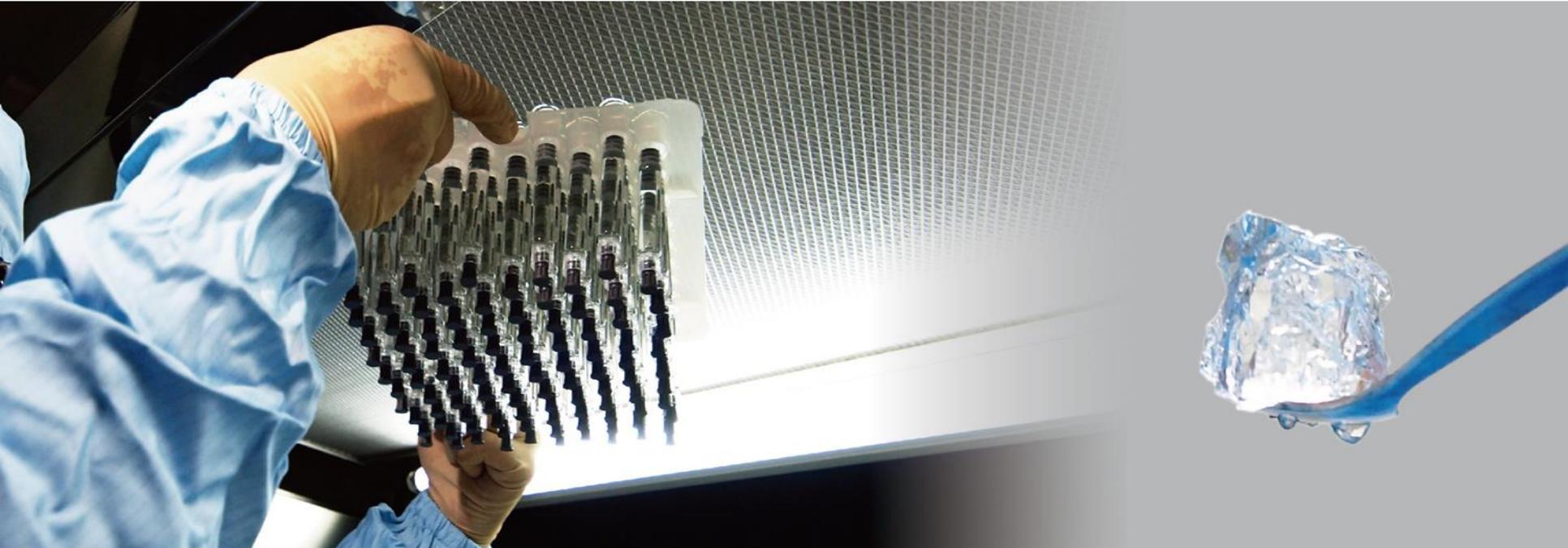
本簡報中對未來的展望，反應本公司截至目前為止對於未來的看法。對於這些看法，未來若有任何變更或調整時，本公司並不負責隨時再度提醒或更新。



# 簡報大綱

1. 公司與產品技術介紹
2. 營運現況

科妍生物科技股份有限公司  
SciVision Biotech Inc.



透明質酸技術的領導者

*The Leading Technology  
of Hyaluronic Acid ~*

*Since 2001*

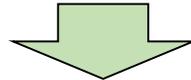
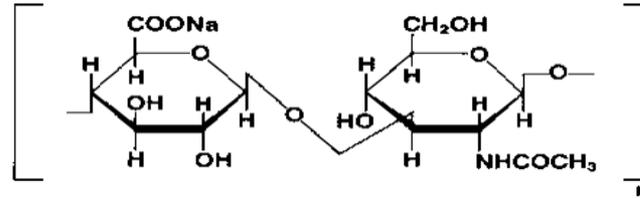
# 關於科妍



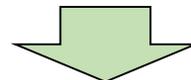
- 2013年11月12日臺灣證交所掛牌上市(股票代號1786)
- 公司定位為**專業醫藥級透明質酸高階醫療器材研發生產公司**
- 位於臺灣高雄市前鎮區高雄加工出口區南一路1號(生技一廠)與南六路9號(先導性工廠)
- 符合醫療器材品質管制系統標準(ISO 13485)、優良製造規範(cGMP)、美國食品藥物管理局(US FDA)及國際醫藥品稽查協約組織(PIC/s GMP)等之規範。
- 醫療器材產品(包含皮下填補劑、關節腔注射劑、可吸收防沾黏凝膠)年產能1,200萬支針劑



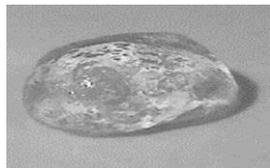
# 科妍核心技術



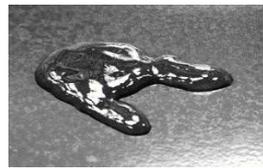
## 透明質酸交聯平臺專利技術 (Crosslinked Hyaluronic Acid Platform, CHAP<sup>®</sup>)



應用CHAP技術可做成各種  
型態及應用範疇之產品



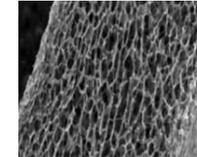
可吸收防  
沾黏凝膠



一針劑型關  
節腔注射劑



皮下填  
補劑



其他新型運用範疇產品

# CHAP<sup>®</sup> 專利涵蓋全球五大市場



**SCIVISION**  
BIOTECH INC.

## 發明專利說明書 公告本

(19) 中华人民共和国国家知识产权局

(12) 发明专利



(10) 授权公告号 CN 101724164 B  
(45) 授权公告日 2011.12.14



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(22) 申请日 2008.10.31 审查员 张娜

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(74) 专利代理机构 北京律盟知识产权代理有限公司  
代理人 刘国伟

(51) Int. Cl.  
C08L 3/24 (2006.01)  
C08L 5/08 (2006.01)  
C08K 5/15 (2006.01)

(56) 对比文件  
CN 101244290 A, 2008.08.20, 权利要求 1-5.

CN 1774272 A, 2006.05.17, 全文。  
CN 101153061 A, 2008.04.02, 全文。  
US 2007/0026070 A1, 2007.02.01, 权利要求 36-38。  
CN 101244290 A, 2008.08.20, 权利要求 1-5。

(54) 发明名称

(57) 摘要

本发明涉及一种制造交联透明质的方法。其包含在约 10℃ 至约 30℃ 的低温下使包含透明质的溶液进行交联反应约 48 小时。本发明的方法不需纯化步骤即可降低交联剂的含量。

(本說明書格式、順序及編號字、請勿任意更改，圖記號部分請勿填寫)

※ 申請案號: 97136520

※ 申請日期: 97.09.23

※ IPC 分類: C08F

※ 發明名稱: (中文/英文)

交聯透明質酸之製造方法

METHOD FOR PRODUCING CROSS-LINKED HYALURONIC ACID

二、申請人: (共 1 人)

姓名或名稱: (中文/英文)  
科研生物科技股份有限公司  
SCIVISION BIOTECH INC.

代表人: (中文/英文)  
韓開程  
HAN, KAI-CHENG

住居所或營業地址: (中文/英文)  
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9, SOUTH 6TH RD., K.E.P.Z., TAIWAN, R.O.C.

國籍: (中文/英文)  
中華民國 R.O.C.

臺灣

中國

日本



(12) United States Patent  
Chen et al.

(39) Patent No.: US 9,371,402 B2  
(47) Date of Patent: Jun. 21, 2016

(54) METHOD FOR PRODUCING CROSS-LINKED HYALURONIC ACID

(75) Inventors: Te-Chern Chen, Kaohsiung (TW); Li-Sue Chen, Kaohsiung (TW)

(73) Assignor: SCIVISION BIOTECH INC., K.E.P.Z. (TW)

(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 351 days.

(21) Appl. No.: 13/116,849

(22) Filed: Dec. 12, 2011

(65) Prior Publication Data  
US 2012/0095296 A1 Apr. 19, 2012

Related U.S. Application Data  
(63) Continuation-in-part of application No. 12/385,902, filed on Apr. 9, 2009, now abandoned.

(51) Int. Cl.  
C08F 3/08 (2006.01)

(52) U.S. Cl.  
CPC 3700/02 (2013.01)

(56) Field of Classification Search  
CPC 3700/02, 3700/03, 3700/04, 3700/05, 3700/06, 3700/07, 3700/08, 3700/09, 3700/10, 3700/11, 3700/12, 3700/13, 3700/14, 3700/15, 3700/16, 3700/17, 3700/18, 3700/19, 3700/20, 3700/21, 3700/22, 3700/23, 3700/24, 3700/25, 3700/26, 3700/27, 3700/28, 3700/29, 3700/30, 3700/31, 3700/32, 3700/33, 3700/34, 3700/35, 3700/36, 3700/37, 3700/38, 3700/39, 3700/40, 3700/41, 3700/42, 3700/43, 3700/44, 3700/45, 3700/46, 3700/47, 3700/48, 3700/49, 3700/50, 3700/51, 3700/52, 3700/53, 3700/54, 3700/55, 3700/56, 3700/57, 3700/58, 3700/59, 3700/60, 3700/61, 3700/62, 3700/63, 3700/64, 3700/65, 3700/66, 3700/67, 3700/68, 3700/69, 3700/70, 3700/71, 3700/72, 3700/73, 3700/74, 3700/75, 3700/76, 3700/77, 3700/78, 3700/79, 3700/80, 3700/81, 3700/82, 3700/83, 3700/84, 3700/85, 3700/86, 3700/87, 3700/88, 3700/89, 3700/90, 3700/91, 3700/92, 3700/93, 3700/94, 3700/95, 3700/96, 3700/97, 3700/98, 3700/99, 3700/100, 3700/101, 3700/102, 3700/103, 3700/104, 3700/105, 3700/106, 3700/107, 3700/108, 3700/109, 3700/110, 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# 科妍核心產品



## 整形美容

全球市值  
14億美元  
(2017年)



透明質酸皮下填補產品  
年複合成長率12%

## 老年照護

全球市值  
27億美元  
(2017年)



關節腔注射產品  
年複合成長率7.5%

## 手術外科

全球市值  
160億美元  
(2017年)



防沾黏產品  
年複合成長率8.9%



# 整形美容

## HYADERMIS/ FACILLE

透明質酸皮下填補劑

### 產品優勢

- ✓ 安全性高
- ✓ 膠體結構堅固
- ✓ 不易位移
- ✓ 優異粘彈性
- ✓ 有效成分足
- ✓ 抗降解能力佳

產品銷售許可證 TW、CE、CFDA



# 老年照護



## HYAJOINT

- 三針型關節腔注射劑
- 一針型關節腔注射劑



## 產品優勢

- ✓ 一針劑型
- ✓ 高安全性
- ✓ 長效性
- ✓ 高舒適感
- ✓ 無需過度注射



產品銷售許可證 TW、CE

## Comparison of Single Intra-Articular Injection of Novel Hyaluronan (HYA-JOINT Plus) with Synvisc-One for Knee Osteoarthritis

A Randomized, Controlled, Double-Blind Trial of Efficacy and Safety

Shu-Fen Sun, MD, Chien-Wei Hsu, MD, Huey-Shyan Lin, PhD, I-Hsiu Liou, MD, Yin-Han Chen, MD, and Chia-Ling Hung, MD

Investigation performed at the Kaohsiung Veterans General Hospital, Kaohsiung City, Taiwan

**Background:** Viscosupplementation has been widely used for the treatment of knee osteoarthritis. Because we found no well-controlled trial comparing single-injection regimens of hyaluronan for knee osteoarthritis, we compared the efficacy and safety of a single intra-articular injection of a novel cross-linked hyaluronan (HYA-JOINT Plus) with a single injection of Synvisc-One in patients with knee osteoarthritis.

**Methods:** In a prospective, randomized, controlled, double-blind trial with a 6-month follow-up, 132 patients with knee osteoarthritis (Kellgren-Lawrence grade 2 or 3) were randomized to receive 1 intra-articular injection of 3 mL of HYA-JOINT Plus (20 mg/mL) (n = 66) or 6 mL of Synvisc-One (8 mg/mL) (n = 66). The primary outcome was the change from baseline in the visual analog scale (VAS) (0 to 100 mm) pain score at 6 months. Secondary outcome measures included the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC, Likert scale), Lequesne index, timed "Up & Go" (TUG) test, single-limb stance (SLS) test, use of rescue analgesics, and patient satisfaction.

**Results:** A total of 121 patients were available for the intention to treat analysis at 6 months. Both groups had a significant improvement in the VAS, WOMAC, and Lequesne index scores at each follow-up visit ( $p < 0.001$ ). Patients who received HYA-JOINT Plus experienced a significantly greater improvement in the VAS pain score at 1, 3, and 6 months compared with those treated with Synvisc-One (adjusted mean difference:  $-12.0$ ,  $-8.5$ , and  $-6.6$ ;  $p = 0.001$ ,  $0.033$ , and  $0.045$ , respectively). There were no significant between-group differences in any of the secondary outcomes except the WOMAC stiffness scores at 6 months, which favored HYA-JOINT Plus treatment ( $p = 0.043$ ). The TUG time did not change significantly in either group during the study ( $p > 0.05$ ), but the SLS time improved significantly in both the HYA-JOINT Plus and the Synvisc-One group ( $p = 0.004$  and  $p = 0.022$ , respectively). No significant between-group differences were observed with respect to patient satisfaction or consumption of analgesics. No serious adverse events occurred following the injections.

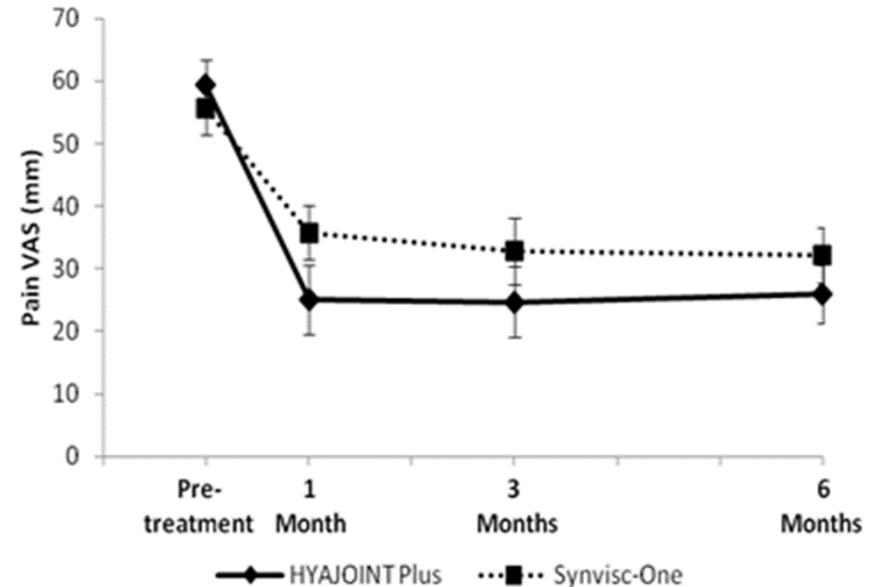
**Conclusions:** A single injection of either HYA-JOINT Plus or Synvisc-One is safe and effective for 6 months in patients with knee osteoarthritis. HYA-JOINT Plus is superior to Synvisc-One in terms of reducing the VAS pain score at 1, 3, and 6 months and the WOMAC stiffness score at 6 months, with similar safety.

**Level of Evidence:** Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

**Peer Review:** This article was reviewed by the Editor-in-Chief and one Deputy Editor, and it underwent blinded review by two or more outside experts. It was also reviewed by an expert in methodology and statistics. The Deputy Editor reviewed each revision of the article, and it underwent a final review by the Editor-in-Chief prior to publication. Final corrections and clarifications occurred during one or more exchanges between the author(s) and copyeditors.

Viscosupplementation with hyaluronan is a well-established treatment option for knee osteoarthritis. The goal of viscosupplementation is to reduce pain and improve viscoelasticity of synovial fluid<sup>1,2</sup>. Hyaluronan may provide biological actions, including anti-inflammatory, antinociceptive, and anabolic effects<sup>3,4</sup>. Moreover, it has been known to

**Disclosure:** The study was sponsored by SciVision Biotech Corporation, the manufacturer of HYA-JOINT Plus. One author (S.-F.S.) received funding from the SciVision Biotech Corporation. Funds were used to pay for consultancy in study planning, and realization. The funding source was not involved in patient enrollment, data collection, data analysis, or manuscript preparation. The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (<http://links.lww.com/JBJS/A147>).



# 婦科骨盆腔手術外科



## PROTAHERE 玻達癒 可吸收防沾黏凝膠

### 產品優勢

- ✓ 生物相容性高
- ✓ 操作方便迅速
- ✓ 黏附性高



產品銷售許可證 TW (2017年取得銷售許可，2018年產品上市)

# 婦科骨盆腔手術外科 防粘黏產品趨勢

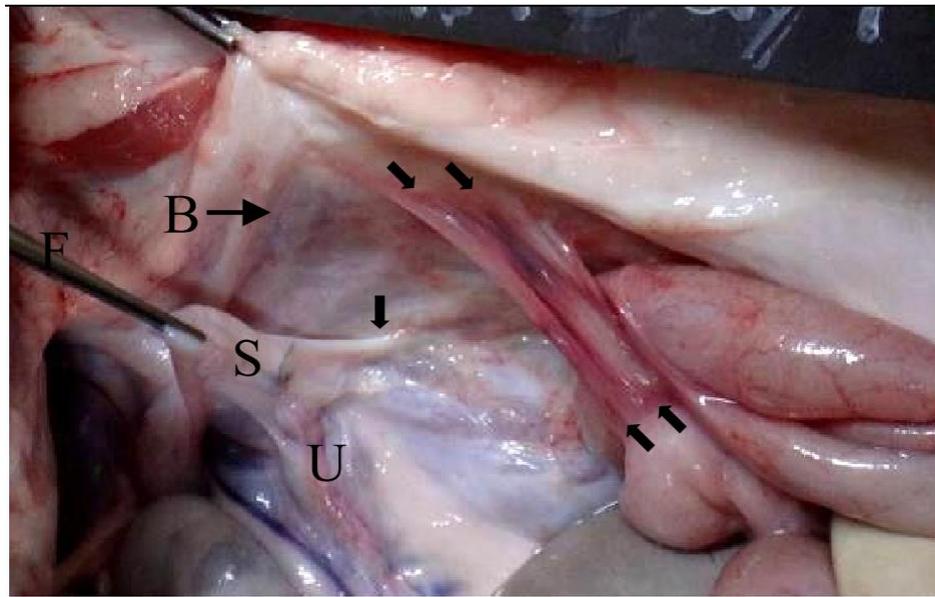


產品	P品牌	S品牌	I品牌	S品牌	H品牌	PROTAHERE
公司	G公司	M公司	J公司	S公司	F公司	SCIVISION (科妍)
材質	拉伸性 鐵氟龍 (ePTFE)	聚乳酸 (polylactic acid)	氧化再生 纖維素 (ORC)	HA交聯羧甲基 纖維素 (HA-CMC)	交聯透明質酸 (cross-linked HA)	交聯透明質酸 (cross-linked HA)
型態	薄膜	薄膜	薄膜	薄膜	凝膠	凝膠 <b>勝</b>
吸收性	-	☉	☉☉	☉☉☉	☉☉☉☉	☉☉☉☉☉ <b>勝</b>
操作性	☉	☉☉	☉☉	☉☉☉	☉☉☉☉	☉☉☉☉☉ <b>勝</b>
黏附性	☉	☉	☉	☉☉	☉☉☉	☉☉☉☉☉ <b>勝</b>
備註	1. 需縫合 2. 不可吸收 3. 需二次手術取出	1. 需縫合 2. 不易吸收	不易使用於 腹腔鏡手術	不易使用於腹 腔鏡手術	1. 可吸收 2. 操作方便 3. 黏附性普通	1. 可吸收 2. 操作方便 3. 黏附性佳

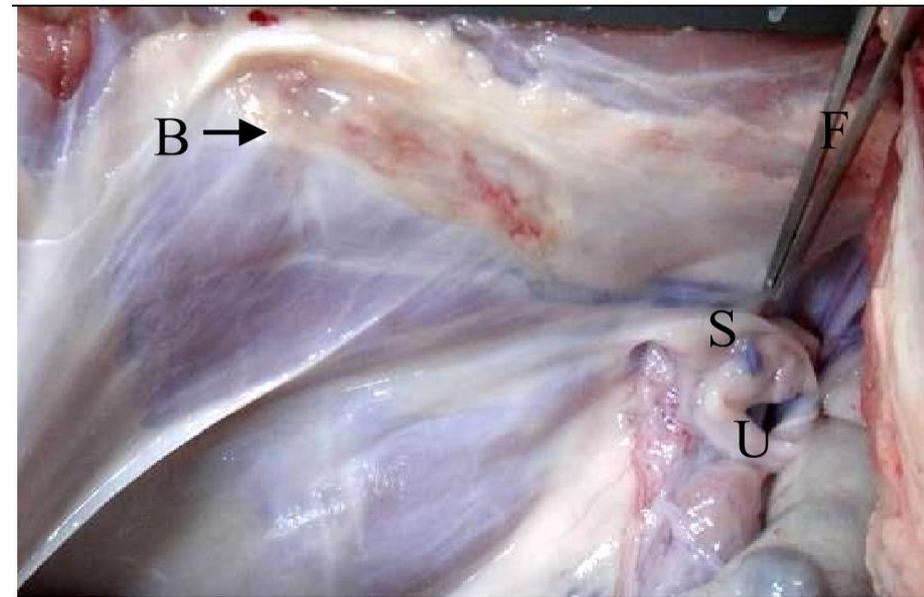
# PROTAHERE 玻達癒 具顯著的防沾黏功效



對照組(未使用)



使用PROTAHERE

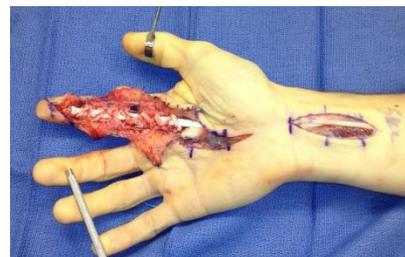


# 韌帶、周邊神經、關節手術外科



**DEFEHERE 德撫癒**

可吸收防沾黏凝膠



## 產品優勢

- ✓ 生物相容性高
- ✓ 操作方便迅速
- ✓ 黏附性高
- ✓ 有效保護時間長



產品銷售許可證 TW (2018年取得銷售許可，產品即將上市)



# 韌帶、周邊神經、關節手術外科 防粘黏產品趨勢

產品	F品牌	H品牌	德撫癒 DEFEREHERE
公司	M公司	A公司	SCIVISION (科妍)
材質	氧化聚乙烯(PEO)及羧 甲基纖維素鈉(CMC)	交聯透明質酸 (cross-linked HA)	交聯透明質酸 (cross-linked HA)
型態	凝膠	凝膠	凝膠
生物相容性	☺☺	☺☺☺☺	☺☺☺☺ <b>勝</b>
抗降解能力	☺☺☺☺ <b>勝</b>	☺☺	☺☺☺
適應症	☺	☺☺☺☺	☺☺☺☺ <b>勝</b>

# 合併上半年度損益表

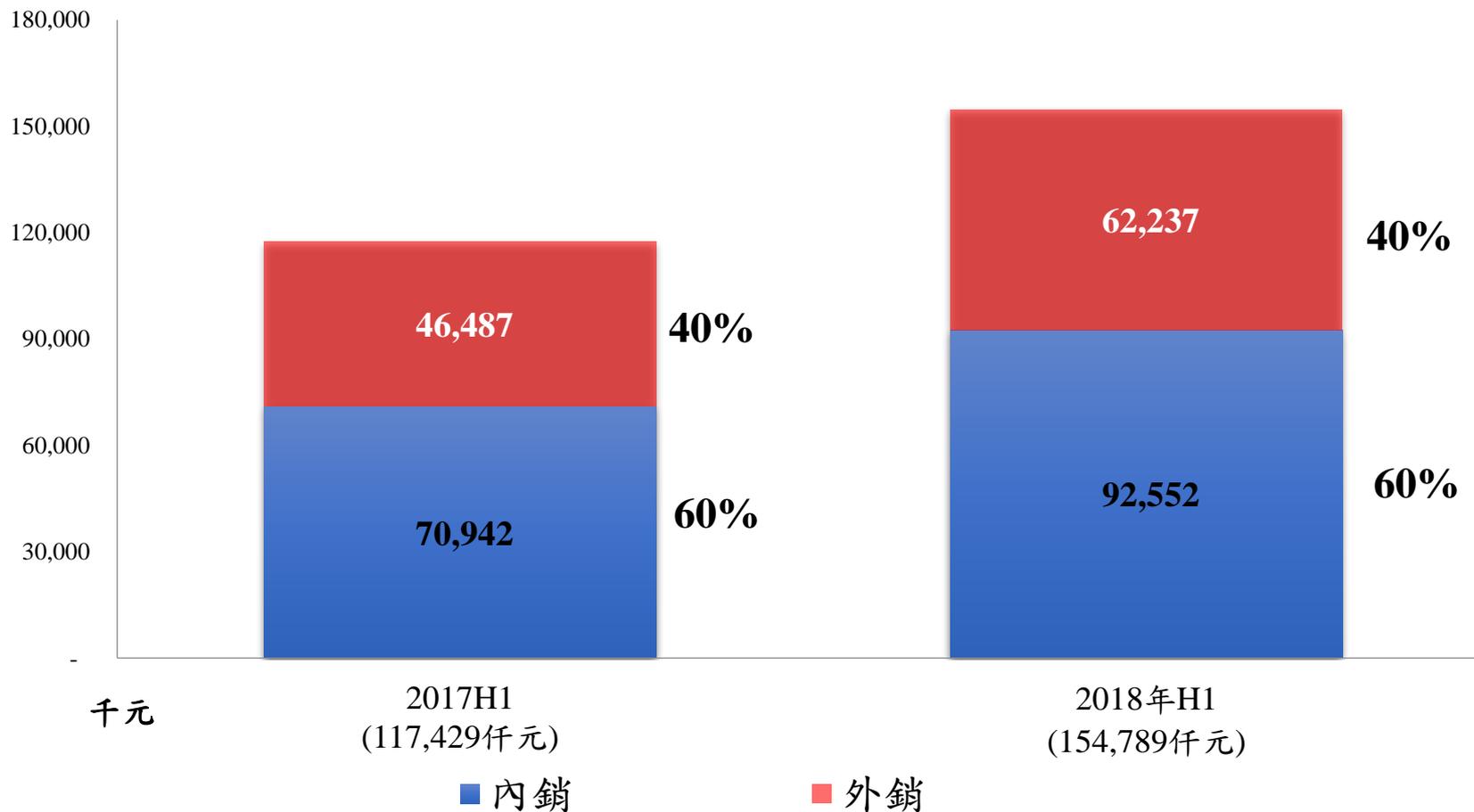
單位：新台幣仟元  
(除每股盈餘外)

	H1, '18 (核閱)		H1, '17 (核閱)		年成長
營業收入	154,789	100%	117,429	100%	31.8%
營業成本	(48,374)	-31%	(51,720)	-44%	-6.5%
營業毛利	106,415	69%	65,709	56%	61.9%
營業費用	(65,829)	-43%	(60,290)	-51%	9.2%
營業淨利	40,586	26%	5,419	5%	649.0%
營業外收(支)	2,872	2%	(6,617)	-6%	143.4%
稅前淨利	43,458	28%	(1,198)	-1%	3727.5%
稅後淨利	39,196	25%	(1,198)	-1%	3371.8%
每股盈餘(新台幣元)	0.76		(0.02)		

# 內外銷比重

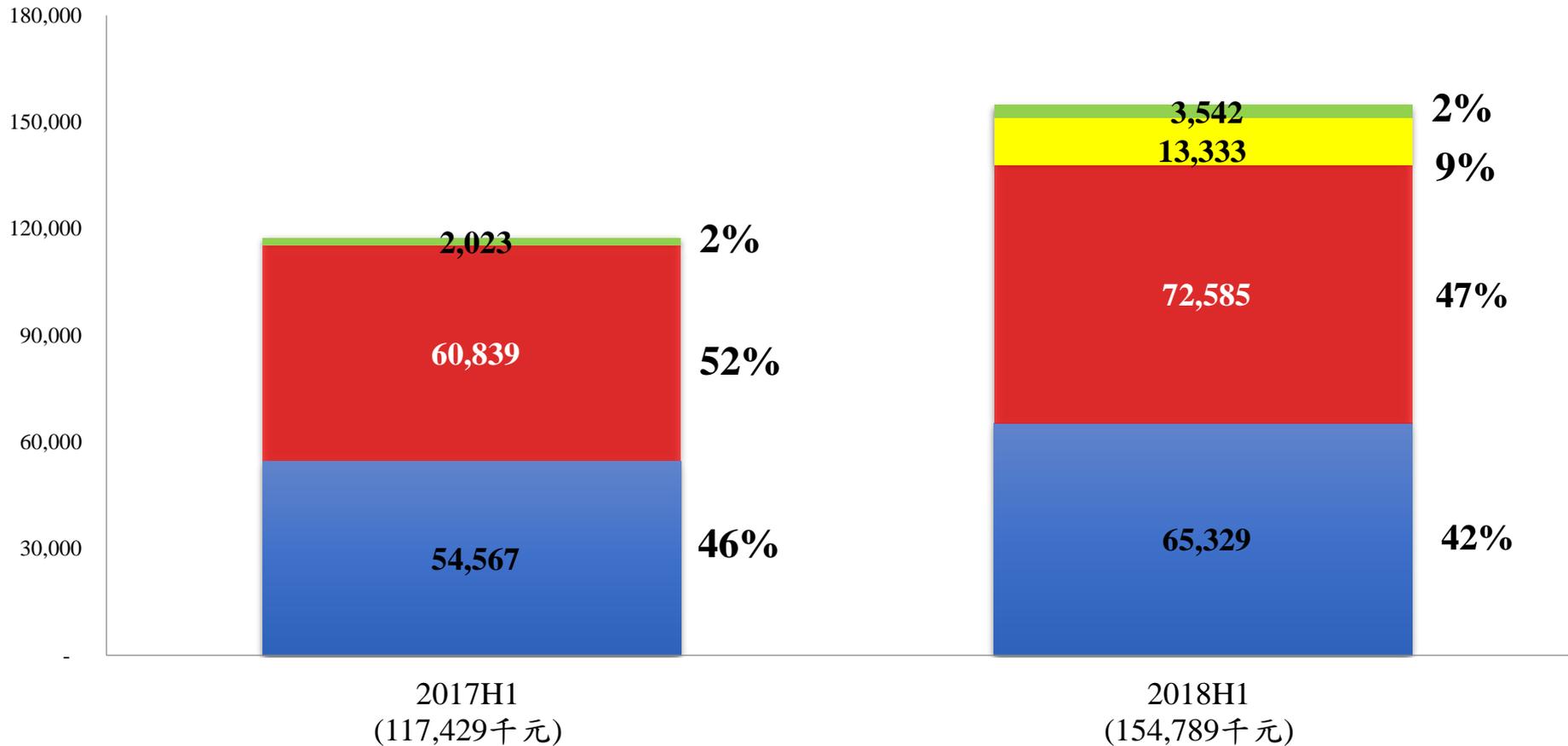


## 2017H1及2018H1



# 產品別營收與比重

## 2017H1及2018H1



■ 皮下填補劑 ■ 關節腔注射劑 ■ 可吸收防沾黏凝膠 ■ 其他

# 科妍主要客戶



# 合併資產負債表

單位：新台幣仟元

	2018/6/30 (核閱數)		2017/6/30 (核閱數)	
現金及約當現金	396,584	24%	419,827	28%
應收帳款	35,163	2%	41,443	3%
存貨	34,165	2%	39,966	3%
透過其他綜合損益按 公允價值衡量之金融資產	3,650	0%	3,801	0%
以成本衡量之金融資產	-	0%	8,925	1%
不動產、廠房及設備	1,022,699	63%	863,955	57%
其他流動及非流動資產	128,662	8%	132,487	9%
<b>資產總額</b>	<b>1,620,923</b>	<b>100%</b>	<b>1,510,404</b>	<b>100%</b>
流動負債	227,617	14%	225,345	15%
長期負債及其他負債	451,321	28%	392,817	26%
<b>負債總額</b>	<b>678,938</b>	<b>42%</b>	<b>618,162</b>	<b>41%</b>
<b>股東權益總額</b>	<b>941,985</b>	<b>58%</b>	<b>892,242</b>	<b>59%</b>
<b>重要財務指標</b>				
平均收現日數	50.95		68.34	
平均銷貨日數	125.97		130.75	
流動比率(倍)	221.09		238.15	
股東權益報酬率(%)	4.22%		-0.13%	

# 合併現金流量表

單位: 新台幣仟元

	H1, '18 (核閱)	H1, '17 (核閱)
營業活動之現金流入(出)	74,692	(9,987)
稅前淨利	43,458	(1,198)
折舊	9,626	9,979
營運資金變動及其他	21,608	(18,768)
投資活動之現金流入(出)	(7,746)	(66,095)
處分透過損益按公允價值 衡量之金額資產價款	6,811	127,512
購買不動產、廠房及設備	(14,557)	(189,481)
籌資活動之現金流入(出)	(470)	162,952
短期借款增加(減少)	0	40,405
長期借款增加(減少)	(470)	122,547
本期現金及約當現金增加數	66,496	85,630
期初現金及約當現金餘額	330,088	334,197
期末現金及約當現金餘額	396,584	419,827
自由現金流量	60,135	(199,468)

# 願景與展望



## 科妍願景

以現代化科學為基礎，創造人類更美好的願景

**Science Creates Better Visions**

## 未來展望

透明質酸產品尖端品牌

成為全球市場客戶最佳選擇

謝謝聆聽