

Advanced Pharmaceutical Industries¹

AMMAN, JORDAN

The Muslim “call to prayer”² sounded in the background but Dr. Rakan Rshaidat, managing director of Advanced Pharmaceutical Industries (API), hardly noticed as he focused on the task at hand. In less than a week, Dr. Rshaidat would travel to Switzerland to discuss a cooperative agreement with Roche Pharmaceuticals, his former employer of some years ago. API was at a critical stage of its young existence and Dr. Rshaidat understood that forming some type of strategic partnership was necessary to ensure API’s success. His concern stemmed from recent developments in Jordan’s inclusion in the World Trade Organization (WTO), which meant enforcement of intellectual property rights (IPR) for pharmaceuticals. He was also concerned with the gradual penetration of new standards for registering companies and their products into Arab pharmaceutical markets. In addition, there was also the possibility that many start-up companies throughout Jordan would go out of business soon, given the fierce regional competition, new registration standards, and the upcoming enforcement of international patent laws.

As Dr. Rshaidat prepared to develop his proposal, he wondered what type of strategic partnership would be most appropriate given the needs of his company and the expectations of Roche. He reflected on the dramatic impact that external factors might have on Roche’s decision to accept the agreement, and what he could do to ensure the agreement would be effective and beneficial for both parties once implemented.

API’s Background and History

Advanced Pharmaceutical Industries (API) was established in 1994 as a public shareholding company to provide high quality pharmaceuticals at reasonable prices for the local and regional population. API was controlled through a Board of Directors consisting of eleven people, all with general industry experience. Dr. Rshaidat had a strong background in the industry and managed the daily operations of the administrative offices and production facility. He spent seven years

studying in the United States, earning a doctorate in Pharmacy (PharmD) from Auburn University in 1986. Upon graduation, he returned to Jordan and joined Roche Pharmaceuticals working two years in Cyprus and four years in Switzerland. Afterwards, he returned to Jordan and became a founding member of API.

API started with nine employees in 1994. From the beginning, Dr. Rshaidat understood the dynamics of the local and regional market and since the market was already very competitive, he sought to distinguish the company through its marketing efforts. To launch the company, he studied the market and then built the company and facility to suit apparent needs. At that time, there were ten pharmaceutical factories operating in Jordan and a few new companies had been established in traditional export markets such as Saudi Arabia and the United Arab Emirates. Syria had emerged as a big producer of pharmaceuticals, establishing forty to fifty small companies from 1995-1997, and Tunisia had opened a number of factories as well. However, Dr. Rshaidat figured that production capacity would not be the determining factor of their success; rather, marketing would be most important. Therefore API studied the market to identify products for which there was strong demand so that his company would be successful.

API initially sought niche products, those high in value with good profiles in terms of minimal side effects and efficacy. The initial product portfolio consisted of a combination of anti-infective, cardiovascular, and central nervous system drugs. The production facility was designed and machinery selected after the product portfolio was developed. The research and development, and quality control facilities were built in 1995 to prepare for actual production that began in 1997. Since API was a newly established company, the production facilities were designed and built according to the latest international standards for pharmaceutical production.

	1997(JD)	1996 (JD)	1995 (JD)
ASSETS			
Current Assets			
Cash	83,959	139,659	2,579,613
Checks under collection	83,613		
Accounts receivable		353,624	
Inventory	210,119	69,701	
Short term investments		26,254	211,235
Letters of credit	14,615	29,016	196,095
Other receivable balances	11,684	10,224	6,334
Total Current Assets	757,614	274,854	2,993,277
Deferred Charges	943,887	311,663	
Long term investments	2,367,108	2,447,498	2,416,888
Fixed assets, net	3,997,181	3,770,847	1,257,859
TOTAL ASSETS	8,065,790	6,804,862	6,668,024
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current Liabilities			
Accounts payable	42,256	139,314	89,940
Promissory notes	37,980	6,610	
Other payable balances	157,810	26,166	28,409
Total Current Liabilities	238,046	172,090	118,349
Shareholders' equity			
Paid up capital	8,000,000	6,632,772	6,541,514
Income c/f (loss)	(JD 172,256)		8,161
Total Shareholders' Equity	7,827,744	6,632,772	6,549,675
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	8,056,790	6,804,862	6,668,024

1JD = \$1.40

Exhibit Ia. Financial Statement

	1997(JD)	1996 (JD)	1995 (JD)
Sales	362,175	240,687	284,449
Cost of Sales	(JD 90,178)		
Operating profit/Income		271,997	240,687
Other Income	6,875	8,161	
Gross profit/income	278,872	248,848	
Expenses			
Selling & distribution	(JD 73,034)		
General and administrative	(JD 206,824) (JD 279,858)	(JD 540,742) (JD 540,742)	(JD 292,214)
Net loss	(JD 986)		(JD 7,765)
Integrated Company Loss	(JD 171,270)		15,926
Net loss/pre-operating expenses	(JD 172,256)	(JD 291,894)	8,161

Exhibit Ib. Income Statement

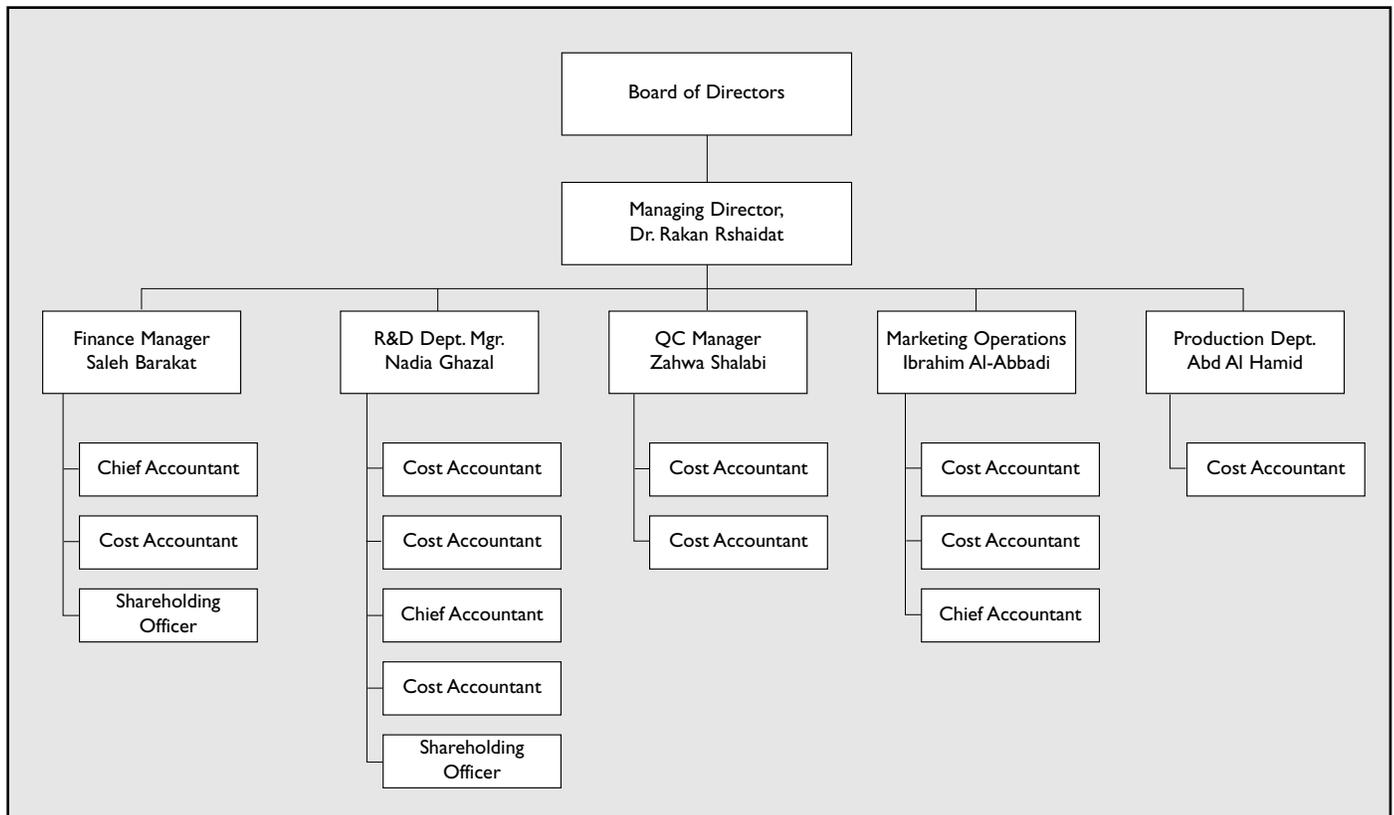


Exhibit 2. Organization Chart

Production requirements for the global pharmaceutical industry were getting stricter, and if API wanted any chance of exporting their products, they had to comply with the international and regional ‘current Good Manufacturing Practices’ (abbreviated ‘cGMP’).³ Dr. Rshaidat knew that quality would be the determining factor in the future. The rules of the entire industry were changing, globally and regionally. Companies that would survive and flourish had to be up-to-date with quality standards and cGMP. However, staying up-to-date all the time proved difficult for companies and those that could not keep up were slowly phased out. Europeans, Americans and regional Arab countries were requesting more quality in terms of systems, facilities and personnel. One country, Saudi Arabia, was moving fast in this direction.

Construction of the laboratories and the production facility, and purchase of production machinery cost approximately \$5.3 million and was completed by the end of 1996. In mid 1997, production commenced with a range of products, including antibiotics, cardiovascular drugs, anti-rheumatics, analgesics, and anti-fungals. The period between production, registration, and marketing of products in traditional export markets was a critical period for API. It required much liquidity when income was low as a result of relying on the local market. The company was passing through the period successfully and was overcoming the liquidity crunch (Exhibit 1).

Sales were growing, administrative expenses had been substantially reduced and current assets were much larger than current liabilities. In fact, company sales reached JD771,700 in 1998 (just over \$1 million, 1 JD = US\$1.41), while gross profit/income increased to JD410,000. API broke even for the first time in 1999.

By 1998, the API employed 93 persons. Women held many of the managerial positions. Exhibit 2 presents the company organization chart. Dr. Rshaidat employed only the best and he found that women were more qualified for certain positions than their male counterparts. This was unusual, especially for a highly patriarchal society, where even the most educated and Westernized groups were very male-dominated. Department managers had extensive experience from different pharmaceutical factories throughout the region and over 90% of the employees were college graduates.

Production

The production facility was located in the Sahab Industrial Estate, twenty kilometers south of Greater Amman. The entire plant was built in accordance with cGMP by the British-owned company Modular Room Construction System Limited (MRC). The modular system was designed to facilitate upgrading and additions to the facility in the future. The actual pro-

duction area was designed to protect manufacturing through the use of High Efficiency Particulate Air (HEPA) filters. The system allowed air to flow from the corridors into the manufacturing rooms as opposed to sending air from manufacturing rooms into the corridors. This control was important because once air entered the corridors, any airborne containment from one pharmaceutical product could jeopardize the production of another pharmaceutical product taking place in a different room. Therefore, HEPA filters were installed to prevent contamination due to airflow from one manufacturing room to another. After the production facility systems were implemented, several auditors, including one from Roche pharmaceuticals, inspected the facility and gave extremely good reports about the operation of the facility and its compliance with requirements of European health authorities.

There were approximately fifteen production personnel all of whom received cGMP training, which covered quality control, precision, and adherence to standard operating procedures. The production department received master formulas for products from research and development after they had been approved by quality control/quality assurance. Since API only began operations in 1997, production capacity utilized thus far was only 10%. Production consisted of tablets, capsules, coating, and dry suspension (Exhibit 3).

Machine	Capacity
Tablets	140,000/hr
Capsules	25,000/hr
Suspension (bottles)	77,000/day

Exhibit 3. Machine Production Capacity

Product Development

API's products covered a range of over-the-counter pharmaceutical products in general demand (Exhibit 4). The majority of API's products were new formulations of patented drugs (those patented by large multinational pharmaceutical firms) sold in the private market through pharmacies. API had a clear understanding of the importance of continuously developing and introducing new products. However, product development was both time consuming and costly because new products had to be developed, tested, and manufactured while meeting regulatory standards and receiving requisite approvals. For this reason, the research and development manager, Ms. Nadia Ghazal, was instrumental in assuring that the R&D labs were designed in accordance with the latest requirements and contained the latest systems. Ms. Ghazal received her pharmacy degree from the University of Jordan in 1994 and was completing her Ph.D. in biotechnology from Bath University in the United Kingdom. Having spent nine years in the pharmaceutical industry in Jordan, she was fully aware of the problems that could arise if a facility was not established according to current Good Manufacturing

Medicine Group	Therapeutic Class	API Brand Name	Generic Name
Anti-Infective	Antibiotic	Zocin	Azithromycin
	Anti-fungal	Candivast	Fluconazole
	Anti-viral	Virpes	Acyclovir
Cardiovascular System	Anti-hypertensive	LowVasc	Amlodipine
	Cholesterol Lowering Agent	Sivacor	Simvastatin
Central Nervous System	Analgesic	Nomal	Tramadol
	Anti-migraine	Apigrane	Sumatriptan
		Zemitron	Ondansetron
Alimentary Tract & Metabolism	Anti-rheumatic	Moven	Meloxicom

Exhibit 4. Product Line

Practices. API had twelve dedicated staff engaged in product development, all of whom held degrees in chemistry, pharmacology, or chemical engineering.

Fifteen products were in the pipeline at various stages of product development in early 1999. Product development focused on formulation, stability and bio-equivalence studies, far less than product development efforts required of multinational pharmaceutical companies (Exhibit 5). API did not engage in basic research to create new medications because a new drug product could cost over \$2 billion to develop. In contrast, the cost of demonstrating bio-equivalence of a product was estimated at approximately \$1 million. The API development budget was approximately \$326,429 – 435,239⁴ per year, between 30-40% of sales revenue.

Product development involved four stages: pre-formulation, formulation, stability and bio-equivalency. The majority of time was spent in formulation. API developed their own product formulas as opposed to receiving product files containing product development information. Eighty percent of the products were produced by direct compression⁵, meaning that the formulas needed to be kept as simple as possible. Stability studies were conducted to determine if the pharmaceutical product was stable in its formulation. API engaged in accelerated stability studies, which involved subjecting products to harsh conditions such as extreme temperatures over a shorter time period. Usually it took one year to develop a product along these stages, however some pharmaceuticals took longer to develop because they were difficult to formulate or complications arose in the stability or bio-equivalency stages.

For API, quality was everything. The strategy of quality pharmaceuticals at reasonable prices meant quality at every step of the operation—in terms of raw materials, machinery, personnel, marketing, promotional materials, as well as the

Product Development Stages	Multinational	Jordanian
Compound Synthesis	x	
Toxicology	x	
Formulation & Stability	x	x
Bio-equivalence	x	x
Clinical Studies	x	
Cost		

Exhibit 5. Research & Development: Multinational vs. Jordanian

product itself. Quality control was involved in all stages of production and, therefore, API set rigorous standards for its manufacturing processes which resulted in final products that performed above expectations. For instance, it was generally accepted by pharmacopoeia standards that a pharmaceutical product such as tablets must not be below 90% of its initial dose. However, API only considered over 95% acceptable. Quality control was also responsible for ensuring the product was packaged correctly with the correct packaging materials. The quality control department was equipped with computerized analytical instruments supplied from ISO suppliers. There was great emphasis on systemizing the internal workflow and providing continuous training for its eight employees. This included well-defined standard operating procedures for receiving raw materials, manufacturing the product and testing the finished product.

Marketing

Marketing was an integral part of API and Dr. Rshaidat believed it to be one of the deciding factors in the future success of the company. The marketing strategy was to concentrate and excel in therapeutic classes. The company was not interested in having small products everywhere or a large number of small products. Instead API wanted to focus on certain therapeutic classes where real marketing efforts could be focused, such as cardiovascular drugs. This would allow API to invest and develop good relations in the market. The reason behind this strategy was that product development was expensive and it was becoming more expensive. First, the formulation took a lot of R&D and management time. Then bio-equivalency studies cost approximately \$40,000 per study. API could not afford to have many small products so they focused on few products to make them successful. Accordingly, each product selected for production underwent extensive analysis, including an overall marketing plan, positioning of product, SWOT analysis, medical and scientific features of the product, benefits and advantages of the product, and finally sales forecasts.

The marketing function was performed by an integrated team of sales representatives, medical representatives, sales managers, and tender and registration personnel under the direc-

tion of Mr. Ibrahim Al-Abbadi. Mr. Al-Abbadi had a degree in pharmacy and joined API in 1996 after four years with UK-based Astra Zeneca, where he was a marketing supervisor. Over 90% of sales representatives were pharmacists or assistant pharmacists. Medical representatives dealt exclusively with sales to doctors, while sales representatives concentrated on sales to pharmacists and pharmacies.

	1997-1998		1998-1999	
	Units	\$	Units	\$
TOTAL	49,300	26,400	115,000	683,100
LowVasc	10,500	80,600	20,700	202,000
Zocin	2,400	29,400	17,700	163,800
Nomal	28,500	4,400	63,800	148,300
Sivacor	3,000	34,900	4,400	96,200
Candivast	3,900	20,300	7,000	53,900
Apigrane			1,200	14,000
Virpes	600	15,900	200	4,900
Zemitron	400	38,900		

Exhibit 6. Local Sales by Product

Sales were continuing to rise in the local market at a balanced pace that was believed to reflect the healthy marketing strategy. LowVasc, one of the first products launched, was ranked 64th out of 200 drugs in its therapeutic class, holding 17% of the Jordanian market for calcium antagonists⁶ and it was API's best-selling product thus far (Exhibit 6). API believed that the local market was a good indicator of potential sales in export markets as it was the testing ground for marketing plans to be used when entering other markets. However, penetration into the traditional export markets was slow due to difficulties in the registration processes on other Arab countries. Before a pharmaceutical product could be sold, a license from the relevant regulatory authority had to be obtained. In Jordan, the regulatory authority was the Ministry of Health. Registration in Jordan, while not necessarily easier, proved faster. Product files submitted in Jordan took on average two to three months to be approved.

Identification of potential markets that warranted product development was accomplished partly through the combined experience of Dr. Rshaidat and Mr. Al-Abbadi. Information was also gathered from each country's Ministry of Health, Ministry of Planning, Jordanian embassies in each country and distribution agents, who, for the most part, were transfer companies (drug stores) that sold to pharmacies.

API had successfully registered the company and seven products in eight Arab countries: Iraq, Algeria, Bahrain, Yemen, Oman, Qatar, Sudan and Libya. Registration was pending in the United Arab Emirates, Palestine, Kuwait, Tunisia, Germany, Uganda, Nigeria, Kenya, and Romania. These registration pro-

cedures, which it expected to complete in the next two years, would enable the company to achieve its sales targets. Registration was the primary barrier to entry in export markets (Exhibit 7). Each country had a different registration process, so the company had to adapt to each country's procedures. The registration process was further complicated by requests, in most cases by the Ministries of Health, for excessive technical information. For example, in certain countries officials required bio-equivalency studies for each product, something the U.S. Food and Drug Administration (FDA) did not even require. These complications were burdensome since the company was new and did not have a large marketing budget to handle registration fees. Despite these difficulties, API was proceeding well with the registration process.

1. Application form (two copies) to be filed completely taking into consideration the following:
 - * Separate application for each pharmaceutical form and/or strength
 - * Address of the branch supplying Jordan to be the same as the manufacturer's one
2. Free Sale Certificate issued by the health authorities, legalized by the Chamber of Commerce and Jordan Consulate, declaring that the product is freely and actually sold in the country of origin and showing:
 - * The whole consumption of the product
 - * Registration number and date
 - * Public price in the country of origin for the same strength and pack
3. Insert leaflet used in country of origin
4. Certificate of Analysis
5. Method of Analysis and Stability data (2 copies)
6. Pro forma invoice including suggested FOB/CIF price in Jordan
7. Insert leaflet (10 copies)
8. Sufficient quantity of the active raw material to be used by the Drug Control Lab for analysis and its relevant analysis certificate.
9. Sample of product (10 original packs)
10. Product specifications (2 copies)
11. Bio-availability and/or bio-equivalence studies
12. Published scientific studies
13. Clinical and toxicological studies, including antidote and method of treatment in case of overdose.

Exhibit 7. Example of Drug Registration Requirements Outside Jordan

The Arab Pharmaceutical Market

Pharmaceuticals were a dynamic market in the Middle East-North Africa (MENA) region. Many countries had extensive welfare systems, particularly in the oil-wealthy Gulf States, which provided subsidies and free healthcare to its citizens.

Rapid population growth rates through the year 2050 for the region meant that pharmaceutical expenditures were expected to soar in the near future.

In 1997, the regional pharmaceutical market was estimated to be over \$2 billion. The largest national markets representing over half of this total in 1997 are detailed in Exhibit 8. By 1999, pharmaceutical sales in the Middle East reached U.S. \$6.89 billion, which accounted for 2% of worldwide sales according to IMS Health's Global Pharmaceutical Forecast: 1999-2003. Traditionally, the Arab pharmaceutical market had a low level of consumption per capita compared to Western consumption levels. Japan, Europe, and the United States typically spent twenty-eight, twelve, and twenty-one times the average MENA citizen on pharmaceuticals, respectively. Although the region contained some of the highest GDPs per capita, the wealth was distributed to only a small portion of the population. Therefore, low-income consumers fueled the demand for lower priced generic drugs. Most MENA countries recognized manufacturing process patents, but not end-product patents. Therefore, slight variations in manufacturing processes permitted formulated equivalents to be registered and marketed under new names in many developing countries where patent enforcement was not tight. For consumers this meant access to pharmaceuticals with the same active ingredients, strength, and medical effects as the patented brand name counterparts but at a cost usually 50% lower than the original price. Jordanian companies alone registered over thirty unauthorized copies (formulations) of U.S. and European drugs during an eighteen-month period from January 1996 until June 1997.

1996	Market Size	Population	GDP per Capita	Drug Cost per Capita
Jordan	\$120	4.2	\$1,702	\$35.70
Egypt	950	60.6	1,115	15.7
Saudi Arabia	750	19	7,267	39.5
Tunisia	250	9.1	2,156	27.5
Lebanon	200	3.2	4,513	62.5
UAE	150	2.5	16,998	60

Exhibit 8. Regional Pharmaceutical Market (Selected Countries)

Regionally, pharmaceutical manufacturers were facing numerous difficulties. There was a high level of competition and many pharmaceutical firms offered competitive products serving the same needs. In addition, many firms made short-term investments to produce products with low barriers-to-entry using limited technology inputs and targeting the same low-income consumer groups. Many firms wanted to raise the price of selected pharmaceuticals in order to increase rev-

enue, but government regulations throughout the MENA region focused pricing strategies on welfare considerations of low-income consumers. Therefore, prices of pharmaceuticals remained low, which meant marginal profits on local and regional sales. As a result of low revenue, research and development for new chemical compounds were virtually non-existent in the region. Despite these difficulties, the regional industry witnessed phenomenal growth with over 150 factories operating in the region, the majority operating in Egypt, Tunisia, and Syria.

1997	
Total Importation in Export Price	\$42,891,333
Total Importation in Public Price	\$62,024,075
Total Consumption in Export Price	\$71,205,584
Total Consumption in Public Price	\$97,873,768
Average Consumption Per Person	\$21.48
Percentage Local Production from Total Consumption	40%
Yearly Increase in Consumption	7.70%
* Public price indicates custom duties, sales tax, etc.	

Exhibit 9. Importation and Consumption of Drugs in Jordan

The Jordanian Pharmaceutical Market

The pharmaceutical industry in Jordan was the second most important exporter in Jordan after phosphate with capital investments of around \$400 million, providing 3,500 direct employment opportunities. Jordanian exports of pharmaceutical products ranged between \$140-190 million per year. However, the Jordanian market consumed around \$195 million in pharmaceutical products in 1997 and consumption rose to \$232 million by 1999. Consumption of pharmaceuticals was segmented into two sectors: private market and institutional market. Private market sales were through pharmacies while the institutional market sales were through tenders of public institutions and large private hospitals. The private market was the larger of the two, amounting to over 76% of the overall market. The Ministry of Health was responsible for the healthcare plan in Jordan, and health care expenditures absorbed roughly 7.5% of the Gross Domestic Product. Respiratory, digestive, and central nervous system diseases accounted for over 55% of prevalent health issues in Jordan (see Exhibit 10).

The Jordanian pharmaceutical industry was fairly competitive with ten pharmaceutical manufacturers operating. The large pharmaceutical sector was primarily attributed to lack of barriers to entry. There were no foreign pharmaceutical companies manufacturing in Jordan, largely due to the relatively small size of the country with a population of only 4.5 million.

Disease Groups	# of Occurrences	%
Diseases of the Respiratory Systems	2,267,141	39.6
Diseases of the Digestive System	554,692	9.7
Diseases of the Nervous System and Sense Organs	531,041	9.3
Infectious and Parasitic Diseases	463,880	8.1
Disease of the Musculo-skeletal System	409,039	7.1
Diseases of the Skin and Subcutaneous Tissue	389,509	6.8
Diseases of the Genitourinary System	275,867	4.8
Disease of the Circulatory System	255,314	4.5
Endocrine, Nutritional & Metabolic	181,016	3.2
Diseases and Immunity Disorders		
Complications of Pregnancy and Childbirth	116,957	2.0
Symptoms, signs, and Ill - Defined conditions	112,021	2.0
Injury and Poisoning	95,701	1.7
Diseases of Blood and Blood Formating Organs	36,191	0.6
Mental Disorders	17,873	0.3
Certain Conditions Originating in Prenatal Period	9,793	0.2
Congenital Anomalies	6,379	0.1
Tumors	8,518	0.1
TOTAL	5,730,942	100

Exhibit 10. Prevalence of Disease in Jordan

However, foreign drug companies remained quite active in marketing and distribution activities. Sixty percent of the domestic market was served through imports, comprising both generic and patented drugs.

Most Jordanian pharmaceutical companies focused on the same product categories, which were in high demand locally and regionally (see Exhibit 11). As a result, the majority of the market growth had been in a few therapeutic categories that accounted for almost half the market. The industry product concentration led to product overlap, high domestic competition and excess production capacity. There were 220 therapeutic categories available in Jordan, but only 110 were produced locally. Therapeutic categories available globally amounted to 349.

Medicine Group	Units (00)	Value	%
Systemic/general Anti-Infective	43,162	20,260	24.9
Alimentary tract & Metabolism	42,323	12,344	15.1
Central Nervous System	51,861	9,200	11.3
Cardiovascular System	11,895	7,525	9.2
Respiratory System	41,953	7,217	8.9
Musculo-skeletal	23,156	6,374	7.7
Dermatological	20,714	5,777	7.1
Genitourinary System and Sex Organs	14,182	5,536	6.8
Various	9,718	3,230	4.0
Sensory Organs	10,605	2,494	3.1
Systemic Hormones	3,329	1,049	1.3
Blood and Blood Forming Organs	3,612	1,016	1.2
Immunomodule	268	549	0.7
Parasitology	2,186	402	0.5
Diagnostic Agents	93	53	0.1
Hospital Solutions	338	36	0
TOTAL	279,395	83,059	100

Exhibit 11. Medicines Produced in Jordan

The Debate

Jordan, like other MENA countries, was preparing to enter the World Trade Organization (WTO), which covered over 90% of international trade. Established as a result of the Uruguay round of multinational trade negotiations, WTO began on January 1, 1995. Strengthening intellectual property protection for pharmaceuticals was a principal concern during negotiations of the Trade Related Intellectual Property Rights (TRIPs) agreement. This agreement established minimum universal standards on patents, copyrights, trademarks, industrial designs, geographical indications, integrated circuits, and undisclosed information. The agreement protected the process as well as the final product from copyright infringement. For developed countries, the TRIPs agreement stimulated drug innovation by protecting the rights of inventors.

However, once a drug was discovered and developed, it was often relatively easy to produce. It was estimated that lack of adequate and effective intellectual property protection for pharmaceuticals and market restricting price controls cost the U.S. pharmaceutical firms more than \$9 billion a year, with Jordan alone inflicting \$25-50 million in losses. The volume of medicine in Jordan subjected to patent protection was estimated at \$12 million, including those medicines exported to traditional markets. Multinational pharmaceutical lobbyists insisted that strong intellectual property protection helped developing nations by stimulating the conditions for investment, encouraging the development of local industry, and by enabling more goods to be produced.

However, developing nations in the Arab world were not optimistic regarding these potential benefits. Many regional producers and consumers feared that complying with the WTO terms would push up prices as foreign companies gained access to markets and producers who could not or had not obtained licensing agreements would be squeezed out. Jordanian companies did not have sufficient resources to conduct discovery research to develop and patent new drugs. For Jordan, the cost of joining WTO was high. All forms of protection for local industry, including subsidies and price fixing, had to be eliminated. The promise for foreign investment was weak because many felt it greatly depended on the economic situation of the country and its market size, and not so much on enforcement of patent protection. Egypt, a country with a population over sixty-five million and market size close to \$1 billion, was a major violator of patent protection. However, the highest concentrations of multinational pharmaceutical investment activities in the MENA region were in Egypt. Many wondered how Jordan, a country with a population of 4.5 million and a market size of \$140 million, would attract foreign investment (see Appendix for background on Jordan).

Intellectual property was an important issue for API. When the feasibility study to establish the company was conducted, patent protection was not an issue. Pharmaceutical producers in Jordan then built their businesses on new formulations of known medications. The Jordanian government permitted

Product	API Price (JD)	Imported Price (JD)	Market Size (units)	API value (JD)	Imported Value (JD)	Loss to Consumer (JD)
LowVasc	11.000	19.750	113,300	1,444,300	2,593,175	1,148,875
Zocin*	8.643	11.223	618,200	5,343,103	6,938,059	1,594,956
Nomal	2.100	2.670	4,233,400	8,890,140	11,303,178	2,413,038
Sivacor	27.000	29.580	58,000	1,566,000	1,715,640	149,640
Candivast	12.250	17.825	39,500	483,875	704,087	220,213
Aprigrane	11.000		38,400			
Virpes	24.000	32.810	4,600	110,400	150,926	40,526
Total						5,567,248

Exhibit 12. Excessive Cost of Imported Pharmaceuticals to Jordanian Consumers

producers to use different processes to manufacture existing products. API like other new companies based their strategies on the profile of products and not on their patent expiration. The issue surfaced after they had established the company but before production began (1995-1996) (Exhibit 12). By that time they had several products in the pipeline that could not be scrapped; API had to put them on the market and register them or else go bankrupt. The new products were more generic medications with expired patents. API still had patented drugs already in product development and those they would continue to develop. Afterwards, API planned to switch to more generic drugs.

Roche Pharmaceuticals

Roche Pharmaceuticals was a Switzerland-based pharmaceutical company with over two-thirds of its sales attributed to prescription medications. Therapeutic areas included the central nervous system, infectious diseases, oncology, virology, cardiovascular diseases, inflammatory and autoimmune diseases, dermatology, metabolic disorders, and respiratory diseases. Roche had extensive research capabilities with a good track record developing new medications to treat disease.

Roche sold its products in over 170 countries through various strategic partnerships and agreements. Strategic partnerships included research alliances, co-development agreements, co-promotion agreements, and distribution agreements. Roche was also involved in license agreements with other pharmaceutical companies and biotechnology firms. In cases where Roche obtained licenses from other companies, Roche would pay a one-time licensing fee, and after the drug was successfully developed by the granting pharmaceutical company and received regulatory marketing clearance, Roche would then pay royalties to the granting pharmaceutical company based on sales. Roche would be in charge of future development of the drug and would have global marketing rights.

As with other multinational pharmaceutical companies, the investment climate played a key role in determining Roche's level of commitment to a given market. In the past, population, income levels and other market characteristics were determining factors in writing licensing agreements. In addition, the status of intellectual property rights laws and enforcement in that market were very important. Companies wanted protection for their drug innovations and that required strong patent protection.

License agreements allowed Roche to share its technology for a fee. They also helped Roche establish a presence in a particular country without the hassle of product registrations or committing personnel to marketing in country and/or a region. Furthermore, forming an alliance with a local company could

be used later to gain concessions within a country and region. Therefore, licensing could prove beneficial to multinational corporations interested in entering existing markets.

The Decision

Dr. Rshaidat understood that these therapeutic areas were prevalent in Jordan and the MENA region, therefore Roche's technological advancements in these areas were attractive.

Dr. Rshaidat was armed with *wastah*⁹—"network of connections"—which he acquired while working in Switzerland. The Jordanian Association of Pharmaceutical and Medical Appliances Manufacturers started an integrated program with the Swedish government to rehabilitate the pharmaceutical industry and ready it to enter international markets. Dr. Rshaidat utilized his contacts to maneuver into a professional relationship with Roche representatives based on this program.

Dr. Rshaidat had examined the internal needs and strengths of API and thought to pursue one of two strategies: (1) contract manufacturing, or (2) licensing agreements. Contract manufacturing was in essence a strategic manufacturing partnership at Jordanian plants. The benefits included obtaining international know-how, scientific knowledge, technology transfer, and filling industry downtime. Jordanian plants would be responsible for manufacturing exclusively with no claims to the manufactured product. Licensing agreements included the same benefits as contract manufacturing but included marketing rights for the product. Under a licensing agreement, produced medications would be considered API products. Licensing would supplement API's current product line and allow API to utilize their strengths in manufacturing and marketing. Initially, Dr. Rshaidat sought to propose a licensing agreement stipulating that API buy all raw materials for the production of products from Roche and pay royalty fees amounting to 5% of product sales.

Licensing agreements were intended to build technological capabilities through the transfer of technology. However, only 2% of Jordanian pharmaceutical production was conducted under license agreements. By comparison, in Egypt and Morocco 40% and 70% respectively of formulation and packaging activities were carried out under licensing agreements with multinational corporations. Multinationals tended to authorize licensing agreements to countries with economic considerations in mind. Dr. Rshaidat also understood that with strengthened patent protection, multinational corporations would have less incentive to authorize licenses. Instead they would export finished products and market them through local or their own distribution facilities. API had to act now if they were to take advantage of the current situation.

Appendix

BACKGROUND ON THE HASHEMITE KINGDOM OF JORDAN

Jordan is located to the northwest of the Arabian Peninsula and has a landmass of 89,213 square kilometers. Syria borders Jordan to the north, Iraq to the east, Saudi Arabia to the south and southeast and the Palestinian National Authority and Israel to the west.

Religion

Islam, meaning submission, is the predominant religion in Jordan. For Muslims (those who accept Islam), Islam is the consummation and correction of its monotheistic predecessors, Judaism and Christianity. The basic principles of Islam are that there is only one God who must be worshipped by man and that the Prophet Mohammed was the ultimate messenger of God's wishes to mankind. Every Muslim has five basic duties called the pillars of Islam: testifying that "there is no god but God and Mohammed is the messenger of God," praying five times a day, setting aside a certain amount of money for the poor, fasting from dawn to dusk in the month of Ramadan and making the pilgrimage to Mecca at least once in a lifetime. Jordan is overwhelmingly Sunni Muslim with only 5% of the population being Christians.

People

Hospitality is the cornerstone of Arab life and it is commonplace for Jordanian families to welcome strangers into their home. The average Jordanian family still has seven children, and the country has one of the highest birth rates in the world. Family values are paramount and have dictated a particularly strict moral code. As a consequence of this strict moral climate, Jordan has a low crime rate.

History

The Kingdom of Jordan has revolved around the fortunes of a single family – the Hashemites. Jordan owes its establishment in 1921 to the fortuitous coincidence of Britain's interest in establishing some sort of political authority under its protection on the east bank of the Jordan River with Abdullah ibn Hussein's presence in the area at the time. Modern Jordan is almost entirely the creation of his grandson, the late King Hussein of Jordan.

Under the Treaty of San Remo in April 1920, Britain had been given the mandate for Palestine and Iraq, and France the mandate for Syria. Faisal, the brother of Abdullah, was invited by the British to become king of Iraq in December 1920, and was crowned in Baghdad in August 1921. At this stage in 1920, the

status of Transjordan, or the east bank, had not yet been decided. In 1920-21, however, Britain was concerned with keeping the French as far from the Suez Canal as possible. With this in mind, it was decided that Transjordan would have some loose form of administrative attachment to Palestine. In March 1921, Winston Churchill invited Abdullah to Jerusalem for talks, at the end of which Abdullah agreed to govern Transjordan for an initial period of six months. Thus, the Kingdom of Jordan came into being.

King Abdullah I was assassinated in July 1951 in Jerusalem. He was succeeded by his eldest son Talal, who had a history of mental instability and was removed a year later in favor of Abdullah's grandson, Hussein. Hussein became King of Jordan in 1953 and ruled until his death in February of 1999.

Jordan's major economic problems ensued when King Hussein cast his lot with Egypt and Syria on May 30 1967, when it was clear that war with Israel was about to break out. By June 10, Israel had occupied the Sinai Peninsula, the Golan Heights, East Jerusalem, and the West Bank of Jordan. The effects on all three countries were devastating, but especially for Jordan, which lost a third of its population and its prime agricultural land, as well as control of the Islamic and Christian sites in Jerusalem. Jordan began to receive substantial financial aid from other Arab states in September 1967 and a considerable part of this went to help the people of the West Bank.

On a regional level, Jordan enjoyed fairly cordial relations with most of its neighbors in the late 1980s. However, Jordan's closest political and economic ties for most of the 1970s and 1980s were with Iraq. Economic exchanges between the two states continually increased. Iraq financed improvements at the Jordanian port of Aqaba and the development of the Jordanian road system. Because Iraq lacked a port in the Persian Gulf, most of the country's imports came through the Jordanian port of Aqaba. Approximately \$40 billion worth of Iraqi imports arrived via Jordan every year in the late 1980s. More cordial relations were inaugurated after the Baghdad summit of 1978, at which Jordan was promised \$1.25 billion annually for not participating in Camp David. Initially, Jordan's economy benefited. But after the Iraq-Iran war, Iraq deregulated foreign trade, however its outstanding debt to Jordan already exceeded the quota agreed upon by the two countries. In the absence of Iraqi trade, the Jordan Central Bank suspended export financing, causing a major flight from the Jordanian dinar. Of all Iraq's creditors, Jordan found Iraq's absence particularly difficult to bear.

More economic problems ensued when King Hussein ended all links with the West Bank in 1988. Ending this link caused the value of the dinar to fall sharply, and money exchanging activities were severely restricted in 1988 and 1989. Austerity measures, including sharp increases in import taxes and charges for work permits and exit visas, were announced in

November 1988. In April 1989, under the first of two IMF and World Bank-sponsored structural adjustment programs, there were increases in the prices of fuel, alcohol, and cigarettes and Jordan's \$6.6 billion external debt was rescheduled. In May 1989, there were mass demonstrations in several towns in response to these measures in which eight people were killed and eighty-three injured. In addition, ten of the country's eleven professional and trade union associations called for the resignation of the government and the formation of a government of national unity. Shortly thereafter, the governor of the Central Bank announced that Jordan had lost a third of its gold reserves over the previous six months.

Its major creditors further rescheduled Jordan's foreign debts. Six Gulf Co-operation Council states deposited some \$400 million in the Central Bank in an attempt to relieve Jordan's most pressing financial problems. It was estimated in April 1990 that the dinar lost two-thirds of its value in less than two years, and that 20% of the economically active population was officially unemployed. Every few months the King was obliged to tour Arab capitals with begging bowls simply to keep the country from imminent bankruptcy.

Economically, the invasion of Kuwait was an utter catastrophe for Jordan, as almost all its aid as well as its agricultural and manufacturing export earnings were suddenly cut off. The volume of trade through Aqaba dropped to half the pre-Gulf War annual average of 20 million tons. As a result, the Jordanian dinar, worth \$2.7 in 1988, was worth only \$1.6 at the end of 1990. Jordan's economic outlook was not particularly bright through the turmoil of the Gulf War and consequently Jordan enthusiastically joined the peace process when it was launched in October 1991. Economic advantages for Jordan were promising.

As expected, Jordan's financial difficulties were substantially eased as a by-product of the peace process. In July 1994, the USA announced the annulment of \$680 million worth of debt, which was believed to be in preparation for the peace treaty that Jordan signed with Israel in October 1994. Jordan has since been the only Arab State to establish formal diplomatic relations with Israel and as a result, diplomatic relations with the United States dramatically improved. In 1996, Jordan was declared a 'non NATO ally' and has since observed joint U.S.-Israeli-Turkish naval military maneuvers. As a reward for Jordan's diplomatic efforts, the U.S. continues to grant Jordan millions of dollars in economic assistance.

Today King Abdullah II, the eldest son of Hussein, rules Jordan. Since taking over the reins of power in February 1999, King Abdullah has made a series of important political decisions that will have far reaching effects on the Kingdom. However, one of the monarch's most vital tasks is to inject some life into his country's fledgling economy.

Hashemite Kingdom of Jordan	
Tablets	140,000/hr
Capital	Amman
Population	4.5 million
Total Fertility Rate	4.64
Religion(s)	95% Sunni Muslims 5% Christians
Language(s)	Arabic (official) English (widely spoken)
Literacy Rate	85%
Total Labor Force	1.15 million

Development in Jordan Today

Jordan is poor in natural resources and lacking in water, and this has affected its industrial development. In agriculture, water resource constraints are among the reasons for agriculture's low shares of the GDP and the work force. Apart from phosphate and potash production and labor-intensive processing industries such as the textile industry, mining and manufacturing industries are immature. Jordan is actively engaged in fostering industry by introducing new legislation on investments, building industrial parks and planning a free trade zone. Tourism is an important source of foreign currency, and Jordan counts on it to grow. Though Jordan is relatively well equipped with electricity, transportation, and other infrastructure needed for industrial development, further improvement is still necessary. The absolute insufficiency of water resources is a hindrance to development, and so is the current waste of water resources through existing pipelines and the inadequacy of water supply and sewage facility maintenance. The country's only seaport, the Aqaba region, is important as an external trade base and industry promotion zone as well as tourist site. It is a priority for development.

Job opportunities are limited in Jordan due to the immaturity of domestic industry, leaving the peoples' livelihoods insecure. While Jordan's educational indices are high, the middle classes, indispensable to industrial development, are too small to play a sufficient role. The middle class, the technically skilled, as well as the entrepreneurs of Jordan continued to emigrate to find jobs. Jordan's chronic "brain drain" has slowed growth of its local industry and hindered economic development. Education did not guarantee stability of employment or improvement in one's standard of living. Jordan's population growth rate is very high and the percentage of the population less than five years of age is very large. Health care standards are relatively high, but rural areas are still under-served and the gap compared with the cities presents problems. Despite attempts to implement structural adjustment reforms, Jordan remains a fragile economy, sustained by international aid and workers' remittances, which totaled \$2 billion annually recently, according to the World Bank.

Economic Indicators	
GDP: purchasing power parity	\$15.5 billion
GDP: real growth rate	2.2%
GDP per capita	\$3,500
Inflation Rate	4%
Exports	\$1.5 billion
Imports	\$3.9 billion
Debt – external	\$7.5 billion
Economic aid – recipient	\$1.097 billion (1995 est)
Exchange rates	JD per US\$1 = .7090

Source: CIA – World Factbook

Foreign Assistance

Jordan has had perennial budget and current account deficits ever since the foundation of the Kingdom and is dependent on foreign assistance and remittances from Jordanians working abroad. In 1988, agriculture, mining, and manufacturing together contributed only 22.5% of GDP, which meant that the economy was dominated by the services sector and thus extremely vulnerable to events entirely outside its control. Remittances, which far outweighed export earnings between 1975 and 1985, began to fall dramatically when oil prices halved in the mid 80s and many Jordanians (along with other expatriates) were obliged to leave oil-rich states.

As a result, Jordan became one of the most indebted countries in the world. Since then, its debt management program has received considerable assistance from the U.S., Japan and European countries largely as a reward for its economic policies and improved political relations with the West. The U.S. and Japan are Jordan's major creditors with \$2.4 billion and \$1.9 billion worth of claims, respectively. Since 1990, the United States has forgiven \$700 million in official debts, given \$624 million in grants, soft loans and loan guarantees for the import of American agricultural products, and given a total of \$368 million in military assistance along with a transfer of \$125 million worth of military equipment.

United States Assistance to Jordan	
Grants	
United States for International Development (USAID)	\$150.0 million
Foreign Military Financing (FMF)	\$45.0 million
International Military Education and Training Program (IMET)	\$1.6 million
Food Aid	
USDA Wheat Donation (416b)	\$15.0 million (estimated value)
Loan Guarantees	
GSM	\$60.0 million
Grand Total	\$271.6 million

Source: US Embassy Website - Jordan

Fifty percent of USAID assistance provides balance of payment support to help Jordan's external debt burden, implementation of its economic reform program and increased credit availability to micro-enterprises and small businesses.

Jordan is seeking exceptional debt relief of 50% forgiveness of its total external debt. There is considerable goodwill to support the country's economic rehabilitation in the aftermath of King Hussein's death. The Group of Seven nations agreed to include Jordan, which is classified as a lower-middle income developing country, on the list of the World Bank and IMF's "41 Highly Indebted Poor Countries." These countries, mostly in Africa, are eligible for a generous debt write-off if they have shown three years of competent economic governance. Jordan's external indebtedness has declined to more manageable levels but still imposes severe constraints. Even with U.S. aid of \$300 million, U.S. assistance to Jordan remains modest compared to Egypt, which receives \$2 billion a year in U.S. aid and had over 50% debt forgiveness after the 1990-91 Gulf War.

IMF and Structural Adjustments

Jordan has been making efforts since the late 1980s to actively promote structural adjustment policies. In the late 1980s, Jordan's economy was plagued by poor trade performance and structural weaknesses in industry, taxation and financial sectors as well as a large external debt amounting to 193% of GDP in 1990. Its fortunes were too dependent on the level of aid and remittances originating from the Arab Gulf states, and when oil prices dropped the country faced a serious balance of payments problem. In 1989, an agreement was reached with the IMF on a five-year structural adjustment package. This agreement was put on hold after the Gulf Crisis in 1990-91. King Hussein's decision to ally closely with Iraq resulted in the severing of aid from the Gulf States, who also expelled thousands of Jordanian and Palestinian guest-workers, causing a significant decline in remittances and boosting Jordan's internal population.

In 1992, another agreement was reached on a second package covering the seven-year period from 1992-1998. The agreements did not involve big government-led projects of the conventional type, but instead stressed private sector initiatives. It aimed to reduce macroeconomic imbalances, continue structural reform, and achieve balance of payments viability. As a result, the country's fiscal, external and current account deficits came under control. In addition, a strong trend of low inflationary growth resulted from a recovery in the construction, agriculture, and mining sectors. Inflation was forced down below the IMF's target of 7% to 3.5%. In addition, the fiscal deficit, 18% of GDP in 1991, was reduced to 4% of GDP in 1996, while the external debt, which was equivalent to twice the GDP, was reduced to 87% of GDP by 1997. The central bank built up enough foreign currency reserves (excluding

gold) to cover nearly five months' of imports, well above the three months stipulated by the IMF. As of June 1999, foreign currency reserves amounted to \$1.75 billion. Subsequently, high real interest rates have underpinned the stability of the Jordanian dinar-U.S. dollar peg at a central rate of JD .711 to \$1.00 since 1995. A strong currency has contained imported inflation. In theory, Jordan's economic prudence brought rewards in terms of high figures for economic growth.

However, revised figures show Jordan's economy is growing much more slowly than the population, which will mean a decrease in average living standards. According to a recent survey, 26% of Jordanian families are already living in poverty. The government says 14% of the workforce is unemployed, while independent estimates suggest figures are more like 20-25%. Planned cuts in the civil service will put more people out of work. Jordan is not a stranger to civil unrest. Opposition to the lifting of state subsidies on staple foods, fuel and water led to rioting in 1989 and 1996. Needless to say, such protest could easily start again as the national economic structural adjustment program takes over following the IMF program that ended in 1998. The Jordanian government will be in control, but with IMF support. Economic liberalization, privatization, greater savings and investments, reduced debt and increased productivity will be the focus of Jordan's economic policies for the next decade. But with the economy growing so slowly and budget deficits likely to rise, the government has its hands tied. Any extra spending could undo six years of hard economic reform. Interest rates, though falling, will remain high enough to protect the Jordanian dinar. However, in light of new economic figures and the volatility of its people, Jordan has no room to make mistakes.

The Economics of Peace

Jordan has long sheltered many Palestinian refugees within its borders, therefore a solution to the Palestinian situation and renewal of the Middle East peace process is vital for Jordan's domestic, political, and social stability. Jordan's peace treaty with Israel contains a substantial economic element. Though both countries have similar populations, Israel's GDP is more than ten times that of Jordan's GDP of \$8 billion. As a result of the treaty, economic relations were to be normalized by removing discriminatory barriers and ending economic boycotts, and talks were launched to establish a free trade area. Agreements on border crossings, tourism, and security were initiated in February 1995 and agreements on agriculture, energy and the environment in May 1995. Topics covered by the draft energy agreement included the transit of neighboring states' oil and gas, trade in oil and gas products, and exchange of information on oil exploration. In addition, an annex to the October 1994 treaty specified that Jordan would receive twenty-five million cubic meters of water per year from resources currently controlled by Israel. In recent years, Jordan suffered from several water crises and repeatedly claimed that Israel did not supply all the water it was entitled.

In 1996, Israel exported \$12.25 million worth of goods to Jordan and imported \$7.75 million in goods from Jordan. Israeli and Jordanian ministers met in 1997 to discuss further removal of obstacles to trade. In a measure designed to reduce non-tariff barriers between the two countries, Israel announced a doubling of its quota of cement imports from Jordan to 30,000 tons per year. As of 1997, bilateral trade between Jordan and Israel was valued at \$31 million for Jordan and \$32.5 million for Israel.

Trade and investment links and development projects in the Jordan Valley are likely to continue to be features of Israeli-Jordanian co-operation in the future, but only if the peace process continues. Even though bilateral trade between the countries is little more than a "trickle," Jordan is well placed to receive considerable economic benefits if Israel continues to improve its regional standing and the Palestinian economy is permitted to flourish.

1. This case was written by Tangela Moore Monroe of Wright State University under the supervision of Prof. Richard Linowes of the Kogod School of Business at American University in Washington, D.C. It was written as the basis for class discussion rather than to illustrate either effective or ineffective handling of an administrative situation.
2. Every day, five times a day, Muslims are called to prayer from the minarets of mosques prevalent throughout the country. Prayer times: dawn, midday, mid-afternoon, sunset and evening.
3. Current good manufacturing practices (cGMP) is a process that ensures that production of pharmaceutical products complies with internationally accepted standards. These standards change over time and manufacturers have to upgrade their facilities regularly to ensure compliance. Compliance involves the following areas: organization and personnel, buildings and facilities, equipment, control of components, production and process controls, packaging and labeling controls, storage and distribution, laboratory control, records and reports and returned drug products.
4. Based on company sales of JD771,700 in 1998.
5. Direct compression: A tablet is made from a powder, which has been compressed so that it forms a coherent mass. This is done by feeding the powder into a metal well (die) in a tablet machine and compressing it between two steel rods.
6. Data taken from IMS Health Incorporated regional sales territory report.
7. IMS Health Incorporated is the world's leading provider of pharmaceutical information and insight. The company offers an array of sales management reports and market research services.
8. Jordanian pharmaceutical exports fluctuated from \$140-190 million per year based on the number of pharmaceutical companies operating in Jordan.
9. The Arabic concept of *wastah*, which translates roughly into "network of connections," functions as the primary guideline for professional and social maneuverings in the Middle Eastern countries. *Wastah* has likely replaced the extended family network of relations that was shaken in the massive uprooting of Palestinians into a diaspora. One relies on *wastah* to select personal associations of minor significance as well as those of vital importance, ranging from one's travel agent to a future spouse. Just as the accumulation of "good" *wastah* is valued as much as financial wealth (which it might lead to), a person's lack of *wastah* is often expressed in an embarrassed change in conversational subject. See Robert B. Cunningham, Robert B. and Yasir Sarayrah, *Wastah: The Hidden Force in Middle Eastern Society*. (Praeger, 1993).

