

# Notice of Investment in IriSys, LLC and Establishment of New U.S. Subsidiary

# $\boldsymbol{I}$ . Investment in IriSys, LLC

#### 1. Purpose of Investment:

GNI Group Ltd., a leader in drug development for fibrotic diseases listed on the Tokyo Stock Exchange (MOTHERS: 2160), announced today the signing of a definitive agreement to invest into IriSys, LLC, a contract pharmaceutical product development and manufacturing service provider specializing in formulation development, cGMP manufacturing of clinical trial materials, commercial pharmaceutical products and consulting related to the drug development process based in San Diego, California, USA. This strategic investment represents a significant initial foothold for GNI Group extending its work into the United States, the largest healthcare market in the world.

#### (1) About IriSys

IriSys, Inc., the parent company of IriSys, LLC, was founded in 2001 by Gerald J. Yakatan Ph.D. Dr. Yakatan is a serial entrepreneur who has founded multiple companies in the pharmaceutical R&D area. Currently, IriSys LLC employs 40 people and occupies a 2,269 square meter facility in San Diego, California.

IriSys, LLC offers pharmaceutical research and development, FDA cGMP manufacturing for clinical trials materials and commercial pharmaceutical products and, most recently, regulatory strategic planning services. The company develops and manufactures pharmaceutical dosage forms under contracts with various product sponsors/owners. IriSys, LLC manufactures products for preclinical animal toxicology studies, and for phases I, II and III of human clinical trials. It works in all therapeutic categories [e.g. Cancer, Chemotherapy, Cardio Vascular, Endocrine/Metabolic Disorders, Central Nervous System, Dermatology, Gastrointestinal, etc.] and manufactures a wide range of dosage forms, [e.g. oral tablets, oral capsules, oral liquids, sterile injectable products, liquid filled hard gelatin capsules, creams & ointments]. The work is regulated by the FDA and the clinical trial materials are made under an IND. IriSys, LLC is routinely audited by the FDA to insure compliance. The work involves both small scale batches and commercial product manufacturing.

#### (2) Investment Structure

GNI USA, Inc. (Delaware, USA), which is wholly owned by GNI Group, will invest into IriSys, LLC through a combination of newly issued LLC interests and purchase of existing interest to acquire in aggregate a 35.0% interest in IriSys, LLC. After this investment, the board of managers will consist of 6 members in which GNI Group will appoint two managers. Moreover, GNI Group will have the right to nominate the CFO of IriSys, LLC. Dr. Yakatan will remain as the CEO of IriSys LLC.

### (3) Financial Impact

In 2013, IriSys, Inc., the parent company of IriSys, LLC, achieved sales of USD 3,908,000 and in 2014 expects sales of USD 5,763,000 (unaudited). GNI will consolidate the financial results of IriSys, LLC via the equity method.

GNI Group expects the investment into IriSys, LLC to be accretive and to have a positive impact on the future growth

and profitability of the Group as a whole, while providing significant new opportunities the company's operations in China, Japan and the United States, especially for filing an IND for F351 in the U.S. Since the company's establishment in 2001, we have combined knowledge derived from innovations in the west with cost effective clinical development programs in China, and now intend on forming co-development partners with international biotech and pharmaceutical companies. Our cost-efficiency programs in China provide a competitive advantage to conduct more clinical trials at lower cost. This approach can reduce the financial risk commonly associated with the U.S. pharmaceutical industry drug development process.

#### (4) Synergies

We expect the following synergies through this investment.

- 1. Help GNI Group file an IND in the U.S. for existing pipelines
- 2. Help our Chinese subsidiary, Beijing Continent Pharmaceutical Co, Ltd., to improve GMP standards up to U.S./International level
- 3. Support our subsidiaries to improve formulation technology
- 4. Assist GNI to identify new drug products to license from U.S. companies for development in China

"We see a lot of synergy between GNI Group and IriSys, LLC," said Dr. Ying Luo, CEO of GNI Group. "In the last 13 years of drug development in Asia, we have been consistently pursuing a strategy of developing new drugs through proof-of-concept stage (POC) first in the China market and then migrating such products to the more established markets such as the United States, Europe, and Japan. We will continue to execute our business strategy and expand into new opportunities in China, the US, and Japan as well in the near future," continued Luo.

"IriSys also sees significant synergy from this relationship," said Dr. Yakatan, CEO of IriSys, LLC. "As we try to increase our business development efforts in Japan and China, our expertise in the manufacture of clinical trial material and our experience with FDA strategy can help GNI and other companies trying to bring products to the U.S."

#### 2. General Information of IriSys, LLC (as of Jan 7, 2015):

(1)	Corporate Name	IriSys, LLC	
(2)	Location	6828 Nancy Ridge Drive, Suite 100, San Diego, CA 92121, USA	
(3)	Chief Executive	Gerald J. Yakatan	
(4)	Business Activities	CMO, formulation R&D and consulting services	
(5)	Capital	USD 1,073,000	
(6)	Date of Establishment	January 7, 2015	
(7)	Major Members and	IriSys, Inc. 100.0%	
	Ownership Ratio	113ys, 111c. 100.076	
(8)	Relationship with GNI	Capital Relationship	No applicable relationship with the company
	Group	Personal Relationship	No applicable with the company
		Transactional Relationship	No applicable relationship with the company
		Related Parties Transactions	No applicable relationship with the company

#### 3. Method of Investment:

GNI USA, Inc. will invest an aggregate of USD 6,300,000 to acquire an aggregate 35.0% interest in IriSys, LLC.

### 4. Ownership Before and After Investment:

(1)	Ownership Before Investment	0.0% (Ratio of voting rights: 0.0%)
(2)	Interest Acquired	35.0% (Ratio of voting rights: 35.0%)
(3)	Investment Amount	USD 6,300,000
(4)	Ownership After investment	35.0% (Ratio of voting rights: 35.0%)

#### 5. Schedule of Investment:

(1)	Executive Committee Meeting Resolution	January 20, 2015
(2)	Closing Date	To be announced

# ${\rm I\hspace{-.1em}I}$ .Establishment of New U.S. Subsidiary

## 1. Purpose of Establishing New Subsidiary:

GNI Group incorporated a new subsidiary in the State of Delaware, to create an initial foothold in the United States. In the near future, GNI Group plans to start developing new drugs in the United States.

## 2. General Information of New Subsidiary (as of Jan 5, 2015):

Corporate Name	GNI USA, Inc.
CEO	Ying Luo
Business Activities	Investment and new drug development in the United States
Capital Amount	USD 1,000
End of Fiscal Year	December 31
Major Shareholders and Share Ratio	GNI Group 100.0%

#### 3. Schedule:

Board of Director's Resolution	January 5, 2015
Establishment Date	January 5, 2015

# **III.** Impact to FY2015 Financial Statements

No significant impact to FY2015 financial statements.