Exploring the Innovative Promise of Glycoscience

Financial Results for the Fiscal Year 2016 (April 1, 2016 – March 31, 2017)



http://healthy-knee.com/



(TSE:4548)

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< Cautionary Notes >

This material contains forward-looking statements regarding future management strategies or performance forecasts. These statements are based on judgments derived from information that is currently available to Seikagaku and are subject to risk and uncertainty. Actual results and developments may differ significantly from these forward-looking statements due to various factors.

Information about pharmaceutical products or medical devices (including products currently in development) included in this material is not intended to constitute an advertisement or medical advice.

Overview of Fiscal Year 2016

	FY2016 Year-on-Year		Comparison with Revised Forecasts		
(Millions of Yen)	Results	Change	% of Change	Change	% of Change
Net sales	29,589	-1,373	-4.4%	-60	-0.2%
Operating Income	1,282	-862	-40.2%	+32	+2.6%
Ordinary Income	2,477	-1,023	-29.2%	-172	-6.5%
Net Income	1,787	-790	-30.7%	-172	-6.5%
R&D Expenses (Ratio to net sales)	7,834 (26.5%)	-814 (-1.4pt)	-9.4%	-15 (±0.0pt)	-0.2%
Average Exchange Rate (1US\$)	¥108.42	-¥11.72		Compa. with 2H forecast +¥5.42	
		FY2016 Results	FY2015 Results	FY2016 Revised Forecasts	
Net Income per Share		¥31.55	¥45.39	¥35.30	
Dividend p	ber Share	¥31.00*	¥26.00	¥26.00	
Dividend Pa	yout Ratio	98.3%*	57.3%	73.7%	
R O		2.5%	3.7%		

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*A year-end dividend of ¥18 per share (including a 70th anniversary commemorative dividend of ¥5 per share) is scheduled to be decided at the Ordinary General Meeting of Shareholders to be held in June 2017.

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Net sales by Business Segment (FY2016)

(Millions of Yen)	FY2016 Results	Year-on- Year	% of Change	
Net sales	29,589	-1,373	-4.4%	
Pharmaceuticals	24,152	-1,365	-5.4%	
Domestic Pharmaceuticals	16,268	-659	-3.9%	
Overseas Pharmaceuticals	6,771	-528	-7.2%	
Bulk Products	1,111	-177	-13.7%	
LAL Business	5,437	-7	-0.1%	
(Overseas sales)	11,029	-551	-4.8%	

*Foreign exchange impact on overall net sales: approx. -1,240 million yen

Domestic Pharmaceuticals

> **ARTZ** (Joint-function improvement agent)

 Sales decrease as a result of the impact of NHI drug price reductions (-7.2%), despite a volume increase accompanying introduction of a new syringe



ARTZ: Joint-function improvement agent with hyaluronic acid as its active pharmaceutical ingredient

> **OPEGAN series** (Ophthalmic surgical aid)

• Sales increase, with the launch of SHELLGAN offsetting the impact of NHI drug price reductions



SHELLGAN: New OPEGAN series product used in cataract surgery (launched July 2016)

MucoUp (Submucosal injection agent for endoscopic surgery)

 Sales at nearly the prior-year level following a one-time increase in shipments in the previous fiscal year



Net sales by Business Segment (FY2016)

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Overseas Pharmaceuticals

Gel-One in the U.S. (single injection)

Local sales up just under 30% on a volume basis
Seikagaku sales down slightly due to the impact of yen appreciation and a decline in local retail prices, despite the volume increase



Gel-One: Single-injection joint function improving agent

➢ARTZ (multiple injection)

- SUPARTZ FX in the U.S:
- Local sales down only slightly amid an increase in the number of competing multiple injection products
- Seikagaku sales down due to the impact of yen appreciation
- ARTZ in China:
- Seikagaku sales down due to a decrease in shipments resulting from a decline in local sales, coupled with the impact of yen appreciation

Net sales by Business Segment (FY2016)

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*Foreign exchange impact on overall net sales: approx. -1,240 million yen

Bulk Products

•Overall sales down, reflecting fierce competition in the market for hyaluronic acid, despite higher sales of chondroitin sulfate

*Bulk Products:

High-purity, high-quality hyaluronic acid and chondroitin sulfate for pharmaceuticals

LAL Business

 Higher overseas sales on a local-currency basis, but overall sales at the prior-year level due to foreign exchange impact







Income in FY2016 (Year-on-Year)

(Millions of Yen)		FY2016 Results	Year-on- Year	% of Change
	Net sales	29,589	-1,373	-4.4%
	Cost of Sales (Cost of Sales ratio)	13,247 (44.8%)	+376 (+3.2pt)	+2.9%
	SGA expenses	15,059	-887	-5.6%
	R&D Expenses (to Net sales ratio)	7,834 (26.5%)	-814 (-1.4pt)	-9.4%
	perating Income to Net sales ratio)	1,282 (4.3%)	-862 (-2.6pt)	-40.2%
С	ordinary Income	2,477	-1,023	-29.2%
	Net Income	1,787	-790	-30.7%
	Depreciation	2,920	-271	-8.5%

Operating Income

Cost of Sales ratio (+3.2pt):

Increase due to the impact of NHI drug price reductions and yen appreciation, coupled with one-time factor accompanying the introduction of a new syringe for ARTZ

SGA Expenses (-887):

Decrease in R&D expenses and other expenses

Net Income

Non-operating Income/Expenses (-161):

- Decrease in profit upon sale of investment securities (-340)
- Increase in foreign exchange losses accompanying yen appreciation (-90)
- Increase of royalty income (+316)

Income Taxes (Tax Rate: 27.8%):

Tax rate increase accompanying contribution of the U.S. subsidiary profit (+1.5pt)

FY2016 Results (Comparison with revised forecasts)

	FY2016	Compa. with	% of	Net Sales
(Millions of Yen)	Results	revised forecasts	Change	Pharmaceuticals Business (-347):
Net sales	29,589	-60	-0.2%	 Overseas pharmaceuticals (-328): Gel-One below forecast LAL Business (+287):
Operating Income (to Net sales ratio)	1,282 (4.3%)	+32 (+0.1pt)	+2.6%	Impact of yen depreciation and overseas sales exceeded forecast
Ordinary Income	2,477	-172	-6.5%	*Foreign exchange impact on overall sales: approx.+320 million yen Operating Income
Net Income	1,787	-212	-10.6%	Cost of Sales Ratio (+1.0pt): Product mix factor (Gel-One decrease), etc.
				SGA Expenses (-340):
Cost of Sales ratio	43.8%	+1.0pt		Decreases in selling expenses and head office expenses
R&D Expenses (to Net sales ratio)	7,834 (26.5%)	-15 (±0.0pt)	-0.2%	Net Income Non-operating Income/Expenses (-205):
Depreciation	2,920	-29	-1.0%	 Decrease in foreign exchange losses due to a yen depreciation Royalty income below forecast

Overview of Forecasts in FY2017

	F	Y2017	I		ts
(Millions of Yen)	Fo	Forecasts Results C		Change	% of Change
Net sales		30,300	29,589	+710	+2.4%
Operating Income		1,500	1,282	+217	· +17.0%
Ordinary Income		3,750	2,477	+1,272	+51.4%
Net Income		2,700	1,787	+912	+51.0%
R&D Expenses (to Net sales ratio)		8,350 (27.6%)	7,834 (26.5%)	+515 (+1.1pt)	
Average Exchange Rate (1US\$)		¥108.00	¥108.42	- ¥0.42	2
		FY2017 Forecasts	FY2016 Results		Rate Sensitivity ge of ¥1against the US\$)
Net Income per share		¥47.65	¥31.55	Net sales	Approx. ¥110 million
Dividend per share		¥26.00	¥31.00*	Operating income	Approx. ¥45 million
Dividend Payout ra		54.6%	98.3%*	* including a 70th an	

Forecasts (Net sales) in FY2017

		FY2017	Year-or	n-Year	
(Millions of Yen)		Forecasts	Change	% of Change	
	Net sales	30,300	+710	+2.4%	
	Pharmaceuticals	24,550	+397	+1.6%	
	Domestic Pharmaceuticals	16,350	+81	+0.5%	
	Overseas Pharmaceuticals	7,200	+428	+6.3%	
	Bulk Products	1,000	-111	-10.1%	
	LAL Business	5,750	+312	+5.8%	
(Overseas sales)	11,900	+870	+7.9%	

*Foreign exchange impact on overall net sales: approx. - ¥80 million

Net Sales

Forecast of higher sales with expected sales expansion for Gel-One and the overseas LAL business

Pharmaceuticals Business

Domestic Pharmaceuticals:

 Forecast of sales at the prior-year level for existing products, despite expected growth from SHELLGAN

Overseas Pharmaceuticals:

Forecast of higher shipments of Gel-One

Bulk Products:

 Sales decrease reflecting fierce competition in the market for hyaluronic acid

LAL Business

Sales expansion at U.S. subsidiary, ACC

Forecasts (Income) in FY2017

	FY2017	Year-on-Year		
(Millions of Yen)	Forecasts	Change	% of Change	
Net sales	30,300	+710	+2.4%	
Operating Income (to Net sales ratio)	1,500 (5.0%)	+217 (+0.7pt)	+17.0%	
Ordinary Income	3,750	+1,272	+51.4%	
Net Income	2,700	+912	+51.0%	
Cost of Sales ratio	42.1%	-2.7pt		
R&D Expenses (to Net sales ratio)	8,350 (27.6%)	+515 (+1.1pt)	+6.6%	
Depreciation	2,950	+29	+1.0%	

Income

Increase in income, with the sales increase and improvement in the cost of sales ratio compensating for higher SGA expenses, mainly R&D expenses

Operating Income

Cost of Sales Ratio (42.1%):

 Cost of sales ratio decrease (-2.7pt) in the absence of one-time factor accompanying the introduction of a new syringe for ARTZ

SGA Expenses (approx. +1,000):

- Increase in R&D expenses related to SI-613 and non-clinical themes
- Increase in selling expenses at U.S. subsidiary ACC, and others

Net Income

Non-operating Income (approx. +1,050):

Planned increase in royalty income

Trend in R&D Expenses

Although R&D expenses remain at a high level (25-30% of net sales), engaging in efficient, prioritized R&D



Domestic Pharmaceuticals

(unit deliveries to medical institutions/Year-on-Year)

	FY2016 Results	FY2017 Forecasts			
Joint-function improving agent ARTZ	 Engaged in active sales promotion accompanying introduction of a new syringe Captured share from 	anniversary of	emorate the 30th ersary of ARTZ launch or growth to exceed		
	ARTZ growth rate: +1.9% (Market growth rate: +0.4%) Market share: 58.5% (+0.8pt)	•ARTZ growth rate +1.0% (forecast)	 Market share 58.9% (forecast) 		
	FY2016 Results	FY2017 Forecasts			
Ophthalmic surgical aids OPEGAN (including SHELLGAN)	 Steady market penetration for the new product SHELLGAN Substantial recovery in market share 	 Mount a offensi emphasizing SH products featur Retake share fro 	ve sales by IELLGAN's es		

Overseas Pharmaceuticals (FY2016 Results Year-on-Year / value basis)

FY2016

Results

-7.2%

Overseas Pharmaceuticals Sales trend



Sales decrease due to yen appreciation and lower sales volumes of multipleinjection products *Foreign exchange impact: approx. -¥730 million

Gel-One (single injection)

- Local sales: Continuing volume up just under 30% growth
- Seikagaku exports: Slight decrease due to yen appreciation and a decline in local selling prices, despite volume growth (volume up 15%)

ARTZ (multiple injection)

• SUPARTZ FX in the U.S.

Only a slight decrease thanks to solid local sales in an increasingly fierce market environment due to an increase in the number of competitive products

ARTZ in China

Sales continue trending down due to the government's price-curbing policy (volume down 10% year on year)

> Seikagaku exports

Decrease in sales to both the U.S. and China due to yen appreciation and volume decline

Overseas Pharmaceuticals (FY2017 Forecast Year-on-Year / value basis)

FY2017

+6.3%

Overseas Pharmaceuticals Sales trend



Sales increase as Gel-One in the U.S. compensates for lower sales of multiple-Forecast injection products *Foreign exchange impact: approx. -¥40 million

Gel-One (single injection)

- Local sales: Forecast of continuing increase volume up 30%
- Seikagaku exports: Increase as higher volumes compensate for a decline in selling prices

ARTZ (multiple injection)

SUPARTZ FX in the U.S.

Forecast of continuing decline despite enhanced provision of academic information

ARTZ in China

Aim for sales at the prior-year level from implementation of sales measures under the new system

Seikagaku exports

Decrease on price decline for SUPARTZ FX in the U.S. and lower shipments in China

Sales of LAL Business (value basis/year-on-year)

LAL Business Sales trend

(Millions of Yen)



FY2016 Results: -0.1% (Year-on-Year)

Overseas

Slight decrease due to foreign exchange impact, despite higher local sales of products such as endotoxin detection reagents used in quality control

Domestic

Increase due to bulk purchases by customers

FY2017 Forecast: +5.8% (Year-on-Year)

Overseas

Forecast of sales increase at U.S. subsidiary, ACC

Domestic

Amebocyte Lysate (LAL).

Decrease in sales to dialysis clinics

LAL Business: The manufacturing and sales of Endotoxin detection reagents* used in the quality control of pharmaceuticals *Endotoxin detection reagents are reagents whose main ingredient is Limulus

Growth Strategy for ACC (U.S. Subsidiary)



OCIATES OF

Acceleration of sales channel expansion at ACC, the core of the LAL Business

Opening up of new sales channels and new business sectors

- Opening up and expansion of new sales channels (Shift from selling through distributors to a direct sales structure)
- Collaborative business start-ups with partners from different industries

Strengthening of existing businesses

- Retaking of share from competitors through the introduction of new products and improved products
- Augmentation of sales capabilities through recruitment of sales representatives
- Expansion and enhancement of contract test services

LAL Business: The manufacturing and sales of endotoxin detection reagents and other products used in the quality control of pharmaceuticals and medical devices ACC: Associates of Cape Cod, Inc. (U.S. subsidiary)



Pipeline List (Research and Development themes)

Aiming for the early, continuous introduction of new products, focusing on glycoscience as an area of specialization



SI-6603 Outline (Treatment for Lumbar Disc Herniation)

Aiming at relieving pain by reducing nerve pressure, result of shrinking hernias



- Substance: Condoliase
- Indication: Lumbar disc herniation
- Method of use: Injection into lumbar disc (under X-ray observation)

Japan : NDA filed

 January 2014: NDA filed, examination ongoing *NDA examination relating to quality control in manufacturing progress ongoing; continuing efforts to obtain early approval

U.S. : PIII

- July 2015: PIII case registration completed
 Follow-up observation ongoing
- August 2016: Conclusion of a license agreement with Ferring Pharmaceuticals
- March 2017 : Open-label trial follow-up observation completed

➡ Now compiling trial results

Expected Features:

- Pain alleviated by reducing hernia-related nerve pressure through the specific degradation of GAGs (chondroitin sulfate, etc.), which are the main components of the nucleus pulposus
- No breakdown of proteins, so no adverse effect on other tissues (blood vessels, nerves, etc.)
- Single-injection treatment with SI-6603 expected to become an alternative to surgery

SI-613 Outline (Treatment of Osteoarthritis)

Aiming at prompt and long-lasting relief of intense pain and inflammation associated with osteoarthritis



- Substance: SI-613 (Hyaluronic acid-NSAID^{*1} conjugates)
- Indication: Osteoarthritis
- Formulation: Injection into joint

Japan : PIII

- January 2016: Phase II (multipledose study) completed
- February 2017: Phase III study initiated
- May 2017: Reached a basic agreement related to co-development and marketing collaboration with Ono Pharmaceutical Co., Ltd.

Positioning SI-613 as a global product, including in the U.S.

Expected Features:

- Provision of prompt and long-lasting relief of intense pain and inflammation associated with osteoarthritis by combining hyaluronic acid with NSAID^{*1} using a proprietary technology, and designing the formulation for sustained release^{*2} of the NSAID
- Mitigation of NSAID side effects compared with oral or transdermal administration
- Expansion of the target patient population by making possible administration for other joints in addition to the knee
- *1 NSAID: Non-Steroidial Anti-Inflammatory Drug
- *2 Sustained release: Gradual release of active ingredients to achieve a sustained therapeutic effect over a long period

SI-613 Phase III study in Japan

Three planned studies to evaluate use for five sites (knee, hip, ankle, elbow, and shoulder)



Japan : PIII

- Verification study (knee joint)
 February 2017 start
- Clinical study for four sites (hip, ankle, elbow, and shoulder)
- Long-term study (knee joint)
 - ⇒ Planned start during FY2017

Annual number of patients examined for osteoarthritis in Japan

Total for knee, hip, ankle, elbow, and shoulder (Seikagaku's estimate)

Approx. 8.7 million per year
 (With the knee joint accounting for approx. 7.5 million)



SI-614 Outline (Treatment of Dry Eye)

Aimed at improvement of symptoms of dry eye by protecting the ocular surface and promoting corneal epithelial wound healing



- Substance: SI-614(Modified Hyaluronate)
- Indication : Dry eye
- Formulation: Ophthalmic solution

U.S. : PII/III

- January 2015: Phase II/III clinical trials completed
 - Proceed with consideration of a PIII trial and sales partner search

Expected Features:

- SI-614 is a modified hyaluronate produced by Seikagaku's proprietary technology.
- It is expected to improve symptoms of dry eye by protecting the ocular surface and promoting corneal epithelial wound healing in dry eye patients.
- Although dry eye is a multifactorial disease, only drugs with relatively strong is available in the U.S. currently. SI-614 will provide a new alternative to the treatment of dry eye through the promising mode of action

Basic Policy on Profit Distribution

Aim to enhance shareholder returns and realize sustained growth by engaging in well-balanced business investment

Shareholder Return Policy

- 70th anniversary commemorative dividend

 (to be proposed at the Ordinary General Meeting of Shareholders in June 2017)
 For FY2016, planned annual dividend of ¥31 per share, including a commemorative dividend of ¥5 per share
- Aim for stable and continuous dividends from a medium to long term perspective
 For FY2017, have a policy to continue to pay an annual dividend of ¥26 per share
- Consider purchases of treasury stock, as appropriate, taking into account future business development and the total return ratio

Business Investment

Business investment in R&D, production system development, and other areas

	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017 (Forecast)
Net Income per share	¥57.33	¥83.55	¥64.27	¥45.39	¥31.55	¥47.65
Annual Total Dividend	¥25.00	¥26.00	¥26.00	¥26.00	¥31.00 [*]	¥26.00
Dividend Payout Ratio	43.6%	31.1%	40.5%	57.3%	98.3%*	54.6%

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*A year-end dividend of ¥18 per share (including a 70th anniversary commemorative dividend of ¥5 per share) is scheduled to be decided at the Ordinary General Meeting of Shareholders to be held in June 2017. 23





Trend in Financial Index



Business Progress & Highlights



Trend in Capital Investments

Facilities	Amounts (¥ bill.)	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017 (Forecast)
SI-6603 Bulk Production Facilities	1.1				start 4.10			
No. 5 Production Building (for ARTZ Dispo)	9.6	Start '12.3				Operation '15.1		
Hyaluronic Acid Bulk Production Facilities	3.1	Start '12.1			Operation '14.2			
Production Facilities for Gel-One	3.0	Start '11.12			eration 13.10			
Chondroitin Sulfate Bulk Production Facilities	1.2		Opera '12					
Amount (Millions of Y		5,718	9,164	7,222	2,095	1,975	1,173	2,000

Trend in Depreciation

Depreciation peaked out at FY2015 and anticipate the level of ¥3,000 million from now on



Trend in NHI Reimbursement Price and Trend in Deliveries of ARTZ to Domestic Medical Institutions



Trend in Deliveries of ARTZ / OPEGAN to Domestic Medical Institutions

Joint-function improving agent



- The first HA joint function improving agent in the world
- Knee osteoarthritis (OA) pain relief
- Distributor: Kaken Pharmaceutical







Ophthalmic Surgical Aid SHELLGAN (Launched July 2016)



Launch of the new product SHELLGAN

- Suited to a surgical procedure that has become more pervasive in recent years
- Can be stored at room temperature
 - A product feature unavailable from competitors
- Strengthening of the OPEGAN series product line
- Seven-product line up provides a wider range of options appropriate to symptoms and physician needs



The OPEGAN series, used mainly in cataract surgery



The OPEGAN series viscoelasticity comparison



Measures to Strengthen Product Presence in the U.S.

Product value enhancement and product line reinforcement as the leading company in the joint function improving agent field

U.S. market share by number of injections





U.S. Market for HA Products



Trend in Overseas Sales of Hyaluronic Acid Products



The LAL Business

What is the LAL business?

The manufacturing and sale of reagents used in the quality control of pharmaceuticals and in water quality Control in dialysis at hospitals

*Endotoxin detection reagents are reagents whose main ingredient is Limulus Amebocyte Lysate (LAL).

*Endotoxins are substances derived from bacteria. Since they cause fever even in minute amounts, testing for endotoxin contamination in pharmaceuticals is compulsory

> Size of the global market: Approx. ¥25.0 billion (Seikagaku estimate, including associated equipment)

Associates of Cape Cod, Inc. (ACC)

- U.S. subsidiary of Seikagaku Corporation (established in 1974, acquired by Seikagaku in 1997)
- Developed the world's first endotoxin detection reagent and obtained FDA approval in 1977
- A sales network spanning 80 countries
- Solid business performance in recent years





Endotoxin detection reagents (for quality control of pharmaceuticals and medical devices)



PYROCHROME®

Basic Policy on Research and Development

Aiming for the early, continuous introduction of new products that meet high treatment needs, focusing on glycoscience as an area of specialization



SI-613 Estimated Target Patients

Estimated patients with severe pain and being treated with oral or topical NSAIDs or intra-articular steroid injection



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Agreements Status for SI-6603 (Treatment for Lumbar Disc Herniation)

Licensing of exclusive overseas development and marketing rights to Ferring Pharmaceuticals Planned receipt of milestone royalties of up to \$90 million in accordance with future progress

Overseas: Ferring Pharmaceuticals (Switzerland)







- An R&D-driven biopharmaceutical group established in 1950
- Worldwide sales: 1.8 billion euros (2015)
- August 2016: Conclusion of an exclusive worldwide (excluding Japan) license agreement



Ferring Pharmaceuticals headquarters (Saint-Prex, Switzerland)

Japan: Kaken Pharmaceutical Co., Ltd.

- Sales partner for the joint function improving agent ARTZ
- December 2012: Conclusion of an exclusive distribution agreement in Japan

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New Mid-term Management Plan (FY2016 to FY2018)



[Final Step]

Achieving the Ten-Year Vision and Making a Further Leap Forward



2009-2011

Cultivation of new leads for achieving the Ten-Year Vision

2012-2015

Step 1

Cultivation of basic strength and systems development

2016-2018

ACT for the Vision

<u>Active spirit Creative mind Takeoff</u> Overcome severe environment in the business, achieve the Ten-Year Vision, and survive as a "Global Category Pharma"



New Mid-term Management Plan: Four High-Priority Strategies

1.

Preparing for launch of SI-6603, a treatment for lumbar disc herniation Powering up as a leader in the knee osteoarthritis market

3.

Enhancement of the

development pipeline

4.

Pursuit of an optimal

production system

Achieving the Ten-Year Vision and Making a Further Leap Forward

New Mid-term Management Plan: Numerical Targets



Topics for Advancing to the Next Stage

(Schematic Representation of Growth)



Special Profile



V SEIKAGAKU CORPORATION

Our Business Segment



Main Hyaluronic Acid (HA) Products

- **ARTZ[®]** Knee osteoarthritis (OA) pain relief by multiple injections
 - The first HA joint function improving agent in the world
 - Main distributors:

Kaken Pharmaceutical (Japan): ARTZ®

Bioventus (U.S.): SUPARTZ FX[™]

Kunming Baker Norton Pharmaceutical (China): ARTZ[®]



Gel-One[®] Knee OA pain relief by a single injection

Requires only 3ml to be as

effective as multiple injections

- Full-scale sales since August 2012
- Distributor: Zimmer (U.S.)



Exploring the Innovative Promise of Glycoscience

Cautionary statement regarding forward-looking information

This material includes forward-looking statements based on assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties. Actual financial results may differ materially depending on a number of factors including adverse economic conditions, currency exchange rate fluctuations, adverse legislative and regulatory developments, delays in new product launch, pricing and product initiatives of competitors, the inability of the company to market existing and new products effectively, interruptions in production, infringements of the company's intellectual property rights and the adverse outcome of material litigation.

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