



SciVision Biotech Inc.

**Inventor Conference
2017**

**Dr. Chun Chang Chen
Project Manager | R&D Dept**

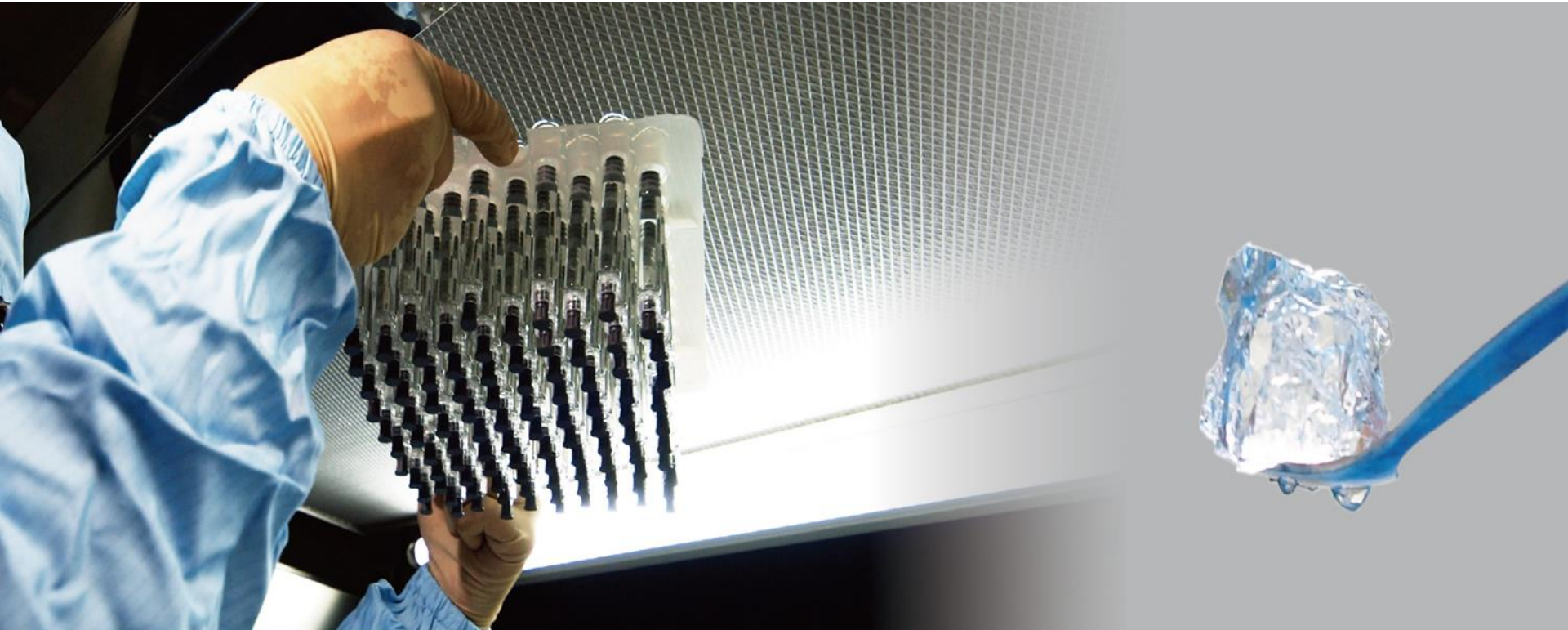
Disclaimer

This slide contains our business prospect, financial condition and sales prognosis which are derived from our existing internal/external data analysis. The actual result of operations may differ from the expressed or implied in these forward-looking statements due to various reasons, including but not limited to price fluctuation, competition, global economic condition, exchange rate fluctuation, market demand or other risks that beyond our control. The forward-looking statement in this release reflect the current belief of SciVision at this point and SciVision undertakes no obligation to update these statements with new information or future events.

Outline

- 1. Company & Product Overview**
- 2. Business Operation**

SciVision Biotech Inc.



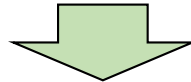
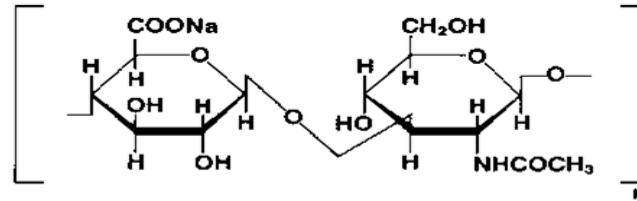
*The Leading Technology
of Hyaluronic Acid ~*

Company Profile

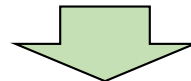


- **Founded on 12th November 2001**
- **Listed on TSE on 12th November 2013 (Code: 1786)**
- **Oriented as Professional in pharmaceutical grade Hyaluronic Acid production**
- **Located at No.6, South Sixth Rd. & No.6, South First Rd. in Kaohsiung Export Processing Zone, Taiwan**
- **Factory covers an area of 19,781.85 m² (5,984 Taiwanese ping)**
- **Factory facilities & equipment conforms to ISO 13485, cGMP, US FDA and PIC/s GMP standards**
- **Produces 12 million syringes of medical device (including dermal filler, synovial fluid supplement and adhesion barrier) annually**

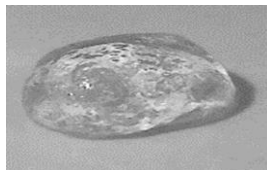
Core Technology



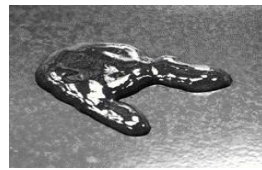
(Crosslinked Hyaluronic Acid Platform, CHAP[®])



CHAP technology can be widely used on various products



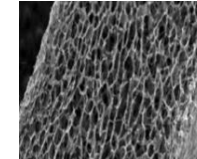
**Absorbable
adhesion
barrier**



**Single
injection
viscosuppl-
ement**



**Dermal
filler**



Other novel applications

Invention Patent

(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

(21) 申请号 200810172328.6 1-5.
(22) 申请日 2008.10.31 审查员 张娜
(73) 专利权人 科妍生物科技股份有限公司
地址 中国台湾高雄市
(72) 发明人 陈拓成 陈丽凤
(74) 专利代理机构 北京律盟知识产权代理有限公司
责任公司 11287
代理人 刘国伟

(51) Int. Cl.
C08J 3/24 (2006.01)
C08L 5/08 (2006.01)
C08K 5/1515 (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

(54) 发明名称
交联透明质酸的制造方法
(57) 摘要

本发明涉及一种制造交联透明质酸的方法，其包含在约 10℃ 至约 30℃ 的低温下使包含透明质酸的溶液进行交联反应超过约 18 小时，本发明的方法不需纯化步骤即可降低交联剂的含量。

China

(12) United States Patent
Chen et al.



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

(54) METHOD FOR PRODUCING CROSS-LINKED HYALURONIC ACID
(75) Inventors: Tor-Chern Chen, Kaohsiung (TW); Li-Su Chen, Kaohsiung (TW)
(73) Assignee: 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.: 13916449
(22) Filed: Dec. 12, 2011
(55) Prior Publication Data
US 2012/0005206 A1 Apr. 19, 2012
Related U.S. Application Data
(63) Continuation-in-part of application No. 12/385,502, filed on Apr. 9, 2009, now abandoned.
(51) Int. Cl. C08J 3/08 (2006.01)
(52) U.S. Cl. C08J 3/08; C08B 1/506; A61K 8/73; CPC: C08J 3/0872 (2013.01)
(58) Field of Classification Search
CPC: C08J 3/08; C08B 1/506; A61K 8/73; See application file for complete search history.
(56) References Cited
U.S. PATENT DOCUMENTS

Int'l. A. & Fushikami, G. H. (2005). The science of hyaluronic acid dermal fillers. *Journal of Cosmetic and Laser Therapy*, 9(1), 35-42.
U.S. 8,868,070, 9/19/08, Mono-Gain (withdrawn).
Y. Takita et al., Hydrolytic degradation of hyaluronic acid, *Polymer Degradation and Stability*, 1995, pp. 269-275, vol. 68.
Hsu, J.C.F., Noh, et al., A Neutron Fluorescence Procedure for the Determination of Aliphatic Epoxide under Physiological Conditions, *Analytical Biochemistry*, 1981, pp. 153-157, vol. 111.
European Search Report for 09904541.8-2115, which is a corresponding application, that cites US2002/0497291, and U.S. Pat. No. 6,736,154, EP 1810344, US 2000/240127, EP 0970906, Jinghua et al., Characteristics of Polyhemic acid derivative film cross-linked by polyethylene glycol of low water content, *Journal of Medical College of PLA, Shanghai, CN, Feb. 1, 2009, pp. 15-15, No. 1*, and Tomihata, K. et al., Preparation of cross-linked hyaluronic acid film of low water content, *Biomaterials*, Feb. 1, 1997, pp. 189-195, vol. 18, No. 3.
European Office Action for 09904541.8-2115, which is a corresponding European application.
Chinese Office Action dated Jan. 30, 2011 for 200810172328.6, which is a corresponding Chinese application, that cites CN 101244290, and US 2007/0026070.
Chinese Office Action dated Jul. 1, 2011 for 200810172328.6, which is a corresponding Chinese application.
Jinghua et al., Characteristics of hyaluronic acid derivative film cross-linked by polyethylene glycol of low water content, *Journal of Medical College of PLA, Shanghai, CN, Feb. 1, 2008, pp. 15-15, vol. 23, No. 1*.
Tomihata, K. et al., Preparation of cross-linked hyaluronic acid film of low water content, *Biomaterials*, Feb. 1, 1997, pp. 189-195, vol. 18, No. 3.
Office Action issued on Oct. 23, 2012 of the corresponding JP patent application No. 2009-219164 (cite WO 2006/011950), JP 60-210101, JP 1007-02092, and JP 1002-13049.
English abstract of Office Action issued on Oct. 23, 2012 of the corresponding JP patent application No. 2009-219164.
English abstract of WO 2006/011950 on 06/23/2006.

United States

發明專利說明書 公告本

(本說明書格式、序頁及編號字、請勿任意更改，※記號請勿填寫)

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※申請日期：97.09.23
※IPC分類：C08J 3/08 (2006.01)
C08L 5/08 (2006.01)

一、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)

科妍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

住居所或營業所地址：(中文/英文)

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國籍：(中文/英文)

中華民國 R.O.C.

Taiwan

(18) 日本國際特許 (IP) (12) 特許公報 (32) (11) 特許案號

(45) 特許公告日 平成 25 年 11 月 13 日 (2013.11.13) (43) 登錄日 平成 25 年 8 月 16 日 (2013.8.16) 特許案號 5340093 局 (P340093)

(51) Int. Cl. C08J 3/08 (2006.01) F1 C08B 37/08 Z

請求項的數 19 外國語別錄 (案 20 頁)	
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(22) 出願日	平成 21 年 8 月 16 日 (2009.8.16)
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(43) 公開日	平成 22 年 4 月 8 日 (2010.4.8)
優先權案號	平成 22 年 9 月 7 日 (2010.9.7)
(31) 優先權主案號	09713620
(32) 優先日	平成 20 年 9 月 23 日 (2008.9.23)
(53) 優先權主案國	台灣 (TW)
(73) 特許權人	科妍生物科技股份有限公司 台灣高雄市前鎮區高雄出口工業區南六路 9 號
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(72) 發明者	陳拓成 台灣屏東市新興路 3 鄰合順路 1 7 4 巷 6 號

(54) 【發明名稱】 製備ヒアルロン酸の製造方法

(51) 【特許請求の範囲】

【請求項 1】
アルカリ条件において、セ氏 10〜30 度の低温で、4 8 時間以上の反応時間をかけて 1 種類又は複数種類のポリマーと架橋剤とを架橋結合させることにより、架橋ヒアルロン酸を形成させるステップを有し、該ポリマーは、ヒアルロン酸、ヒアルロン酸塩、ヒアルロン酸とセロキシ基を有する多糖類との混合物、及びヒアルロン酸塩とヒドロキシ基を有する多糖類との混合物からなる群より選択されるものであり、
前記低温で架橋結合を行うステップの前に、さらに、セ氏 35〜60 度の高温で架橋結合反応を行うステップを有し、さらに、
ヒドロキシ基を有する前記多糖類が、カルボキシメチルセルロース (CMC)、アルギン酸、コンドロイチン-4-サルフェート、コンドロイチン-6-サルフェート、キサンタンガム、キトサン、ペクチン、琼脂、カウゼラン、グアルガムからなる群より選択されるものであることを特徴とする製備ヒアルロン酸の製造方法。
【請求項 2】
前記ヒアルロン酸塩がヒアルロンナトリウム、ヒアルロンカリウム、ヒアルロン酸亜鉛からなる群より選択されるものであることを特徴とする請求項 1 に記載の製備ヒアルロン酸の製造方法。
【請求項 3】
前記アルカリ条件が 0.05〜1.5N' であることを特徴とする請求項 1 に記載の製



(19) European Patent Office



(11) EP 2 236 523 A1

(12) EUROPEAN PATENT APPLICATION

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(84) Designated Contracting States:
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Designated Extension States:
AL BA RS

(71) Applicant: Scivision Biotech Inc.
Kaohsiung Export Processing Zone
Glanzhien D Kaohsiung (TW)

(54) Method for producing cross-linked hyaluronic acid

(57) A method for producing cross-linked hyaluronic acid comprising cross-linking one or more polymers at a low temperature from 10 to 30 °C for a reaction time greater than 48 hours under basic condition with a cross-linking agent to form a cross-linked hyaluronic acid, wherein the polymer is selected from the group consisting of hy-

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Pingtung (TW)
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Nanzi District (TW)

(74) Representative: Hauck Patent- und Rechtsanwälte
Neuer Wall 50
20354 Hamburg (DE)

aluronic acid, hyaluronate, derivatives thereof and a mixture thereof. Whereby, a cross-linking agent present in a product of the method is decreased so the product does not require purification.

EU

International Strategic Alliance



雀巢®



Nestlé®



曜亞國際股份有限公司
DYNAMIC MEDICAL TECHNOLOGIES INC.



Product Launch

Osteoarthritis Improvement

- Improvement of cartilage cell metabolism
- Inhibition of inflammation
- Promotion of synovial fluid biosynthesis



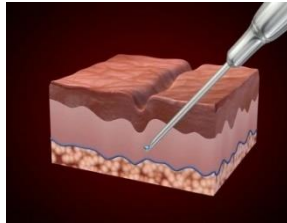
SciVision Biotech Inc.

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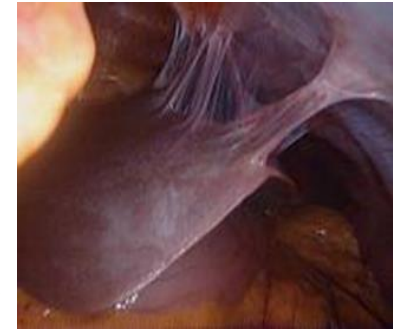


Geriatrics care- Viscosupplement



Facial Aesthetics

-Dermal Filler



Surgery

-Absorbable Adhesion Barrier

Potential and Advantage of Our Products

**1.3 billion of
global market value
In 2016**



HA Dermal Filler

CAGR: 12%

**2.5 billion of
global market value
In 2016**



Viscosupplement

CAGR: 7.5%

**2.4 billion of
global market value
In 2016**



Absorbable Adhesion Barrier

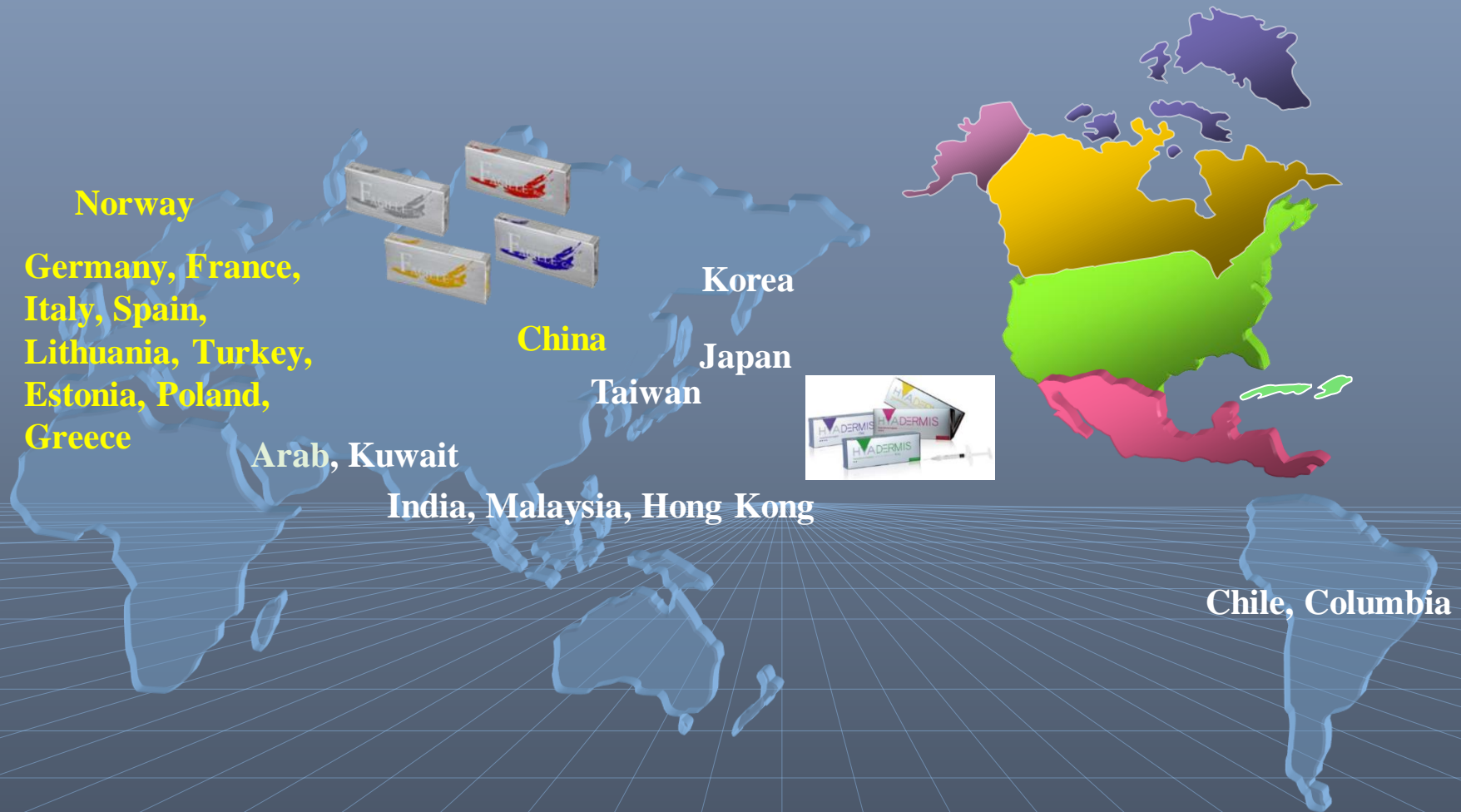
CAGR: 8.9%

Facial Aesthetics -HA Dermal Filler

● Blink 亮眼 ● Kiss 輕吻 ● Smile 微笑 ● Chic 別緻

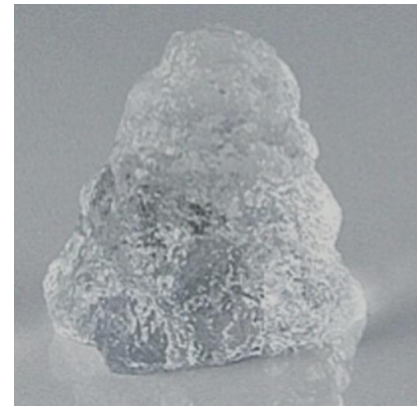


Sales Territories



HYADERMIS/ FACILLE

HA Dermal Filler

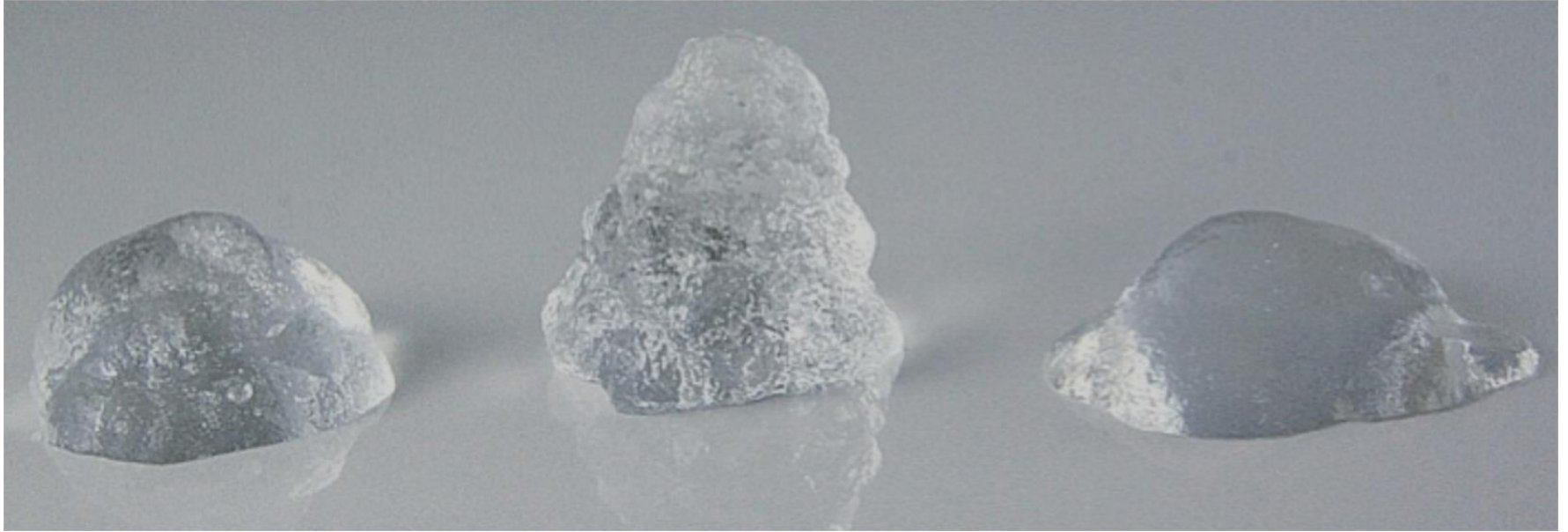


Features

- ✓ High safety performance
- ✓ Strong structural support
- ✓ Lasting effect
- ✓ Excellent viscosity
- ✓ High proportion of active ingredient
- ✓ Superior degradation resistance



Strong structural support



Competitor 1

Our Product

Competitor 2

Geriatrics care

- Single Injection Viscosupplement



Osteoarthritis Improvement

- Improvement of cartilage cell metabolism
- Inhibition of inflammation
- Promotion of synovial fluid biosynthesis



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Viscosupplements



5 Injection type:

Inject for consecutive 5 weeks/ last for six months

3 Injection type:

Inject for consecutive 3 weeks/ last for six months

Single Injection type:

Single injection/ last for a whole year



Sales Territories

Germany, France,
Netherlands, Belgium,
Luxembourg, Spain,
Lithuania, Poland, Turkey,
Romania, Estonia, Greece

Jordan,
Saudi Arabia, Qatar

Taiwan

India, Malaysia,
Myanmar

Australia

Chile

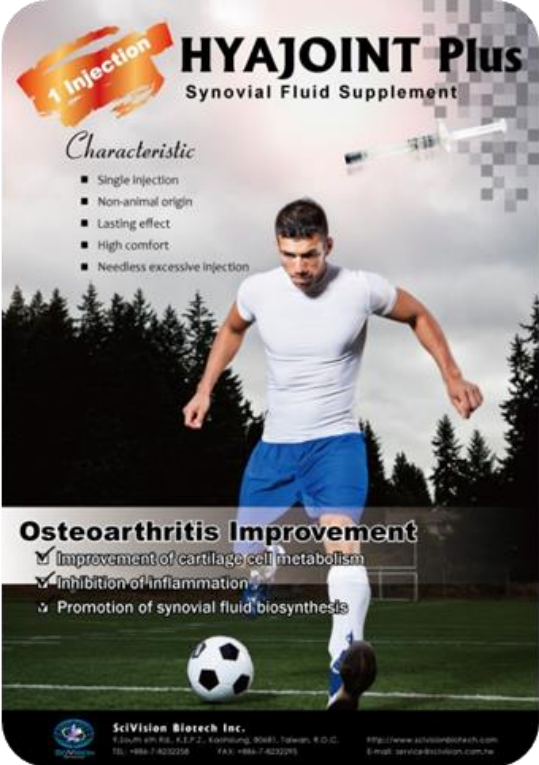


HYAJOINT Plus / HYAFELIC Uno

Single Injection Viscosupplement

Features

- ✓ Single Injection
- ✓ High Security Performance
- ✓ Long Lasting Effect
- ✓ High Comfort
- ✓ Needless of Excessive Injection



1 Injection **HYAJoint Plus**
Synovial Fluid Supplement

Characteristic

- Single Injection
- Non-animal origin
- Lasting effect
- High comfort
- Needless excessive Injection

Osteoarthritis Improvement

- ✓ Improvement of cartilage cell metabolism
- ✓ Inhibition of inflammation
- ✓ Promotion of synovial fluid biosynthesis

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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^{1,2}. Hyaluronan may provide biological actions, including anti-inflammatory, antinociceptive, and anabolic effects³⁻⁶. 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>).



HYAJOINT Plus

VS



Synvisc-One

Our product performs better in pain relieving

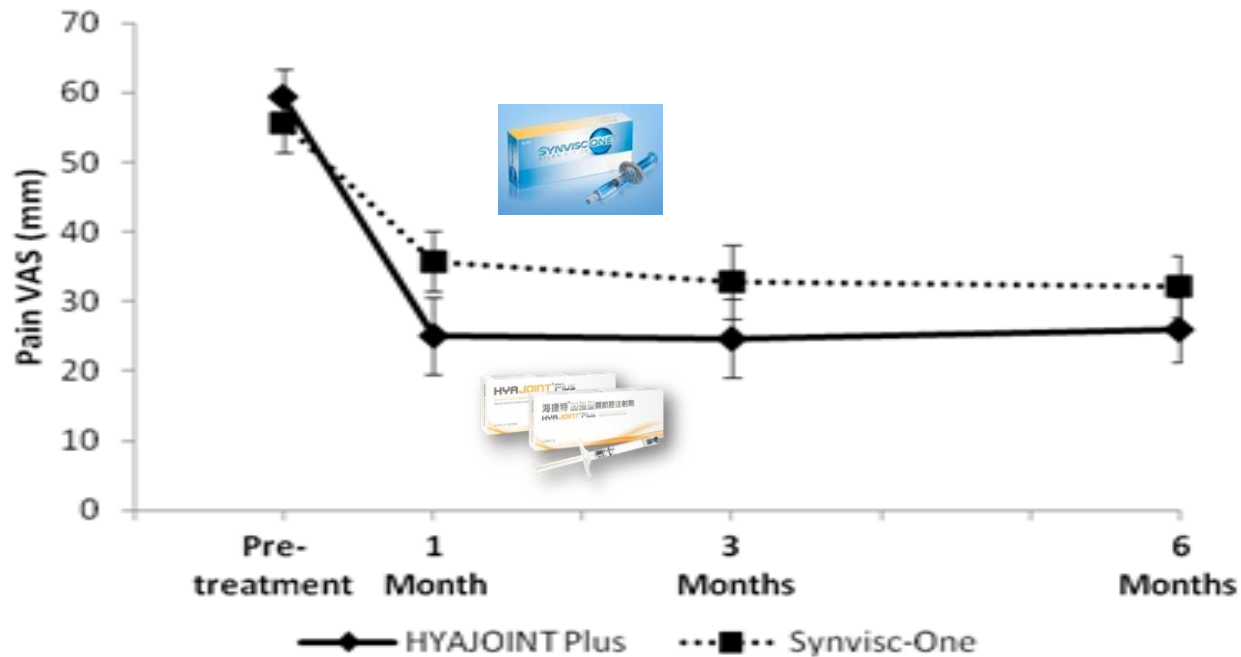


TABLE III Comparison of VAS, WOMAC, and Lequesne Index Scores Between Groups

	HYA-JOINT Plus*	Synvisc-One*	Adjusted Mean Difference (95% Confidence Interval)	P Value†
VAS score (mm)				
Baseline	59.3 ± 15.8	55.7 ± 16.4		0.212
1 mo	25.1 ± 18.4	35.8 ± 22.1	-12.0 (-19.1, -5.0)	0.001‡
3 mo	24.7 ± 19.0	32.9 ± 24.0	-8.5 (-16.4, -0.7)	0.033‡
6 mo	26.0 ± 15.6	32.3 ± 19.6	-6.6 (-13.0, -0.2)	0.045‡
P value§	<0.001‡	<0.001‡		

Our product performs better in improving serious OA symptom

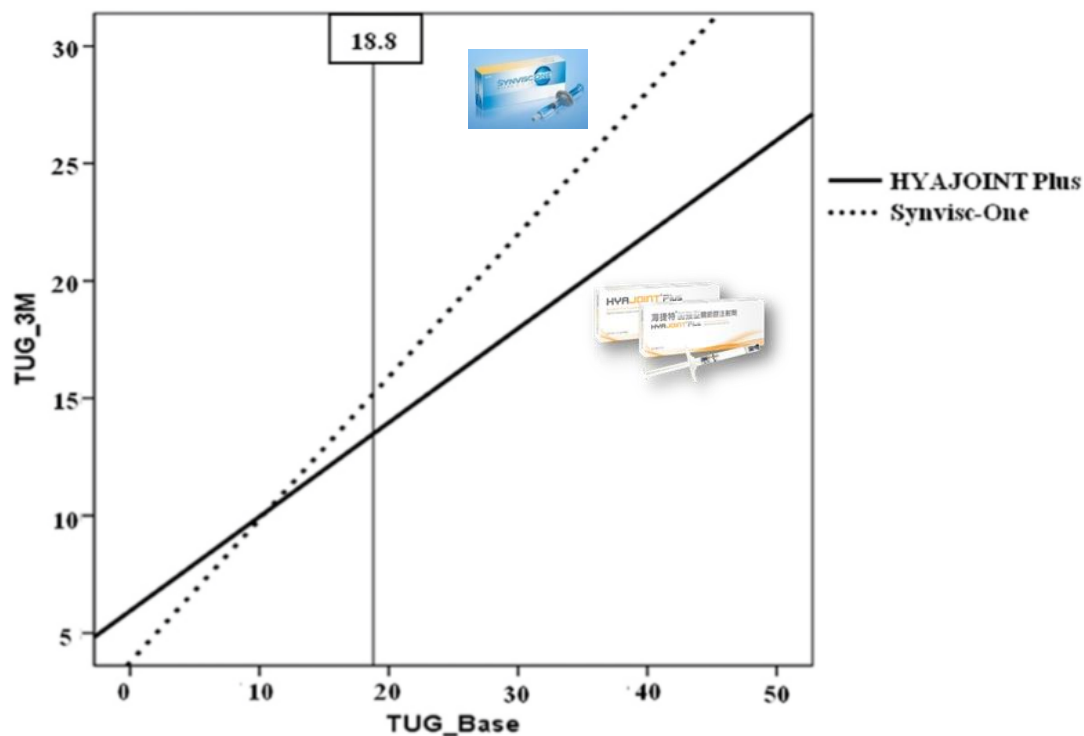


TABLE IV Comparison of TUG and SLS Times Between Groups

	HYA-JOINT Plus*	Synvisc-One*	P Value†
TUG time (sec)			
Baseline	12.3 ± 8.7	12.6 ± 13.3	0.902
1 mo	11.2 ± 6.1	10.4 ± 3.9	0.925
3 mo	10.9 ± 4.3	10.4 ± 3.7	HYA-JOINT Plus superior when baseline >18.8 sec
6 mo	11.1 ± 5.0	11.4 ± 5.6	
P value‡	0.078	0.23	0.145

Surgery

-Absorbable Adhesion Barrier



Trends of Anti-adhesion Product

Major ingredient Evaluated item	Rubber / silicone for medical use	PLA	Chitosan	ORC	Sodium Hyaluronate
Source	artificial synthetic	artificial synthetic	animal source	artificial synthetic	Microbial fermentation
2nd surgery needed	Yes	No	No	No	No
Inflammatory reaction	moderate	high	moderate	low	low
Adhesiveness of product	low	moderate	moderate	moderate	high

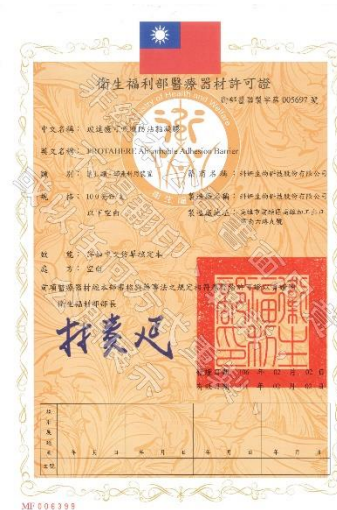
PROTAHERE

Absorbable Adhesion Barrier



Features

- ✓ High Biocompatibility
- ✓ Effective Adhesion Prevention
- ✓ Safe, Natural, Absorbable
- ✓ Easy to apply
- ✓ Cost-Effective



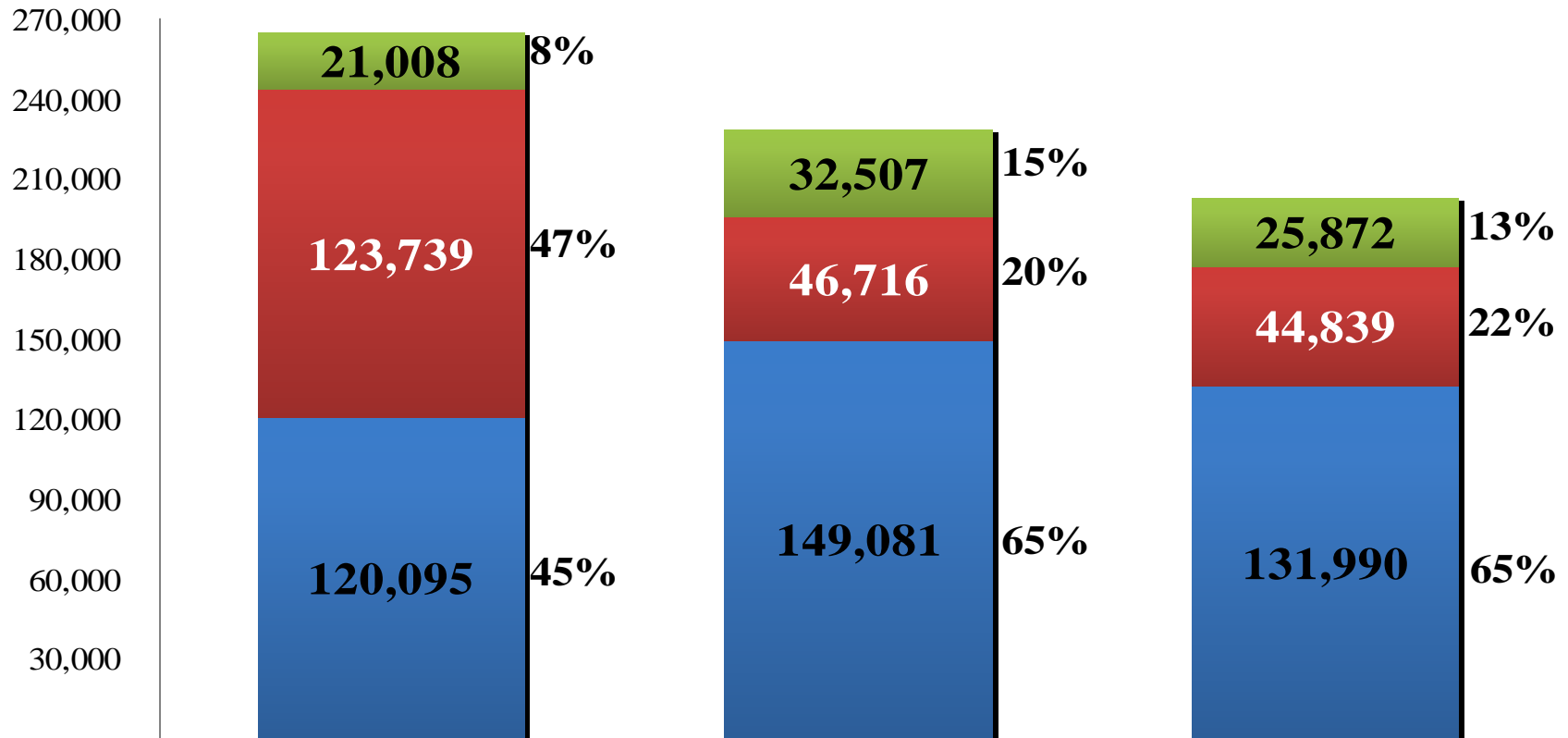
Outline

1. Company & Product Overview

2. Business Operation

Revenues

2015 to Oct, 2017



Unit: NT thousand dollars
Year 2015
(264, 842)

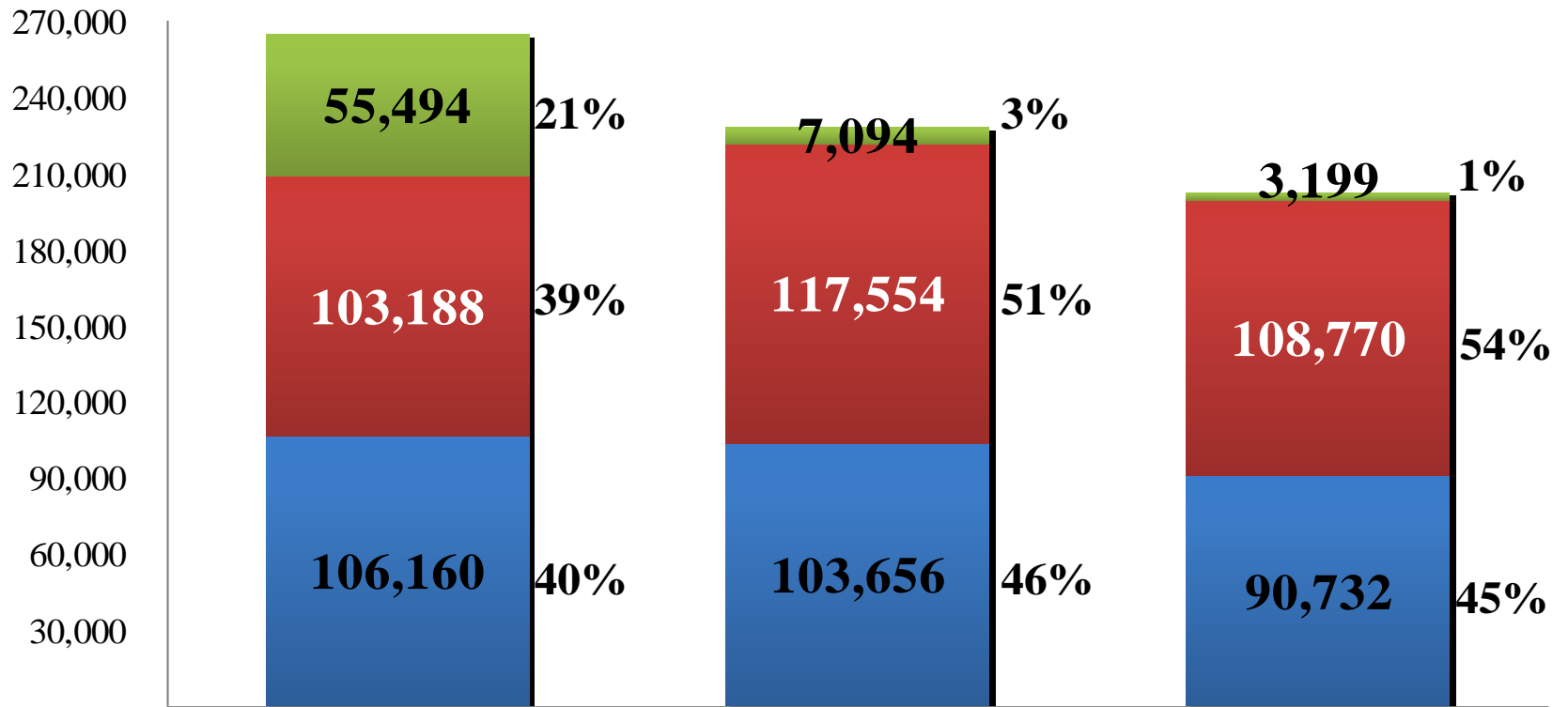
Year 2016
(228, 304)

2017/1~10
(202, 701)

■ Taiwan ■ Asia ■ Europe/America

Product Portfolio

2015 to Oct, 2017



Unit: NT thousand dollars

Year 2015
(264,842)

Year 2016
(228,304)

2017/1~10
(202,701)

■ Dermal filler ■ Viscosupplement ■ Other

Vision & Prospect

Vision

Science Creates Better Visions

Prospect

Leading HA brand in the world

The best in global market

Thank You



SCIVISION
BIOTECH INC.