

# **Acquisition of Noven Pharmaceuticals, Inc.**

**Hisamitsu Pharmaceuticals Co., Inc.**

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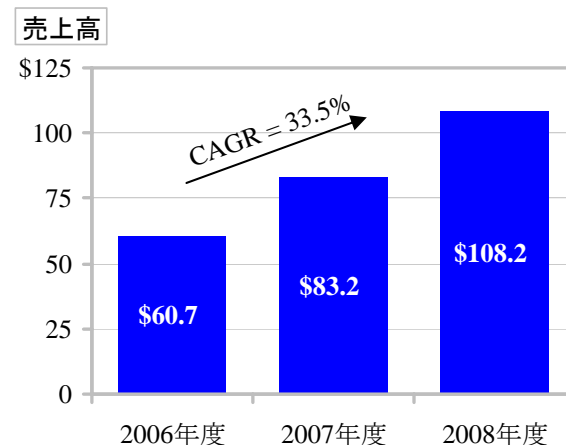
1. Overview of Noven Pharmaceuticals, Inc.
2. Purpose of Acquisition, Strategy after Acquisition
3. Overview of Acquisition

# 1. Overview of Noven Pharmaceuticals, Inc.

## Overview

- Headquarters: Miami, Florida, USA
- Established: 1987
- Sales (FY2008): US\$108.1million
- Net Profit (FY2008) US\$21.4million
- Stock Listing: NASDAQ
- Market Cap (as of Jul 13, 2009 ): US\$335.8million
- Number of employees (as of Dec 31, 2008): 610

## Sales (US\$ million)



## Business Description

- Noven Pharmaceuticals, Inc. is a specialty pharmaceutical company which researches, develops, market and sells ethical pharmaceutical products.
- Noven Pharmaceuticals, Inc. has transdermal patch products for ADHD and post-menopausal hormone replacement therapy with its proprietary transdermal drug delivery system as its main products, and has several other pharmaceutical products for treatment of psychiatric diseases.
- There are multiple pipeline products in CNS and gynecology fields.

# Overview of Noven Pharmaceuticals, Inc.



Noven	Noven Transdermals	<ul style="list-style-type: none"><li>■ Research on transdermal drug delivery system (TDDS) patches utilizing DOT Matrix technology and development and manufacturing of TDDS products.</li><li>■ Development and manufacturing of Vivelle Dot which has more than 50% share in TDDS hormone replacement therapy</li><li>■ Development and manufacturing of the world's first ADHD treatment patch, Daytrana</li></ul>
	Noven Therapeutics	<ul style="list-style-type: none"><li>■ In-licensing, development and sales of CNS products</li><li>■ Pipeline products such as Mesafem (Phase 2)</li><li>■ Mesafem; Non-hormonal treatment of vaso-motor symptoms post-menopausal women</li></ul>
	Novogyne	<ul style="list-style-type: none"><li>■ Joint Venture established by Noven and Novartis in 1998 to market and sell Vivelle-Dot, CombiPatch</li><li>■ Noven has 49% equity share</li><li>■ Sales in 2008: US\$169.6million</li></ul>

# Strength of Noven

## R&D

- Know-How on TDDS formulation development utilizing DOT-Matrix technology
- Know-How on clinical development and FDA approval processes on TDDS products
- Know-How on products development and FDA approval processes gained through approvals of Vivelle-Dot and Daytrana

## Manufacturing

- Know-How on manufacturing of TDDS products such as Vivelle-Dot and Daytrana
- Highly capable staff with excellent skills

## Marketing / Sales

- Strong marketing and sales capability in USA
- Existing infrastructure of sales and marketing
  - Marketing and sales employees: 223 (as of Dec 31, 2008)

## Management, Human Resources

- Experienced management teams
  - Reliable insight with long-term experience in pharmaceutical industry
- Excellent human resources

# Products on the Market

Products <sup>(1)</sup>	Indication	Mode of action
Noven Therapeutics		
	<ul style="list-style-type: none"> <li>Depression, Panic Disorder, OCD, GAD</li> </ul>	<ul style="list-style-type: none"> <li>Selective Serotonin Reuptake Inhibitor (SSRI)</li> </ul>
	<ul style="list-style-type: none"> <li>Bipolar disorder</li> </ul>	<ul style="list-style-type: none"> <li>GSK-3 <math>\beta</math> inhibitor</li> </ul>
	<ul style="list-style-type: none"> <li>Bipolar disorder, Migraine, Seizures</li> </ul>	<ul style="list-style-type: none"> <li>GABA-T inhibitor</li> </ul>
Noven Transdermals		
	<ul style="list-style-type: none"> <li>Menopausal syndrome, Osteoporosis</li> </ul>	<ul style="list-style-type: none"> <li>Estradiol transdermal system</li> </ul>
	<ul style="list-style-type: none"> <li>Menopausal syndrome, Osteoporosis</li> </ul>	<ul style="list-style-type: none"> <li>Estradiol/norethindrone acetate transdermal system</li> </ul>
	<ul style="list-style-type: none"> <li>ADHD</li> </ul>	<ul style="list-style-type: none"> <li>Norepinephrine and dopamine reuptake inhibitor</li> </ul>

(1) DentiPatch (topical anesthesia prior to superficial dental procedures) is soled by several independent marketers.




# Product Pipelines

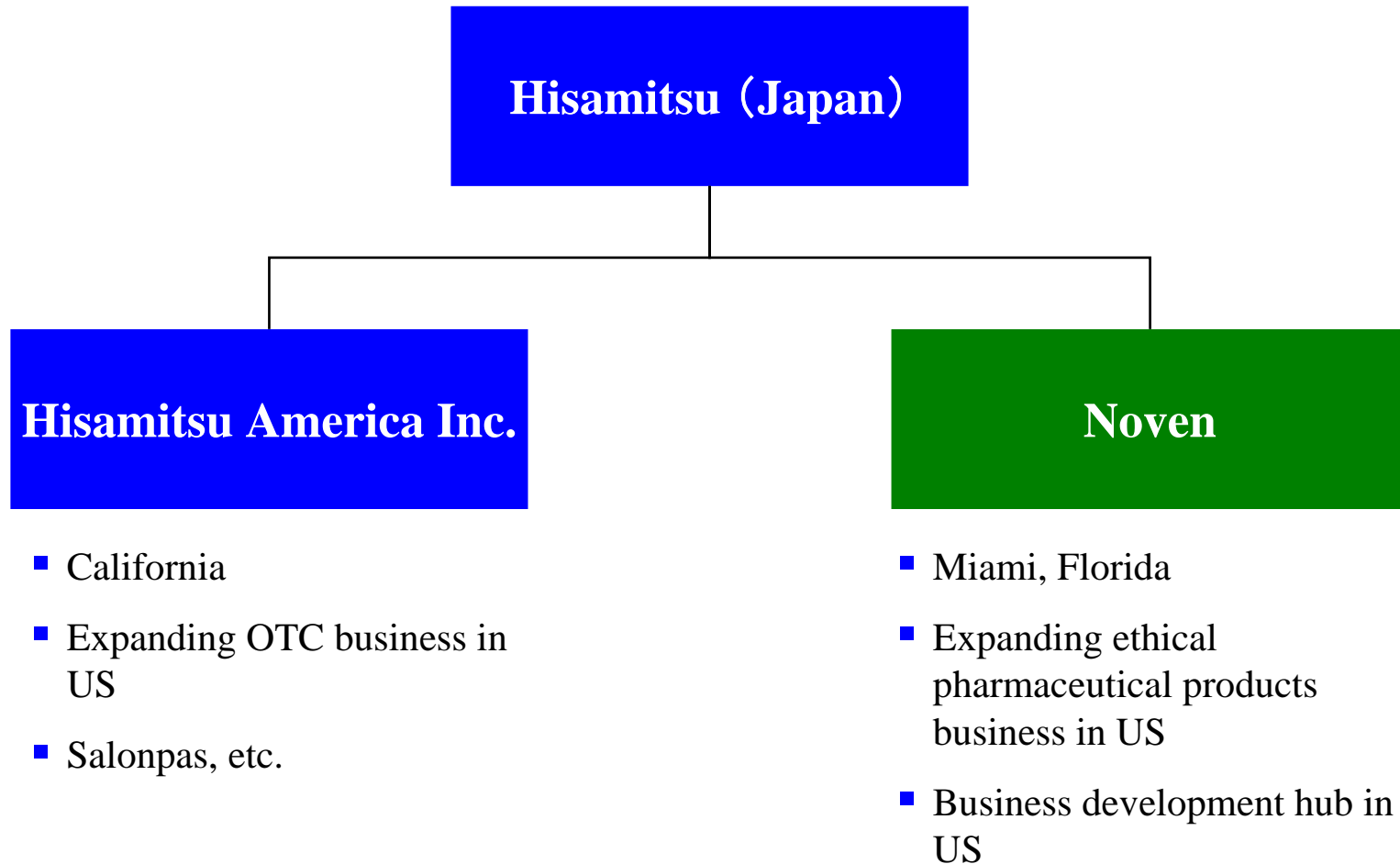
Product	Comments
Noven Therapeutics	
Mesafem	<ul style="list-style-type: none"><li>■ Indication: Vasomotor symptoms (VMS) associated with the menopause<ul style="list-style-type: none"><li>■ Oral formulation of low-dose paroxetine mesylate</li></ul></li><li>■ Promising pipeline product targeting 23 million VMS patients in US</li><li>■ Current stage: Phase 2</li><li>■ Launch: 2H 2011</li><li>■ Non-hormonal product, Mode of action: GABA-T inhibitor</li></ul>
Noven Transdermals	
Amphetamine Patch	<ul style="list-style-type: none"><li>■ Indication: ADHD</li><li>■ Phase 1 completed</li><li>■ Mode of action: Norepinephrine and dopamine reuptake inhibitor</li></ul>
Testosterone Patch	<ul style="list-style-type: none"><li>■ Indication: Hypoactive Sexual Desire Disorder (HSDD) in post-menopausal women</li><li>■ Partnered with P&amp;G Pharmaceuticals</li><li>■ Product: Low-dose testosterone patch</li></ul>

## 2. Purpose of Acquisition

# Purpose of Acquisition

**Hisamitsu needed to have business infrastructure including product development, manufacturing, and commercialization in the United States in order to achieve further growth.**

- Hisamitsu has built a strong presence in Japanese market with leading products such as Mohrus Tape.
  - Hisamitsu urgently needed to have business infrastructure including product development, regulatory affairs, manufacturing and commercialization in the United States.
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- This transaction allows Hisamitsu to build its presence and brand in the US market by leveraging Noven's capabilities in drug development, regulatory affairs, manufacturing and commercialization. In order to assure the future growth of the company by leveraging TDDS technologies of the both companies to maximize the value of pipeline products, this investment is significantly important for Hisamitsu.



# Strategy after acquisition

## Value chain

### Business Development

- Business development hub in the US
- Expansion of disease fields such as pain into view

### R&D

- Leveraging TDDS technologies of the both companies
- Expansion of pipelines by product development at Hisamitsu (Japan), Hisamitsu (California), Noven
- Possibility of addition of Hisamitsu products to pipeline
- Pain
  - Ketoprofen Patch
  - Diclofenac Patch
- CNS
  - Sales expansion of Daytrana
- Gynecology
  - Launch of Mesafem

### Manufacturing

- Establishment of manufacturing site in the US for Hisamitsu products
- Investment in facility as needed
- Sharing expertise and manufacturing know-how regarding TDDS products and achievement of improvement of quality

### Marketing / Sales

- Sales by own organization utilizing relationship with medical professionals, medical conference
- Utilizing infrastructure of Novogyne in gynecology
- Enhancement of sales efficiency and marketing capability due to sales of Hisamitsu products

# Expecting effect

## Enhancement of business infrastructure in the US

- Acquisition of development, manufacturing and sales infrastructure with actual achievement

## Avoidance of time and cost for building business infrastructure

- Avoidance of time, cost and risk for building business infrastructure by Hisamitsu itself in the US

## Application and development of TDDS technology

- Acceleration of product development mostly utilizing TDDS technology of both companies

## Sales of Hisamitsu products by itself in the US

- Maximization of values by Hisamitsu's own sale of pipeline products

## Acquisition of a company with sales and profit

- Contribution of self-sustainable company to Hisamitsu's sales and profits soon after acquisition

### 3. Overview of Acquisition

# Overview of Acquisition

## Acquisition for US\$16.50 per share

- 24.2% premium vs 1-month average stock price US\$13.28.
- Total consideration: approximately US\$430million.

## Acquisition through tender offer

- Tender offer period shall commence within 10 business days following date of agreement with Noven (Jul 14 ,2009, US time) and last for 20 business days. The tender offer period may be extended in the event that the result of the tender offer does not meet certain criteria.
- Acquisition procedure is expected to complete 2Q 2009.

## Acquisition fund will be applied by cash and loan

- Cash: JP¥23billion
- Loan: JP¥15billion



# Impact on business performance

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- Loss and profit of Noven will be accommodated from September 2009.
- EPS will be increased from FY2010
  - Announcement on amortization of goodwill will be made as soon as details are determined.
- Cash EPS will be increased.
- No change in shareholder return policy.
  - Stable and long-term shareholder return policy will be maintained as it is now.
  - Dividend: JP¥68/share, no change in present term forecast.