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FIRM LEVEL MANAGEMENT AND TECHNICAL ASSISTANCE TO MONOJO

Final Report - Confidential

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FINAL REPORT

USAID JORDAN ECONOMIC DEVELOPMENT PROGRAM

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BEARINGPOINT, INC.

USAID/JORDAN
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1.0 EXECUTIVE SUMMARY

MonoJo was established in 2005 as a private shareholding company, focused on developing and producing monoclonal antibodies for cancer diagnostics, targeting local and regional markets. Currently, the Company has 20 cancer diagnostics antibodies in the pipeline, five almost ready for market, while 15 others still under development. MonoJo is planning to develop and distribute diagnostic kits as an added value product and source of additional revenues.

At present, the company has the necessary technology and the skills to develop the monoclonal antibodies in-house, and it is outsourcing only animal related work during the initial phase of the product development process, and the testing of the final product. For the medium and longer term however, the production facility will have to be expanded to accommodate for new product lines, and the technology used will have to be upgraded in order to cater for the research and production needs. Also, the current R&D expertise is not entirely adequate. If MonoJo is to succeed in such a competitive industry environment, it will have to improve R&D efforts, and hire additional full time researchers and technical staff to be able to increase and broaden the in-house innovation and R&D capabilities.

The monoclonal antibody market is strongly driven by innovation. The ability and speed to develop new products, new product attributes or new applications for existing products is an important factor that determines a company's potential to successfully compete with major players in market. Industry competition comes from the major international biotech or pharma players that dominate the international markets, but also from the thousands of small and medium size contract manufacturers and suppliers, specialized in the development of large scale production of monoclonal antibodies, and hundreds of others who offer custom production of research-scale antibodies. These companies have strong research and development capabilities and significant financial, sales and marketing resources. In Jordan, and to a larger extend in the region, the largest players competing in the diagnostics monoclonal antibody market are DAKO, BioGenex, Ventana, Abbott and Becton Dickinson and Company.

MonoJo's challenge is to position itself into the local and regional markets as a flexible producer of diagnostic monoclonal antibodies of high quality and at competitive price. In the future, MonoJo is planning to extend its product offerings and will target customers in markets outside the MENA region, such as research centers and international biopharma drug producers.

The Company's short and medium-term growth objectives are:

- Obtain ISO 900:2000 and 13485:2003 certification and CE mark by the first quarter of 2009.
- Achieve first five products' market readiness (in terms of purity and stability) by end of Q1 2009.
- Introduce the first five products into the market by end of 2009.
- Achieve financial sustainability by the beginning of 2010.
- Introduce a total of 17 products into the market by end of 2011, by developing at least four new products annually during 2008-2011.
- Build a strong regional position as a provider of monoclonal antibodies for cancer diagnostics: penetrate the Saudi and Egyptian markets by end of 2010.
- Achieve 20% market share in Jordan by end of 2010.
- Reach sales growth in the regional markets in line with those markets' growth rates.
- Generate the funds needed to develop antibodies for therapeutical use (bio-generics)
- Obtain GMP certification for antibody production by end of 2012.

- Make sales to international buyers no later than beginning of 2013.

To achieve these objectives, MonoJo will pursue a diversification strategy, by developing new products and extending into new markets. The diversification strategy will follow a three-stage path, starting from penetrating into the Jordanian market, expanding into regional markets and then moving into international markets:

- **Phase one** will comprise of building the capabilities and capacity to be able to enter the Jordanian market. MonoJo will position itself as a local producer of diagnostics antibodies that provides high quality products, customer service and flexibility in providing the product attributes that customers require. MonoJo will target local hospitals, and clinical labs at will offer products at competitive prices. In order to compete in the Jordanian market MonoJo will obtain the necessary quality certifications, make solid progress in improving and managing the quality of its products, build brand identity, diversify its product pipeline and develop the resources necessary for sustainable research and product development activities. The Company will build in-house storing facilities to provide local customers with just-in-time delivery, and will build partnerships with the academia, the local industry and international firms for product development, technology licensing and distribution in regional markets. MonoJo will also establish a commercial business unit to act as a trade arm of the company, conducting marketing and sales operations.
- **Phase two** - of expanding to regional markets will begin during 2009, once the company has obtained the necessary certification and in parallel with the development and introduction of new products into the local market. During this phase, the Company will invest in product development to diversify its pipeline, improve its R&D, marketing, human and financial resources and will identify key potential distribution partners in the target markets of Saudi Arabia and Egypt and establish distribution partnerships. MonoJo will price its products at a cost-plus pricing, while considering the prices that customers in the target market are ready to pay and what buyers are offering. The company will develop the website to e-commerce level and acquire the related resources needed to be able to do worldwide e-transactions. In terms of promotional strategy, MonoJo will upgrade its promotional materials and will actively participate in key regional trade shows.
- **Phase Three** - MonoJo will focus on the U.S. and European medical research market (research centers, scientists) and commercial biopharma companies with research quality customized antibodies at competitive prices. The company will build production capacity, improve R&D efficiency and increase spending, become GMP certified. It will form partnerships and alliances with foreign firms for collaborative research and diagnostic antibody development, technology licensing and marketing arrangements. At a later stage, MonoJo will pursue strategic alliances to leverage the resources and capabilities of potential partners for the development of bio-generics and for their marketing in international markets. This phase should also include relocation of R&D and production to new and modern facilities - not only to accommodate for the physical expansion of production capacity, but also to upgrade the company's image to customers and partners. The physical aspect of the company and its location is as important as the promotional and communication materials and tools to conveying a positive image to customers, partners and suppliers.

The assessment for MonoJo's management systems captured all areas including human resources and training, quality assurance, communication, security management, information technology, laboratory safety, procurement and many other areas that contribute to enhancing the organizational performance and provide a strong base for the company to grow and expand.

This assessment was conducted based on several meetings held with key parties carrying out different responsibilities at MonoJo. Observations obtained upon site visits to the company and its laboratory enriched the assessment with fruitful recommendations that would benefit MonoJo on both the short and long term.

2.0 SITUATION ANALYSIS

2.1 COMPANY ANALYSIS

2.1.1 COMPANY BACKGROUND

Jordan Company for Antibody Production (MonoJo) was established in 2005 as a private shareholding company with a start-up capital JD 400,000. MonoJo is a spin-off from the National Biotechnology Research Center, which is affiliated to the Higher Council of Science and Technology. The company is pursuing a strategy of developing and manufacturing monoclonal antibodies for cancer diagnostics and cancer research targeting local and regional markets, in addition to providing technical training for the educational and medical sectors.

MonoJo is hosted in a rented apartment building in Jubeiha, next to the Higher Council of Science and Technology and close to the University of Jordan; 300 sqm area is dedicated for laboratories and training, and 250 sqm are occupied by offices. Although the facility is considered by management as adequate for present operations, it is believed that it will not be suitable in the future, under the planned business expansion.

The Company currently employs ten people, seven full time staff and three part time employees – the sales director and two R&D consultants. The company's management is comprised of a board of directors and the CEO who is responsible for managing the day-to-day operations. The 7-member board is made up mostly of representatives of the company's institutional investors. In addition, the company has four technical advisors, including the director of the Cambridge Institute of Biotechnology in the UK, and has formed strategic alliances for scientific cooperation with four Jordanian universities and the National Center for Biotechnology. Any future product development will require the addition of skilled in-house talented researchers and other technical staff, as well as sales and marketing people.

The Company's vision is to become a global manufacturer of monoclonal antibodies for cancer diagnostics and a provider of technical training for educational institutes and medical industry. MonoJo's mission is to provide high quality products and services that improve the quality of life.

According to its business plan and the company's commercial strategy, MonoJo is focused on developing the top 18 highest selling monoclonal antibodies targeting customers in the Gulf region; it was expected that the first five products developed will be introduced in the market in the second quarter of this year. According to company earlier forecasts, they also anticipated to achieve a 20% share of the local market in 2008. Expected sales of monoclonal antibodies in 2008 were JD 326,441 and were forecast to increase by 14.2% and 10% respectively over the next two years.

The company has identified the following competitors for their key products in the local and regional markets (listed according to their believed market share in Jordan):

- DAKO (represented in Jordan by Al Nahil – a MonoJo investor)
- BioGenex
- Ventana
- Abbott
- Becton Dickinson and Company, BD
- Roche (listed, but does not compete in the same range of products)

2.1.2 PRODUCT ANALYSIS

To date, MonoJo has a pipeline of 18 cancer diagnostic antibodies, five ready to market and the rest under development. None of the products have been commercialized so far. The company also offers custom made antibodies, upon customer's request. Table no. 2-1 below summarizes the status of MonoJo's product pipeline:

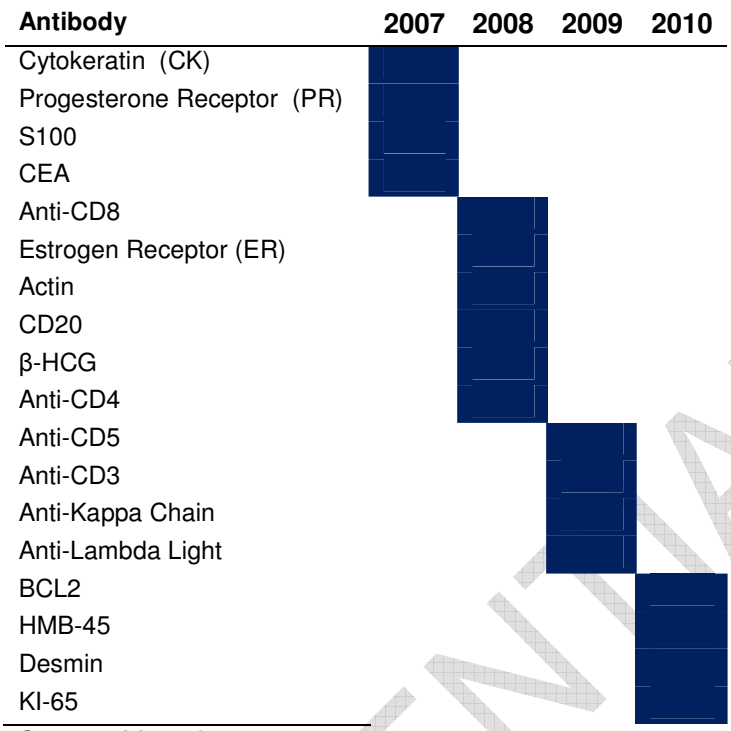
Table 2-1: MonoJo's Product Pipeline

Antibody	Use
Cytokeratin	For identification of carcinoma (Tumor that begins in the lining layer of all organs in the body. At least 80% of all cancers are carcinomas)
Progesterone Receptor	For prediction of prognosis and therapeutic response of breast carcinoma
S100	For Identification of neoplasms
CEA	carcinoembryonic antigen -Used in almost all cases of colorectal adenocarcinoma and in the large majority of thyroid carcinoma (malignant tumor of the thyroid gland)
Anti-CD8	Used for the detection and classification of malignant lymphomas (a tumor of the lymphatic system)
Anti-CD5	Used for the detection and classification of malignant lymphomas
Anti-CD3	
Anti-Kappa Chain	
Anti-Lambda Light	
Anti-CD4	
β-HCG	Used in classification of germ cell tumors
BCL2	Used in cases of lymphomas, leukemias, adenocarcinomas, carcinomas and neuroblastomas (cancer that arises in nerve cells and affects mostly infants and children)
HMB-45	An mAb that reacts against an antigen present in melanocytic tumors such as melanomas
Desmin	used for identification of leiomyosarcoma and rhabdomyosarcoma (a malignant tumor of muscle tissue)
KI-65	Used in malignant lymphomas and in the differentiation between benign and malignant lesions
CD20	Used for the detection and classification of malignant Lymphomas (a tumor of the lymphatic system)
Actin	Used for identification of all cases of leiomyomatous tumors, (a malignant tumor of smooth muscle cells that can arise almost anywhere in the body, but is most common in the uterus, abdomen, or pelvis)
Estrogen Receptor	For prediction of prognosis and therapeutic response of breast carcinoma

Source: list provided by MonoJo and included in the business plan

MonoJo's product development timeline, as provided by the company is illustrated in figure no. 2-1. Of these products, the first five are said to be ready for the market, while the rest are in different stages of development and may still achieve the planned launching schedule:

Figure 2-1: MonoJo's Product Development Timeline



Source: MonoJo

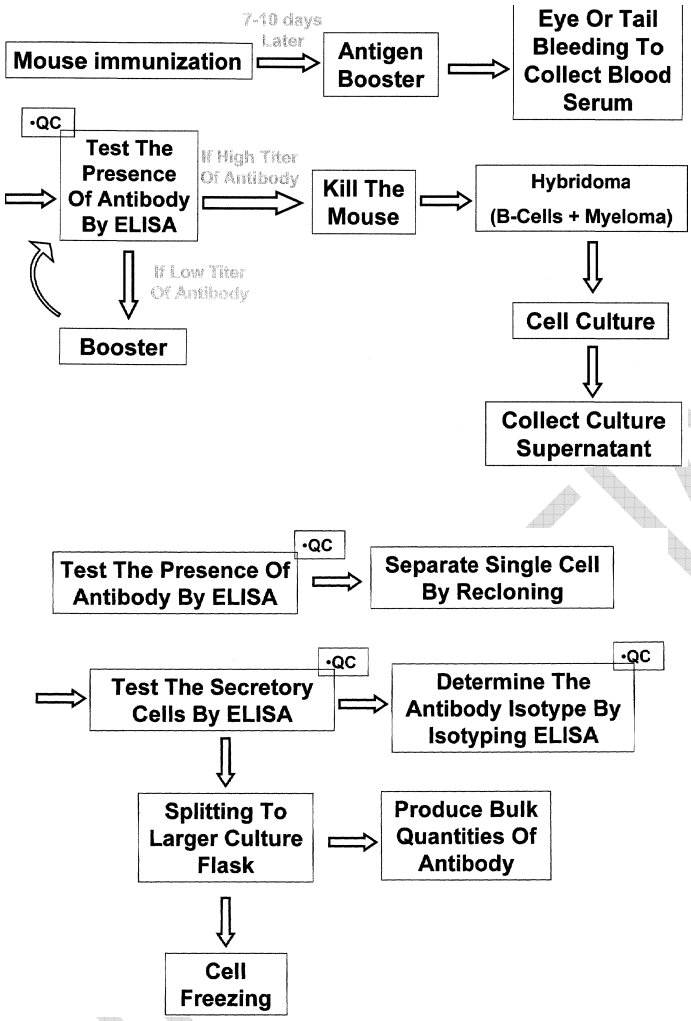
The company is planning to develop diagnostic kits in the future, as an added value to the current offer, and a product appreciated by customers. However, the process of developing these kits is estimated to require around 5-6 months and would engage all currently available technical personnel in activities of R&D, testing, quality control, production, etc. Given that the same personnel is engaged in the production of the already planned items, and the Company has no plans to hire in the current year, the development of the kits will have to be postponed for 2009 or 2010.

The successful development of a diversified product pipeline in the future will be associated with the company's innovation capabilities, and to the success in finding and hiring full-time researchers with innovative skills and the necessary R&D expertise.

2.1.2.1 PRODUCTION PROCESS

MonoJo carries out research and product development in-house, with the exception of the animal related work and the final product testing which are outsourced with the Yarmouk University and the Islamic Hospital, respectively. The following diagram illustrates the production process of the diagnostic antibodies at MonoJo**:**

Figure 2-2: MonoJo's Production Flow Diagram



Source: MonoJo

MonoJo is working with Cambridge University to develop novel antibodies for therapy.

2.1.2.2 QUALITY CONTROL

The company has internal quality control systems, with several quality control points along the production process. MonoJo is also working to obtain the ISO 9001:2000 and ISO 13485:2003 quality management certificates and the CE mark, which are the requirements that allow manufacturers to commercialize in vitro diagnostics (IVDs) antibodies in the local, regional and European markets. In Jordan, public sector buyers require the CE mark only from foreign manufacturers. Also related to product quality, the company's research team is working to solve some challenges related to the purity of its antibody products.

2.1.2.3 PACKAGING AND LABELING

The packaging and labeling are of medical grade imported materials similar to those used by other international manufactures. These and other supplies as well as all laboratory and other equipments are purchased from international approved suppliers, who, according to the company, are reliable in providing the needed quality and quantity of supplies, and there are no supply problems reported. The company believes that it has adequate technologies for its production operations and for manufacturing of good quality products but it has noted

that the packaging and filling steps are manual, and therefore the company is looking to upgrade these processes to automatic.

2.1.2.4 PRICING

MonoJo does not have a product costing and pricing system. The company says that it is currently preparing pricelists both in Jordanian dinars and US dollars. The management believes that manufacturing costs are lower than those of the EU and US competitors, due primarily to lower labor costs. The selling price is believed to be 25-35% less than that of any other key foreign manufacturer competing in the local or regional markets. MonoJo's suggested prices and those of competitors are available in table no. 2-13 (subchapter 2.3.9. on pricing) of this report and in the company's business plan.

2.1.2.5 PROMOTION

In terms of promotional materials, the MonoJo has a company brochure, and brochures for each product, including specification sheets. The Company's website is under development. As promotional activities, MonoJo has participated in several local, regional and international conferences and shows, and is currently promoting its products on an on-line sales website (www.bionity.com).

2.1.3 FINANCIALS

MonoJo's financial performance is summarized in the table 2-2 below.

Table 2-2: MonoJo Income Statement

	2006	2007
Non-operating revenues	11,399	3,307
Administrative Expenses	(84,137)	(95,555)
Profit	(72,738)	(92,248)

The company's future revenues depend substantially upon the ability to sell its diagnostics products. To date, revenues from sales of diagnostic antibodies, which were anticipated to start beginning of year 2008, have not been materialized yet. The greater portion of the company's growth in the near-term is dependent on anticipated sales of the 20 products currently in the pipeline, and the expected diversification of the product offerings (i.e. diagnostic kits and other product lines with good sales potential). In the long term, the company's revenue growth will be dependent on successful development of new markets and new products, and the successful launch of in-licensed or acquired products. Overall, MonoJo will have to make efforts to significantly increase its financial resources if it is to develop new products, implement marketing plans, as well as establish a new, modern manufacturing facility. In particular, since MonoJo's strategy includes product development, this will be a key concern and considerable resources should be going into research and development. In addition, as the company will grow from small-scale production to larger scale commercialization of monoclonal antibodies, it will need to commit more funds not only to product development, but also to marketing and sales operations, and thus it will need to find new sources of capital.

2.1.4 TRAINING SERVICES

In addition to diagnostic antibody products, MonoJo is providing standard and customized technical training courses. Revenues generated from training courses were estimated to be at an annual value of JD 15,840 for or the period between 2008 and 2010. The company reported that revenues from training courses are limited to the inability of students to fully pay for the training courses.

2.2 MANAGEMENT ASESSMENT

2.2.1 Organizational Structure

Upon the assessment of its organizational structure, MonoJo was found to have an up-to-date organizational chart; the company is essentially a flat and decentralized organization.

As the company is planning to grow significantly in the future, having a clear organizational structure will be continuously an obligatory requirement. An organizational chart should be designed, approved by the board of directors (BOD), updated and revised on a regular basis.

2.2.2 Human Resources and Training

Due to the fact that MonoJo is a small size company, it does not possess an HR system nor has personnel handling HR major duties and responsibilities. However, as the company is considering a growth strategy for the coming years, the need for a well designed HR system should be recognized.

Not being able to assess any documentation, HR practices at MonoJo were assessed 'on the ground' and the following areas were considered:

2.2.2.1 Recruitment and Employment

MonoJo was found to lack recruitment systems including documented policies and procedures, clear job descriptions for all part time employees, documented duties in the contracts for short-term consultants and assessment tests. However, job descriptions are provided for full time employees within the employment contract. It is recommended that general job descriptions are mentioned in the contracts and detailed ones that get reviewed at least once a year are designed and developed as separate documents that include the following sections:

- Title, position, grade, team
- Position Scope and Benefits
- Reporting to and direct reports that includes subordinates titles
- Major duties and responsibilities
- Related policies and procedures employee should adhere to.
- Competencies, Skills and attributes
- In-house and external training required for the position
- Basic job requirements and qualifications

As a note, no online application system is currently available nor is it needed given the current small size of the company.

No proper resource planning was found to be practiced by the management to determine the actual need for new resources and short term consultants. Employees were hired upon the state need of the company and according to the witnessed workload. The management has no clear and standard selection criteria for job applicants who, accordingly, were evaluated on an individual basis upon conducting the interview.

MonoJo suffers from high turnover percentages in the secretary position. This is due to several reasons including job dissatisfaction and low salaries compared to the market. Other reasons for employee resignations were not identified due to the fact that no employee satisfaction surveys are conducted.

Company by-laws document is available that covers all the basic rules and regulations and there is proof that all employees have signed to attest their understanding and commitment to its implementation.

2.2.2.2 Employee Appraisal and Performance Evaluation

Employees at MonoJo are evaluated by the CEO. Evaluation is conducted verbally and raises are determined according to the CEO's and financial manager's opinion on yearly basis. No evaluation or self appraisal forms are used in the evaluation process and no documented procedures are available. Also no clear career path is available for employees to determine possible promotions upon evaluations.

MonoJo management has not set any clear objectives for all employees nor has a mechanism for individual goal setting cascaded down from the strategic plan and establishing a performance appraisal mechanism to be achieved during the evaluation period.

It is worth mentioning that no Key Performance Indicators have been set by MonoJo management to be achieved by all functions and monitored regularly as per the measurement period set for every indicator. Due to limited financial resources available and being in such an industry, it is recommended that MonoJo set in the very near future key performance indicators for the whole technical team in general and for the outsourced consultants in specific taking into account that no clear duties or expected measurable achievements have been set for the two currently hired part time consultants.

It is worth stating that the CEO does not have clear criteria for evaluation by the board members and this is an issue that needs to be considered as the CEO is a critical position that carries crucial responsibilities which must be assessed on regular basis since it is the driving force for the company's success or failure.

2.2.2.3 Payroll and Employee Benefits

MonoJo does not maintain a clear salary scale as salaries are determined according to the CEO's opinion and estimations based on verbal salary surveys. No real market salary surveys are conducted for benchmarking purposes or to ensure that employees are well and fairly paid.

Employees working overtime are paid an amount of 125% per hour for extra working hours during working days and 150% for each hour worked during holidays. These ratios are determined with reference to the Jordanian Labor Law. However, no documented policies and procedures are available for overtime payments and the only control to monitor the process is through obtaining approval from direct supervisor on the extra working hours claimed by employees.

Upon the completion of the three month probationary period, employees benefit from the health insurance offered by the company. Life insurance is not included within the offer package provided to employees upon employment. Having witnessed the work environment at MonoJo, it is recommended to consider adding life insurance as a standard benefit in line with many copies in the private sector.

2.2.2.4 Timekeeping and Attendance

Employees' attendance is monitored at MonoJo through a daily attendance sheet which employees sign upon their arrival to the company. However, effective working hours cannot be traced as employees do not fill timesheets on daily basis to report their accomplishments throughout the day and the time they dedicated for each task or activity. Unfortunately, this may lead to inefficient use of employee time and may encourage undocumented and unauthorized leaves for personal issues. Timesheets are also recommended to increase accountability and maintain effective working. These timesheets should be capable of capturing the time spent in any of the following fields:

1. Experiments.
2. Business development and visits.
3. Training whether internal or external.
4. Internal projects.
5. Leaves (personal, sickness, vacations…etc.).
6. Administrative work and meetings.

Having accurate timesheets that are submitted on time will enable the management to:

1. Track the time spent for each task by each employee. This information will help estimating the time expenses for future reference.
2. Track the overall time spent on the same task by all employees; for example this may enable the Technical Team to quantify the level of efforts (measured in days) to conduct an experiment.
3. Once the process is measured, it can be improved and the time taken to perform the tasks can be reduced in a convenient way.
4. Plan the available resources in an effective manner for future tasks and activities.
5. Measure the personal productivity by different employees on similar tasks that will help in reassigning some tasks and realigning roles.
6. Link payment, raises to performance, attendance and quality of working hours.

2.2.2.5 Training

Newly hired employees at MonoJo, do not receive any type of orientation or training on the company's profile, by-laws, or polices and procedures and no induction programs for new hires were found to be available at the company.

Due to limited financial resources, the company does not set a budget for training nor does it conduct a 'training needs' assessment for its current employees. Employees can receive training only with the aid of external funding agencies.

Despite the fact that MonoJo possesses a highly qualified and experienced staff, the company should not highly rely on the technical experience and knowledge maintained by those people. The experience and knowledge need to be documented and transferred to the company's database so that it won't be affected by losing any of its staff members for any reason. As part of succession planning, successors should be indentified for key positions and trained accordingly. Training programs should be established and training materials should be prepared for new hires including presentations, documents, and on-the-job training.

2.2.3 Quality Assurance

In terms of quality, MonoJo practices quality checks at different processing stages when producing the antibodies. However, no quality system was found to exist as an entity that governs the quality assurance activities in the company. No workflow descriptions are available for operational activities nor are there SOPs manuals containing workflow descriptions. Quality audits do not take place and no regular quality reports are issued.

All functions of MonoJo are in real need for having their Standard Operating Procedures (SOP) documented to detail the sequence of activities, standards, and instructions for performing their operations. This will enable the company to ensure uniformity, consistency, and reliability and will be a tool to train and guide new hires.

The need for a Quality Assurance unit should be highly considered as the company is close to the stage of production in the near future. It will enable the company to mitigate risks, detect deviations, correct errors, improve efficiency and reduce costs.

It is also recommended that once standard operating procedures (SOPs) are documented, quality checklists be specifically designed and developed and quality assurance audits be conducted by an outsourced professional organization; especially if MonoJo intends to seek quality certifications as part of its strategic business plan in the near future.

The below table shows all the factors that influence the quality of the laboratory. It is recommended that all these factors are taken into account by each member of the technical team in order to raise the quality of the antibodies to be produced.

Pre analytical	Analytical	Post analytical
Right specimen	Laboratory professionals	Recording
Right collection	Reagents	Interpretation
Right labeling	Equipment	Turnaround Time
Right quantity	Selection of Test – SOP	Report to right user
Right transport	Records	
Right storage	Bio-safety	

Lessons learned from current experiments conducted by the technical team are not properly documented thus cannot be communicated properly to any new hire in the technical area. It is recommended that at the end of every experiment, all lessons learned are captured, properly documented in a separate section along with the experiment results. These should be properly filed and shared directly with the technical committee and they should be easily accessible, readable and understandable for any new hires.

2.2.4 Facility Safety Practices and Hygiene

Safety considerations should be of a high priority to MonoJo since it is mainly involved in the preparation and production of highly sensitive monoclonal and polyclonal antibodies that require storing and handling hazardous chemicals, handling different classes of microorganisms, preventing chemical and biological contaminations in addition to storing and transporting chemical laboratory wastes in a safe manner.

Upon the assessment of the safety practices in the company, MonoJo was found to maintain generic safety operating procedures and instructions relevant to its operations. However, these procedures are neither classified nor customized according to the operations taking place in each room.

Machines and equipment are not properly labeled with what identifies their function, name, specifications, operating conditions, setup requirements or safety precautions. Besides, no regular maintenance or inspection is done for them.

Protocols have been designed and developed showing the set of methods for producing and using monoclonal antibodies in biological science. It is recommended for these protocols to be documented in the format of standard operating procedures.

Chemicals are kept in two cabinets where each cabinet has an inventory list of all items it includes. A need for additional cabinets was noticed as technicians were observed to utilize one of the unused laboratory machines as a storage area for keeping materials where this action is not encouraged under no circumstances. It is highly recommended that these cabinets be made of glass and not black boxes as the current ones. These cabinets are also recommended to be positioned on upper areas rather than the ground as this would keep the chemicals away from humidity and would prevent their spoilage.

No safety regulations and training for using chemicals are provided to the laboratory technicians and there is a noticeable lack of awareness between technicians on the materials and chemicals being used and their effect if spoiled. Chemicals are not categorized per type when storing them in the cabinets; this action is considered to be very dangerous as some chemicals might interact with each other upon spoilage and may result in dangerous incidents and/or injuries. Additionally, the laboratory is not equipped with a fume hood for opening hazardous and poisonous chemicals.

Goggles, gloves, masks, overheads and other safety tools are used by the technicians at the lab. Fire detectors are only available in one room in the company which is not sufficient especially that people in the company are neither trained on using the fire extinguishers nor on first aid principles although all working areas contain first aid boxes.

Technicians are obliged to wear lab coats while working. However, it is recommended that separate lab coats are dedicated for those who work in the sterilization area for cell culturing. Due to the complexity of the processes and usage of hazardous chemicals, it is recommended that safety assessments to address potential health and environmental risks are taking place regularly by an outsourced professional organization experienced in this field.

It is worth mentioning that during the course of the assessment, the technical supervisor has started to develop a Safety Data Sheet for all the materials. It is recommended to keep this sheet up-to-date, shared with the technical team and included as part of the training program for any new hire. This sheet includes the following information:

1. Material name, composition of ingredients
2. Hazard identification
3. Physical and chemical properties
4. Stability and reactivity
5. First aid measures
6. Fire-fighting measures
7. Accidental release measures
8. Exposure controls and personal measures
9. Toxicological information
10. Handling and storage

2.2.5 Procurement Management

The standard worldwide procurement cycle consists of the following phases:

1. Identify and recognize the need.
2. Transmit the need through a purchase request.
3. Seek suppliers through tenders (usually three).
4. Evaluate suppliers and select the winning supplier (the one conforming to the required specifications with the minimum price).
5. Issue a purchase order to the supplier.
6. Follow up on the order.
7. Receive the order and inspect material.
8. Pay invoice and issue the payment voucher.

In obtaining its needed supplies, MonoJo was found to implement almost all phases of the procurement cycle except that it has no clear documented criteria for selecting suppliers.

Due to the sensitivity and extremely accurate required specifications, employees tend to choose brand names that produce the required materials irrespective of the price. For the time being, and as MonoJo needs to enter the market with the maximum achievable quality, this can be justified as it can not take the risk of wasting time and effort looking for suppliers providing an acceptable level of quality at a reasonable price. But as MonoJo grows and succeeds in penetrating the market, it will have to set a supplier selection criteria and look for other reliable and certified suppliers. MonoJo also needs to document all its procurement procedures.

Although purchased machines and equipment are guaranteed for two years, it is recommended that MonoJo signs contracts with qualified suppliers to maintain all purchased machines on regular basis. This issue should be assigned to a responsible employee having good relationships with suppliers.

The stock reordering level to purchase materials is estimated according to personal opinion. There has to be clear criteria for the reordering level of each material in stock especially that some materials are obtained from suppliers outside Jordan and require long lead times to be delivered.

2.2.6 Inventory Management Software

MonoJo possesses efficient inventory management software. Despite this fact, the company experiences inventory problems that require manual cycle counting every now and then which is time and effort consuming. This is because of the inefficient use and lack of awareness of the various features provided by the software and wrong data entry to the system. It is recommended that the employee accountable for data entry be fully trained on

all the features of the software to ensure a higher level of utilization of the software and lower percentages of errors.

2.2.7 Information Technology

MonoJo's website is currently under construction. However, no intranet system or share point directories are available at the company.

IT assessment for its equipment, servers and software was conducted through a phone call with the outsourced company handling the IT issues related to both client services (windows, Microsoft office, printing, sharing, and mails) and application services (exchange, Symantec antivirus, mail forwarding, and web access).

Scheduled backup procedures are being implemented at the company as follows:

- Daily backup for the Accounting folders only
- Weekly backup for the Outlook

A private folder was created for every employee to save all important files and documents however the backup process is not automatically scheduled and the time interval between backups can reach up to almost a month.

ADSL service is not stable at MonoJo as the service is deteriorating by the suppliers however MonoJo may consider having lease line in the future.

No UPS is available for the server; this may result in data corruption in case of electricity shut down. Also there is a need for backup hard disk in case the only one used in the server stopped functioning for any reason, the

The current state of IT is not sufficient for a company that is planning to grow. It is recommended that MonoJo hires an IT person (preferably part time for 1-2 hours a day) who holds the responsibility of updating the company's network with antivirus and performing all necessary backups for files and databases on daily basis. It is also recommended that UPS and hard disk are purchased and installed in the very near future.

2.2.8 Security Management

MonoJo lacks advanced security settings. The office assistant holds the responsibility of a security guard. No security systems are used and no building passes are provided to employees. Only external doors are locked and all other rooms are accessible to anyone inside the company even the ones including produced cells. This exposes the cells to a number of threats including loss or theft.

It is urgently recommended that an integrated security system be installed at MonoJo. Access to specific rooms and laboratories should be limited to authorized employees only and the antibody cells should be kept inside a room that is password or security badge protected.

2.2.9 Communication

Upon the assessment of the communication aspect in MonoJo, clear communication lines were found to exist between employees. However, basic and necessary communication channels are lacking in such a type of an organization including bulletin boards and regular meetings.

No regular meetings are arranged by the technical committee to discuss work progress, strategic decisions, or any major issues or challenges that face employees. The last meeting was noticed to take place a year ago (5th Aug 2008) and the previous one was conducted during Sep 2006 which resulted in no regular follow-up on the status of the production. As a

result, a six-month delay in the purification stage was not properly communicated to the Technical committee and the technical team was not able to meet and identify clear roles and responsibilities to distribute work, solve all obstacles encountered in the purification stage and get it done within an agreed timeframe. The supervisor was witnessed to conduct one to one meetings with employees and was not able to arrange for a meeting that involves all employees which, of course, hinders the progress of work.

It is highly recommended that meetings be conducted on regular basis (on monthly basis or as the need requires) where a clear agenda is set and minutes of meeting are properly documented. There also has to be a documented process for the meetings that do not require the attendance of the CEO.

2.2.10 Financial Management

Considering the growth strategy for which MonoJo is planning, a paradigm shift in the way it manages its financial issues will be needed.

In assessing the current situation, no documented financial procedures were found to be followed. Financial statements (Income Statement, Balance Sheet, and Cash Flow Statement) are not issued on monthly basis; they are only issued semiannually or upon request. No internal audit is conducted by the accountants of the company; however, external audit is done annually through an external auditing company.

With regards to the business plan and taking CEO feedback into account, financial figures in which the strategic plan has been set were not found to be practical due to baseline statistics were not accurate. However, it is recommended that the business plan be reviewed on regular basis and be based on validated data and assumptions that represent the current and forecasted financial state of the company.

Upon meetings conducted with the CEO, it was understood that for the company to grow and start introducing its products to the market, a high capital investment is required. It is believed by the Board of Directors that financial aid can be obtained from donor-funded programs rather than individual investors as the products are still under development and attracting investors at this stage would be almost impossible. However, it is recommended that the CEO be assigned the responsibility of identifying the needs and urging the Higher Council to find the means to obtain the required financial support with the aim of increasing the financial capital. The CEO should also be assigned the responsibility of finding an outsourced consultant who has the right qualifications to train employees, do necessary branding for the company, provide assistance in sales and packaging, and has the ability to market the product and open new lines of investment.

2.2.11 Products and Services

In addition to producing antibodies, MonoJo provides training services and participates in scientific open days and workshops. The technical assessment of the company captured two major parts; training as a service, and antibodies production.

2.2.11.1 Training

MonoJo provides training services to university students and other interested individuals. The training program includes theory-based sessions as well as practical sessions conducted in the company's laboratories.

The first training course provided by the company was delivered by an in-house instructor. The training was conducted without proper planning, therefore it was very generic and not customized according to the students' needs.

However throughout following sessions, the company has developed a training brochure and a timetable that covers the training duration that is available for each course. A manual for each training course is available and is provided to trainees upon the start of the training program and an evaluation for training is completed upon its completion.

In terms of facilities and logistics, the company owns a fully equipped training room. Laboratory safety instructions are given to the trainees to read and sign before experiments take place. Attendance of trainees is captured through a designed attendance sheet.

As a source of revenue, it is highly recommended that MonoJo invests in training services, but this will require the following:

1. Proper planning for training programs and this could be done through site visits to the universities to identify students' training needs, preferred training hours, and reasonable training fees.
2. Setting clear selection criteria and documenting it as a reference for choosing the best qualified trainer to conduct the training.
3. Designing a questionnaire to be filled by the trainees upon the completion of the training course to test their level of satisfaction and level of benefit obtained from the course.
4. Designing training certifications that are signed or stamped by the Board of Directors.
5. Assessing training costs including equipment, hospitality expenses, and instructor's rate. As a matter of fact the current assessment of costs do not include instructor's daily rate.

2.2.11.2 Antibodies Production

So far, four ready antibodies in the purification phase and another four are under processing at MonoJo. Although antibodies can be produced to the local market with the current purification level, they still need to pass the cycle of testing their shelf live, preservation, stabilization, packaging, branding, sales and marketing.

Several technical related issues were found to impede the progress of producing the antibodies. These issues include, but are not limited to, the following categories:

a) Tools and Equipments

Request for equipment is done in an ad-hoc manner without having any plan set by the technical team. This is due to the lack of experience as the technical team does not have the "know how" experience to request funds. They also lack the experience to adequately assess and identify their needs for machines and equipment.

As a result, a few machines in the laboratory are unused and several problems were encountered as listed below:

1. The "Purification" system was not equipped with a monitoring screen or printer at the time of purchase and it took almost a year afterwards to fully automate the system.
2. The air handling unit that is responsible for anti-contamination in the sterile area now requires an air condition to maintain the required temperature while processing the antibodies. This need should have been recognized at an earlier stage as indicated in the specifications sheet and prior to setting the budget and purchasing the unit.
3. The laboratory supervisor expressed the need for another microscope as there is only one available at the lab. This is considered an urgent request because if the current microscope stops functioning for any reason, cells testing during all phases of production will be affected.

4. The water treatment system is currently not functioning and the required distilled water is brought from Dar Al Hikmah for free.
5. The laboratory is always under the threat of sudden electric shutdown, therefore there is a need for an electric generator as a backup procedure to protect the refrigerators that are used to keep the cells.
6. Several incidents occurred where some of the tools in the laboratory were mishandled and therefore damaged by employees. It is recommended that rules and regulations for mishandling tools to be set and clearly communicated to those who use the laboratory.

There is a need to establish an equipment management program to accomplish the following:

- Assign responsibilities for all activities related to routine and preventive maintenance
- Train all personnel on equipment management.
- Develop standard operating procedures (SOP) for maintenance
- Maintain history cards and log books
- Monitor equipment management activities in terms of routinely reviewing all records and ensuring all procedures are followed.

From the previously discussed problems, MonoJo is advised to hire a technical manager who has the ability, knowledge and experience to:

1. Research, investigate, and develop new technologies for enhanced performance.
2. Handle the overall management of the technical team.
3. Lead staff to plan and evaluate laboratory activities.
4. Assess the current situation and establish strategic goals not only to produce the monoclonal antibodies but also polyclonal antibodies and communicate job specific results.
5. Maintain quality service and professional/technical knowledge and contribute to team efforts.
6. Benefit from the existence of the outsourced consultants by encouraging and enabling knowledge transfer to the team.

b) Laboratory Experiments

Upon conducting experiments in the laboratory, the technicians fill an experiment sheet however; this sheet should be amended to include the following information:

- Objective of carrying the experiment
- Methodology (Description of method of testing)
- Interpretation of the obtained results
- Description and identification of sample received
- Record of all data secured in the course of the test
- Record of test results and how they compare with standards of identity, strength and quality
- Record of all deviations and modification of test
- Record of standardization of reference standards
- Record of calibration of equipments

A checklist should also be designed for laboratory clearance at the end of the day to be signed by the technician who has been using the laboratory the whole day.

Tables for trouble shooting were found to be available at the laboratories but they were not classified by topic making the process of looking for them a difficult one for future reference. Verbal reporting is done by the technical team upon conducting the experiments. Therefore, any accomplished progress can not be monitored by the management to take necessary actions or make any required decisions. Accordingly, it is highly recommended that the technical team updates the management with the cells' status by submitting a monthly technical report.

Filing is taking place at MonoJo for the antibodies under production. Each file contains the specifications sheet for each antibody, testing results, and any other necessary documents. It is recommended that all forms utilized are revised better formatting of data to be recorded and information to be interpreted.

c) Standard Operating Manuals (SOPs)

There is an urgent need for MonoJo to create standard operating manuals for all its procedures. A list of recommended SOPs for the Production area is provided in the following table:

2.3 MARKET ANALYSIS

2.3.1 THE MEDICAL BIOTECHOLOGY MARKET ENVIRONMENT

Biotechnology is defined as " the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services"(OECD). Biological products are generally large complex molecules produced using living organisms. The entire development process of a biological drug is a very lengthy and costly process[1].

The global pharmaceuticals and biotech markets are highly competitive and strongly regulated markets, and are driven by innovation. The biopharma[2] sector is showing growing trends of integration and consolidation. The large[3] pharma companies are facing patent expirations from some of the most profitable drugs in history in 2011 and 2012, which makes them look for acquisitions or investments in smaller biotech companies as a way to strengthen their product pipeline and introduce new products into the market. The leading pharmaceutical and biotechnology companies are re-aligning their business model by moving into the co-development of drugs and diagnostics, and are looking to increase R&D partnerships with small and mid-tier pharma and biotech companies, academic institutions and government agencies. At the same time, small- and mid-tier drug developers are looking to large pharma for new molecules that they could develop, as well as to potential alliances to leverage the big pharma's product marketing and distribution strengths.

An interesting global trend is the great interest shown by governments around the world in promoting and providing support for the development of national biotech industries, including the creation of biomedical research centers (often funded by government grants) to drive the development of new ways to prevent, diagnose and treat diseases. In recent years, the biotech industry around the world, including in many developing countries has seen a large number of start-up companies, with funding for R&D projects available both from governments and from venture capital.

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[1] from clinical trials through regulatory reviews takes around eight years and costs around $1.2 billion, and less than one third of biopharmaceutical drugs that enter clinical trial ever receive marketing approval.

[2] Biopharma refers to companies that use biotechnology to manufacture therapeutic products for human healthcare applications.

[3] 'Large pharma companies' refers to companies that have achieved several consecutive years of profitability, based on product revenues of at least hundreds of millions of dollars.

At 12.5 percent growth in 2007, the global biotech market showed a nearly double growth rate compared to the global pharmaceutical market (IMS Heath). During the past five years, the range of biotech products and their use in multiple therapy areas have steadily increased, creating a major source of market growth. Twenty-two biotech products generated sales exceeding $1 billion in 2007, compared with just six products in 2002. Targeted oncology therapies, auto-immune agents, anti-diabetic agents, and pure vaccines represented both the majority of the market and majority of growth in 2007. The U.S. remains the largest market for biotech products, representing 56 percent of total sales last year. The five major European countries - France, Germany, Great Britain, Italy and Spain - have steadily increased their share of this market over the past five years, to 24 percent in 2007. Japan's share of the market has declined slightly and now represents 5 percent of global biotech sales (IMS Health) (Annex 1 provides information on biotech industry statistics).

Deloitte Research reports the following two major trends taking place in the biopharma market:

- the convergence of the technologies used by biotech and pharma companies, and
- the convergence of the therapeutic areas pursued by the two groups (pharma and biotech).

Our internet research of various market reports suggests that in the future, biotech companies will face the following challenges:

- Competition in technological innovations and the related need of wanting to be the first mover, or waiting for proof of the effectiveness of new technologies before they are adopted (and possibly loosing time and competitive advantage in the process).
- A shifting demand in the marketplace, including a potential reduction of pricing power and an increasingly demanding customer base in relation to product performance, product potential for overall cost-effectiveness, price, convenience of use and service.
- The growing cost of clinical trials and finding patients for clinical studies, which is increasingly becoming a major bottleneck in drug development process.
- The threat of loss of patent protection on blockbuster products.
- Regulatory demands for more safety and comparative efficacy information.
- The escalating cost of gaining and preserving intellectual capital.

Increasing healthcare costs create pressure to control the prices of drugs, including biologics. Payers and physicians demand higher efficacy, and proof for added value to patient care, in order to justify the premium price for innovative biotech therapeutics. Reimbursement is also an issue that affects bringing new products to the market. For diagnostics, which have historically been perceived as being of lesser value than drugs, there is more reluctance to pay high prices.

Intellectual property (IP) is an important value driver for the biotech industry, and therefore, the protection of intellectual property is becoming a major concern, as the economic value of intellectual property and the financial viability of some biotech and pharma companies depends on legal and regulatory changes related to drug patents, generic biologics, and potential price controls on technology transfer. Even though outsourcing is a growing trend in the world, patent and proprietary information concerns have caused biotech companies to keep projects in-house, due to fear of sharing sensitive manufacturing processes with contract manufacturing organizations (CMOs) in emerging markets.

The global biopharma industry is one of industries highly influenced and regulated by state government controlling agencies. The global industry is influenced in principal by the leading regulatory agencies such as the US Food and Drug Administration (U.S. FDA), the European Medicine Agency (EMEA) and the Japanese Ministry of Health and Welfare. These three agencies regulate almost every aspect of the biopharma industry in their respective regions, and helped the formation of three strategic industry groupings - the American, European and Japanese groups of companies. In addition to pre-marketing

approval or clearance, the post-marketing clinical research has also become a key feature of product lifecycle management.

The following is a summary of the main factors that affect the global biotech markets, as identified during our market research.

Table 2-3: The PEST Analysis of the Global Biotech Market:

Political Factors (legal issues)	Economic Factors
- Product approvals getting more strict-strong regulatory agencies ((the US, EU and Japan) strictly regulating the major markets, in addition to regulatory agencies in each country. - Increased security concerns leading to increased need to regulate the entire supply chain. - Insecurity about the development of legal framework (new regulations) - Industry self-imposed regulations - Stricter monitoring of drugs after launch to market (due to recent high profile drug recalls).	- Biotech has become a key topic of economic policies/strategies of both developed and developing countries - Biotech is seen by many countries as a "national prestige" issue, thus competition between countries is on the rise - Governments' willingness to sponsor biotech research - Interesting investment opportunity due to potential of breakthrough in research, thus increased possibility for private funding (venture capital) - Lower cost barriers for new companies related to the increased availability of basic research - Reduced R&D costs due to shifts to emerging markets - Competition is increasing from emerging markets (India, China etc) due to outsourcing - Pressure from growing healthcare costs - Industry consolidation due to need to fill product pipelines and due to patents running out.
Technological Factors	**Social Factors**
- Increased potential for growth based on new technologies (biotechnology still in the developing phase) - Increased availability of basic research - Growing demand for product performance, efficacy and convenience of use - Intellectual property protection is a major concern (patent protection, technology transfer)	- Growing interests to increase health and living standards of population - Aging population and growing need for new, targeted diagnostics and treatment - New diseases, threat of pandemics and globalization of diseases - Unhealthy lifestyles, poor diet, obesity, smoking, and/or lack of exercise-leading to growing incidence of chronic diseases

2.3.2 ANALYSIS OF POTENTIAL MARKETS

While the biopharma industry operates in a global market characterized by similar trends, differences however exist between the healthcare environments in various countries, which ultimately affect the demand for biopharma products and the way companies operate in those markets. Following are aspects related to the healthcare environment and the biopharmaceutical markets in the United States, the European Union and selected countries of the Middle East which MonoJo is targeting.

The United States

Population: 302,841,000; population growth: 1.0%

Gross National Income per capita (PPP intl.$), 2006	44,260
Per capita total expenditure on health (PPP intl. $), 2006	6350
Total expenditure on health as % of GDP, 2005	15.2
Per capita Government expenditure on health (PPP int.$), 2005	2,862
Government expenditure on health as % of total expenditure on health, 2005	45.1

Source: World Health Organization (WHO)

The United States population is rapidly aging. By 2030, the number of Americans aged 65 and older will be around 71 million, comprising roughly 20 percent of the U.S. population. By 2030, the US healthcare spending is projected to increase by 25% due these demographic shifts (The State of Aging and Health in America 2007 Report, CDC). As a result, there is a growing need to more actively find ways to improve and preserve the health of older adults.

The U.S. healthcare industry spends about $1 trillion annually. Most of the cost is funded by private health insurers with annual spending of $700 billion, and government and health insurance programs such as Medicare and Medicaid with combined annual payments of $1 trillion. Manufacturers of drugs, medical devices and other supplies have combined annual revenue of $300 billion, and the health care providers have annual revenue of $1.5 trillion. The industry is one with large government participation, both as direct care provider, and as operator of health insurance. Healthcare providers compete based on location and reputation, and to some extent on cost. Health insurance providers compete mainly on cost.

As a result of the growing cost pressures, spending on research and development in the U.S. is higher than ever. It is estimated that over the past 10 years, the biomedical research budget for the National Institutes of Health has doubled, while the pharmaceutical companies have spent 250 percent more on research and development. Yet, the number of innovative new therapies submitted to the FDA for approval has actually declined by nearly 50 percent during the same time. A major reason for this is believed to be the long and inefficient process for preclinical and clinical testing of drugs. It can require an investment of more than $1 billion and take 12 to 15 years to bring one product to market, and despite massive investments in research and growing public demand for treatment, cancer drugs have the highest failure rate in clinical development.

Due to recent drug scandals in the US and the growing imports of ingredients from overseas, the FDA is looking into measures to even stricter regulate the drug supply chain, including the increase of overseas inspections. For that, the FDA is working to establish five satellite offices in India, China, Central and South America and the Middle East. All the above suggests that even under conditions of growing market liberalization, drug makers in the world can expect that they will be faced with tighter regulations in the future.

Ernst & Young estimates that there were 4,203 global biotech firms in 2005. Burrill & Company estimated 363 publicly-held U.S. biotech companies as of 2005. By other estimates, there are about 1,470 total biotech firms within the U.S.

The European Union

The European Union, representing 27 member states, contains five of the ten largest economies of the world. The EU27 population is approx. 493 million (2007), and the yearly growth rate is at a 0.39%. Germany, France, UK, Italy and Spain are countries with the highest population. According to age structure, almost 70% of population is between the ages of 15-64 years, and around 31% is between 50 and 79 years of age. Table no 2-3 below shows population projections for the five largest EU countries.

Table 2-4: Population Projections in Selected EU Countries

	2005	2015	2025
EU 27	458.5	467.3	470.1
Germany	82.6	82.9	82.1
France	60.2	62.6	64.4
UK	59.9	61.9	63.8
Italy	58.2	586	57.8
Spain	42.9	45.3	45.6

Source: Eurostat population projections

The EU has developed a single market through a standardized system of laws which apply in all member states. The countries of the EU share common policies, political structures and trade practices.

In 2006, total healthcare expenditure represented an average of approx. 8% of GDP across EU-27 countries, lower than the 15% spend by the United States (EDMA, the European Diagnostics Manufacturing Association). However, research and development expenditure in the EU-27 is targeted to increase to 3% of GDP by 2010, compared to 1.84% in 2005, as the EU is making the transition to a knowledge-based economy.

Europe is the world's second largest biotechnology market (after the US). It hosts many large pharmaceutical and biotech companies. After the US, European based international biotech companies form the largest concentration of pharma and biotech power. Apart from the well-known large biopharma companies, there are hundreds of smaller bioscience companies investing billions in R&D, and employing hundreds of thousands of people. These companies enjoy the support from thousands of universities and science researchers, hospitals for clinical research and national governments that provide financial and know-how support to promote biotechnology and R&D. Numerous collaboration initiatives are reported between the industry, academia, research institutions and government in various countries. Many biotechnology centers have emerged in Western European cities such as Amsterdam and Leiden in the Netherlands; Brussels and Louvain, Belgium; the French cities of Paris, Montpellier and Lyon; the United Kingdom's Cambridge, Oxford and London; and Germany's Heidelberg, Munich and Berlin.

According to the 2006 ranking of biotech companies by Biomedical Market Newsletter, the UK was home to 220 companies in 2006, Germany to 210, followed by France and Switzerland.

In terms of the regulatory environment, faster lead times for getting new drugs to market in Europe has prompted many US biotech companies to either set up shop in Europe or merge with or acquire biotech and biopharmaceutical entities. It also prompted US firms to increase research collaboration with European biotech companies and tapping into Europe's wealth of expertise at the university level. Europe has been the first region to establish a specific regulatory approval process for biosimilars (or bio-generics, which is the equivalent of generics in the pharmaceutical industry), This regulatory framework lays down a clear biosimilar approval pathway. It takes a case-by-case approach both for changes to the manufacturing processes of existing biopharmaceuticals and for the approval of new biosimilar products. Comparative quality, non-clinical and clinical studies have to be provided by the biosimilar manufacturer to substantiate the similarity of structure/composition, quality, safety and efficacy between the new biosimilar and the reference medicinal product. Since 2006, eight biosimilars have received European regulatory approval, so biosimilars have recently become a commercial reality in European markets.

The Middle East and North Africa (MENA) Region

Jordan itself is a small market, with limited long-term growth opportunities; in contrast, the MENA region is a large market, characterized by fast-growing populations, changing lifestyles and aging populations, which will continue to drive demand for healthcare services, products and infrastructure. As a result, opportunities for biopharma products are set to increase - a fact of which international biopharma companies are well aware of. Big international players are increasingly interested in the opportunities provided by the emerging MENA markets and have started investing in the region[4]; partnerships with these companies can make very good long-term business sense for MonoJo. On the other hand, the same trend will only lead to increased competition in these emerging markets.

As lifestyles change, people are expected to live longer and get more chronic diseases of old age such as cardiovascular, diabetes and cancer. This will drive increased healthcare spending, and therefore, Governments are pursuing plans to privatize healthcare services to cope with the rising demand. A General Electric study estimates that the healthcare demand in the GCC region will rise to 240 percent over the next 20 years. The medical practice is expected to shift from treating symptomatic 'late-stage' disease to a focus on earlier pre-symptomatic disease detection and earlier, more effective treatment options.

The MENA region's public and private spending on healthcare services is currently low compared to other regions of the world, and inside the region there are big variations between health expenditures in various countries: Jordan invests around 10.5 percent of GDP on healthcare expenditure and ranks fourth among MENA countries in terms of per capita health expenditure; in comparison, Egypt invests around 6.1 percent and Saudi Arabia invests only 3.4 percent of GDP respectively.

Table 2-5: Main Healthcare Indicators for Selected MENA countries, 2005-06

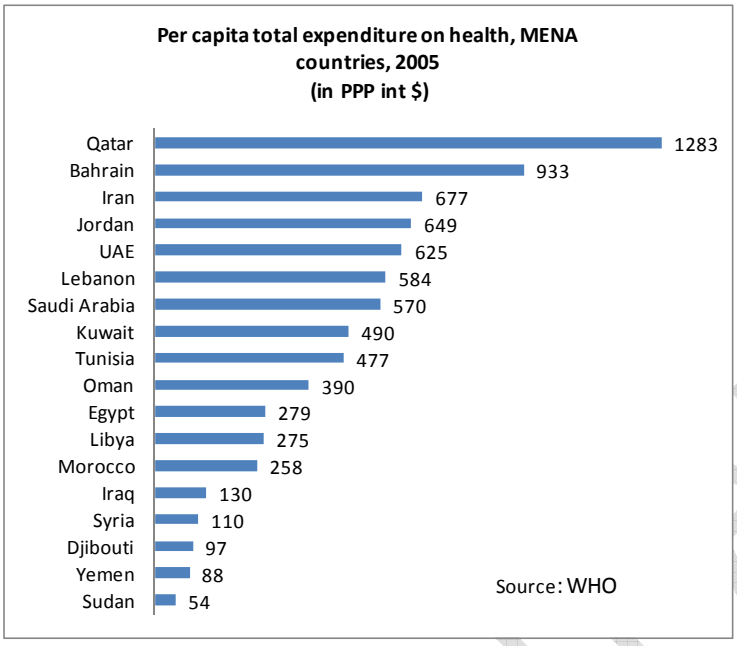
Country	Gross National Income per capita (PPP int.$[5])	Per capita government expenditure on health (PPP int. $)	Per capita total expenditure on health (PPP int. $)	Total expenditure on health as % of GDP	Population annual growth rate	Percent population over 60
Egypt	6,690	30	279	6.1	1.8	7
Jordan	6,210	109	649	10.5	3.3	5
Saudi Arabia	n/a	341	570	3.4	2.4	4

Source: WHO Health Indicators

[4] The US biotech firm Genzyme and Amgen - the world's largest biotechnology firm – have announced in the past to have set up investments in the DuBiotch park in the UAE. (Amgen is also the second largest oncology rugs developer, after Merck)

[5] PPP int. $ = International dollar is a unit that takes into account differences in the relative purchasing power of various currencies.

Figure 2-3: Per Capita Expenditure on Health in the MENA region, 2005



Saudi Arabia

Saudi Arabia has witnessed important socioeconomic development in the past 30 years driven by oil wealth and related to health, education, housing and environment.

Population: 28.1 million; Population growth: 2.0% (US Census Bureau, IDB, 2008 midyear estimates)

	2006	2007	% change
population aged 65+ (in thousands)	676	699	3.3%
real GDP growth (% change)	4.3	4.1	-
inflation (% change)	2.2	4.1	-
annual gross income (in $ mil)	103,190	110,087	6.7%
annual disposable income (in $ mil)	98,294	104,864	6.7%

Source: Euromonitor

The healthcare system in Saudi Arabia is represented by a network of primary healthcare centers and clinics and a network of hospitals and specialized treatment facilities (located mainly in urban areas). Public spending accounts for 80 percent of all health spending; the Saudi Ministry of Health is the largest buyer in the GCC region, representing around 60% of the GCC market for medical products.

Saudi Arabia is expected to experience a sharp increase in its healthcare needs; population growth, a slowly aging society, and the conditions such as obesity, diabetes, and cardio-vascular diseases, as well as cancer, will create a growing demand for healthcare services. According to WHO, there is a sharp increase in non-communicable diseases, in particular cardiovascular diseases and diabetes. WHO projects that by 2030, the three main causes of death in Saudi Arabia will be related to cardiovascular diseases, other chronic diseases, and malignant neoplasms,

The market is characterized by tight price controls and late payment for tenders, especially in the public sector where funding is dependent on oil revenues. Imported pharma products account by some estimates for round 90 percent of the market, and little manufacturing is done locally.

Multinational companies and increasing their presence in the Saudi market thorough growing exports and direct investments. However, PhRMA - the Pharmaceutical Research and Manufacturers of America representing the US leading pharmaceutical research and biotech companies, which is closely following market access barriers and intellectual property rights violations in world markets, requested that Saudi Arabia be elevated on the Special 301 Report's Priority Watch List in 2007 regarding inadequate levels of intellectual property rights protection and enforcement, and market access for companies relying on IP protection. PhRMA reported problems with patent protection, the negative decisions related to the Saudi Ministry of Health's pricing of pharmaceuticals, as well as getting marketing approval practices which are not transparent and can take unreasonable long time. This indicates that foreign companies may show extra cautiousness when targeting the Saudi market, whether in the form of export operations or direct investments.

Egypt

Population: 81.6 million, Population growth rate: 1.8% US Census Bureau, IDB 2008 midyear estimates)

	2006	2007	% change
population aged 65+ (In thousands)	3,529	3,661	3.7%
real GDP growth (% growth)	6.8	7.1	
inflation (% growth)	7.6	11.0	
annual gross income (in $ mil)	89,412	106,846	19.5%
annual disposable income (in $ mil)	77,617	92,639	19.4%

Source: Euromonitor

The Egyptian healthcare expenditure accounts for 61% of GDP in 2006, according to WHO. Egypt's highly competitive medical market is estimated at $255 million, with an annual growth rate of 10%, due to the increase in number of new hospitals and modern facilities, and increased demand for quality products and services The single main healthcare provider is the Ministry of Health (covering approx. 29% of health insurance), and there are also many private healthcare providers.

According to WHO, in 2006, neuro-psychiatric disorders and digestive system diseases are leading causes of morbidity accounting for 19.8% and 11.5% of the non-fatal diseases respectively, followed by chronic respiratory diseases (6.9%) and cardiovascular diseases (5.6%). The most common cancers are breast, liver, bladder and lymph nodes. Lifestyle-associated disorders are growing in importance, such as smoking, substance abuse, lack of exercise and overconsumption of fatty and salty foods. WHO projects that by 2030, the three main causes of death in Egypt will be related to cardiovascular diseases, other chronic diseases and malignant neoplasms.

The pharmaceutical industry is the only sector in Egypt that has been placed under government price controls which has negatively impacted access to new pharmaceutical products and competition in the market. Egypt is also known for its poor intellectual property regime. PhRMA reports that lack of appropriate implementation of intellectual property protection, especially related clinical data protection, patents and trademarks, and the existence of several market access barriers related to product registration and price controls facing the industry are causing an unsatisfactory investment environment.

Egypt's large domestic manufacturing industry may act as barrier for exports or investment. Egypt is the largest producer of pharmaceutical products in the region. BMI estimates that about 7,600 drugs are manufactured locally, which accounts for about 93% of the domestic consumption.

In 2006, Egypt agreed to eliminate price and regulatory restrictions on Jordanian pharmaceuticals imported into Egypt, however, it has been reported that protective barriers to entry have essentially shut Jordanian producers out of the Egyptian market to date (Jordan's Competitive Report 2007, Pharmaceuticals).

Jordan

In Jordan, public and private sector efforts focus on promoting industries and activities which are drivers of sustainable economic growth, and the promotion of science and technology for economic development is a key national goal. Industries such as pharmaceuticals, which were identified having high potential for growth, have strong government support. Recently, we began seeing moves towards the development of a biotech industry in Jordan. The King Hussein Cancer and Biotechnology Institute (KHCBI), launched in 2006 as an initiative of King Abdullah II, aims to create a regional and international center in Jordan that will advance biotechnology research and development in Jordan and improve patient care in the oncology field.

The country has a reputation in the region for its high standards of services provided and both public and private hospitals have been expanding and upgrading in recent years. In 2005 total health expenditure represented 9.8% of GDP, with 13.8% of that for drug expenditure. In terms of health insurance, only 60 per cent of Jordanians have access to health insurance, resulting in out-of-pocket payments among the uninsured that are double the payments of those insured (WHO). The rising cost of medicines will have an impact on overall health-care costs. With 70% of its medicines imported, Jordan's import bill is putting a heavy burden on the healthcare system.

According to WHO figures, cardiovascular diseases were the leading cause of mortality (42%) in Jordan, followed by cancer (13%) and accidents (10.5%). WHO estimates indicate that new diabetes cases will exceed population growth, growing from 195,000 cases (2000 estimate) to 680,000 by year 2030.

While the pharmaceutical sector is represented by 20 generic manufacturing companies, the only private biotechnology company to date is MonoJo. The pharmaceutical industry's largest player, Hikma, has a 7.6% share of the domestic market and further consolidated its dominance by the recent acquisition of Arab Pharmaceutical Manufacturing Co. Ltd (APM), in addition to previous acquisitions of foreign pharmaceutical companies.

The generic pharmaceutical companies have benefited from the strong Intellectual Property protection laws both by gaining new export markets and by starting to engage in innovative research. International research-based pharmaceutical industry has also greatly increased its presence in the Jordan market. Under the terms of its accession to the WTO in 2000, Jordan was required to introduce TRIPS-provisions[6] in its national patent laws. The FTA with the US, which entered into force in December 2001, has introduced a new framework of TRIPS-plus rules, which increase Jordan's obligations with respect to intellectual property rights protection.

Total pharmaceuticals production in 2006 valued nearly USD $450 million, with over 75% destined for export markets. Of these, over 80% of Jordan's exports are destined for the Middle East and North Africa region, with the top export markets Saudi Arabia and Algeria, followed by Sudan, Lebanon, UAE, with Egypt on the 11th place (Jordan's Competitiveness

[6] The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement administered by the World Trade Organization (WTO) that sets minimum standards for various forms of intellectual property regulation.

Report 2007, Pharmaceuticals). Jordanian pharma manufacturers benefit from tax breaks from profits on any drugs that are destined for export markets, in addition to being exempted from customs tariffs on imported raw, packaging and other inputs.

2.3.3 MARKET SIZE AND POTENTIAL OF MONOCLONAL ANTIBODIES FOR CANCER DIAGNOSTICS AND THERAPUTICS SEGMENTS

Biotechnology has been essential for the creation of monoclonal antibodies. Monoclonal antibodies (mAbs in technical literature) are antibodies that are identical, each derived from one type of immune cell and each a clone of a single parent cell. mAbs can be deployed to find a single targeted substance, such as an antigen found only on a cancer cell, and make it possible to pinpoint the cell and destroy it. The specificity of the antibody reaction is exploited in early diagnosis of a wide variety of illnesses, such as in the development of tumor-specific markers for cancer detection based on mAbs. mAbs are used in biomedical research, in diagnostic tests for pregnancy, AIDS, Hepatitis, influenza, in drug screening, in addition to a host of therapeutical applications such as infectious diseases and cancer. The antibodies can be also used to reduce the problem of organ rejection in transplant patients and to treat viral diseases that are traditionally considered untreatable. Reports and manufacturers' product catalogues suggest that there are more than 100 different monoclonal antibody diagnostic products currently available in the markets.

The supply-side market segments for mAbs, according to their application area are:

- Diagnostic agents
- Therapeutic agents

According to therapy area for the mAbs, the market segments are:

- Oncology
- Autoimmune/inflammatory diseases
- Infectious disease
- Respiratory
- Ophthalmology
- Cardiovascular
- Hemostasis

As MonoJo is operating in the segment of monoclonal antibodies for cancer diagnostics, our research focused primarily on that segment. However, as the two sub-segments of mAb diagnostics and therapeutics are closely related, and the company has showed interest in therapeutics, our research included the mAbs for therapeutics.

Market reports indicate that cancer products are forecast to continue to dominate the market of mAbs, in terms of commercial value and pipeline development, and that cancer testing is one of the most important growth opportunities for the next five years in the global diagnostics segment. Future projections are that the cancer market will reach CAGR of about 18 percent by 2011, or around $80 billion in value (*Source: Tufts Center for the Study of Drug Development).* This comes as a result of projected growth in future cancer incidence due to risk factors such as population aging, tobacco use, obesity, sedentary lifestyle and infections, but also due to the fact that more cancer patients in developed and developing countries are gaining access to modern targeted therapies.

According to the World Health Organization (WHO) and the "World Cancer Report" published by International Agency for Research on Cancer (IARC):

- More than 10 million people are diagnosed with cancer each year
- Cancer is a leading cause of death worldwide: it accounted for 7.9 million deaths (around 13% of all deaths) in 2007.

- About 80% of all cancer deaths in 2007 occurred in low- and middle-income countries. Deaths from cancer worldwide are projected to continue rising, with an estimated 12 million deaths in 2030.
- Differences exist between regions: in developed countries, prostate, breast and colon cancers are more common, while cancers triggered by infections – liver, stomach and cervix cancers – are more prevalent in the developing world.
- The most common cancers worldwide are lung (12.3% of all cancers), breast (10.4%) and colorectum (9.4%).
- The most frequent types of cancer worldwide, per gender, are:

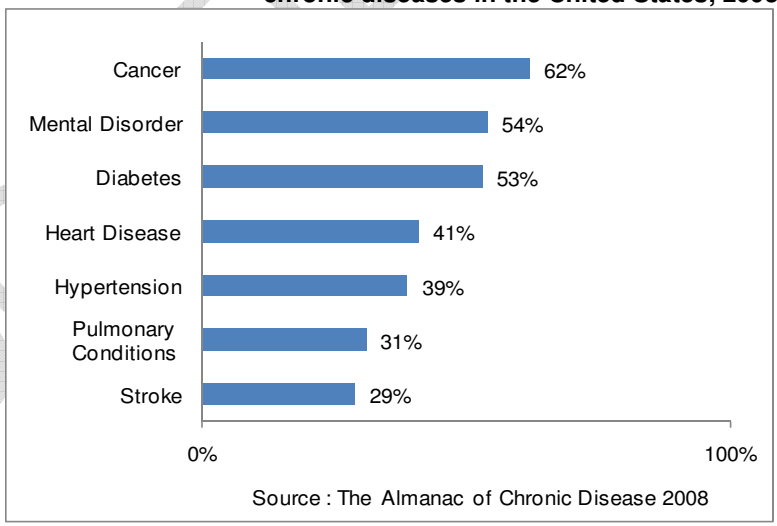
Men	Women
Lung	Breast
Stomach	Lung
Liver	Stomach
Colorectal	Colorectal
Oesophagus	Cervical
Prostate	

- A steadily increasing proportion of elderly people in the world will result in approximately a 50% increase in new cancer cases over the next 20 years.
- By 2020, the highest number of cancer incidence will be registered in Eastern and South Eastern Asia, Europe, North America, Central and South America.

The United States

According to a study by the Milken Institute, there will be 230 million reported cases of chronic disease in 2023, an increase of 42 percent from 2003. Cases of cancer, diabetes and mental disorders are expected to rise most substantially, by 53% to 60% per illness. The number of obese Americans, currently one third of the total population, is also projected to increase. Certain diseases, like heart disease and cancers, will be the most costly.

Figure 2-4: Projected rise in cases of seven of the most common chronic diseases in the United States, 2003-2023



In the United States, the growth of the cancer diagnostics products is expected to be driven by the increasing number of people who fall within the higher risk age groups for cancer (see table no. 2-5 below)

Table 2-6: % of US population in the high risk age groups for cancer

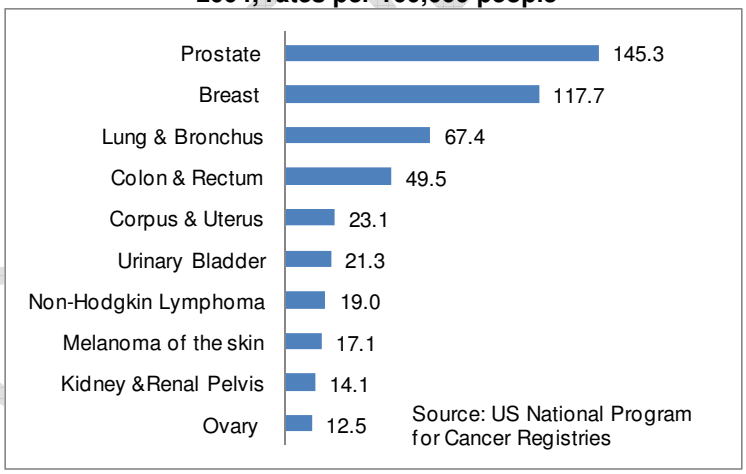
Age group	% population 2007	% population 2015
45-49	7.6	6.5
50-54	7.0	6.9
55-59	6.1	6.7
60-64	4.8	5.8
65-69	3.6	4.8
70-74	2.9	3.4
Total	32	34.1

Source: US Census Bureau, IDB

According to the US Census Bureau's population database, by 2015, the US population within the ages of 45-74 will represent 34 of total; among these age groups, the highest growth is forecasted to be registered in the 65-74 group which will represent 8.2% of the total population.

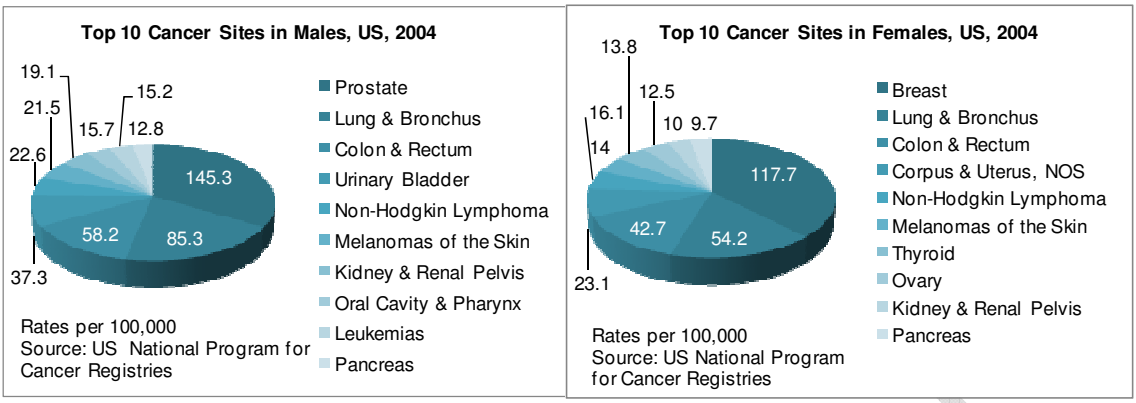
The US National Cancer Institute estimates that about ten million Americans have or have had some form of cancer. Overall costs of the disease are $126 billion annually. Pharmaceutical companies are developing more than 300 new medicines for cancer, some of which are in development for more than one type of the disease, for a total of more than 500 ongoing R&D projects. In the US, the highest rates of cancer are prostate cancer, breast, lung and colon cancers. Figure below shows the frequency of cancer according to sites, with average adjusted rates per 100,000 people.

Figure 2-5: Top 10 Cancer Sites, Both Sexes, U.S., 2004, rates per 100,000 people



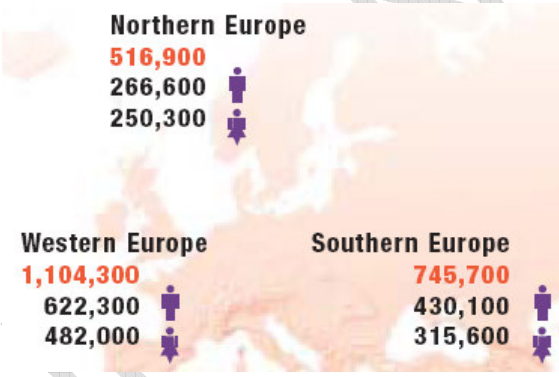
Per gender, prostate cancer is the cancer with the highest incidence among men, with a rate of 145.3 men to every 100,000, almost twice the rate of lung and bronchus cancer incidents in men. In women, breast cancer had the highest incidence with 117.7 per 100,000 women, more than double the rate of lung cancer- which has the second highest incidence in women.

Figure 2-6 and 2-7: Top 10 Cancer Sites, by gender, US, 2004



The European Union

More than 3 million people are diagnosed with cancer each year in Europe. By 2020, IARC Globocan 2002 estimates that around 2.4 million Europeans will be diagnosed with cancer; the highest incidence is expected in Western Europe (with the highest concentration of population), followed by Eastern and Southern Europe and Northern Europe.



Source: copy from IARC's Globocan 2002

The increase in cancer incidence is generally attributable to ageing populations and the growing adoption of unhealthy lifestyles (bad diet and lack of exercise). Cancer will remain an important public health problem in Europe and the ageing of the European population will cause these numbers to continue to increase even if age-specific rates remain constant

In 2006, cancer (excluding non-melanoma skin cancers) was diagnosed in 3,191,600 people in Europe. According to World Cancer Report, the most common cancers among Europeans (greater Europe) were:

	Number of cases	% of all cancer cases
Breast	429,900	13.5
Colorectal	412,900	12.9
Lung	386,300	12.1

Table 2-7 shows cancer incidence, per gender, in Europe-25 (except Bulgaria and Romania):

Table 2-7: Projected Number (thousands) of New Cancer Cases, per gender, EU-25

Europe 25	Incidence (thousands)			
	Males	Females	Total	%
Breast (women)	-	320	320	14
Prostate	302	-	302	13
Colon and rectum	163	134	297	13
Lung	194	71	265	11
Bladder	83	22	105	4
Uterus	-	83	83	3
Stomach	50	31	81	3
Non-Hodgkin Lymphoma	40	33	73	3
Oral cavity and pharynx	55	16	71	3
Kidney	39	24	63	2
All cancers except non-melanoma skin cancer	1252	1036	2288	100

Source: Responding to the challenge of cancer in Europe Report, Institute of Public Health of the Republic of Slovenia, 2008

The report referred to above estimates that by 2020 the cancer incidence in Europe will increase by an average of 20% compared to 2002. By age groups and gender, the incidence will increase in the age 65 and over group by 26%; in men aged 65 and above the increase is projected at 31%, and in women of the same group the increase is projected at 20%.

Table 2-8: Estimated increase in cancer incidence, Europe, 2002-2020

Persons	2002 (thousands)	2020 (thousands	Increase since 2002 (%)
Aged less than 65	1,240	1,391	12
Aged 65 and over	1,581	1,990	26
All ages	2,821	3,381	20

Source: Responding to the challenge of cancer in Europe Report, Institute of Public Health of the Republic of Slovenia, 2008

Saudi Arabia

The US Census Bureau estimates that the Saudi population reached 28.1 million by midyear 2008 and is expected to grow to 31.6 million in 2015, and 35.7 million by 2025. According to the same source, by year 2015, the higher cancer risk age groups of 45-74 will include around 10% of the Saudi population.

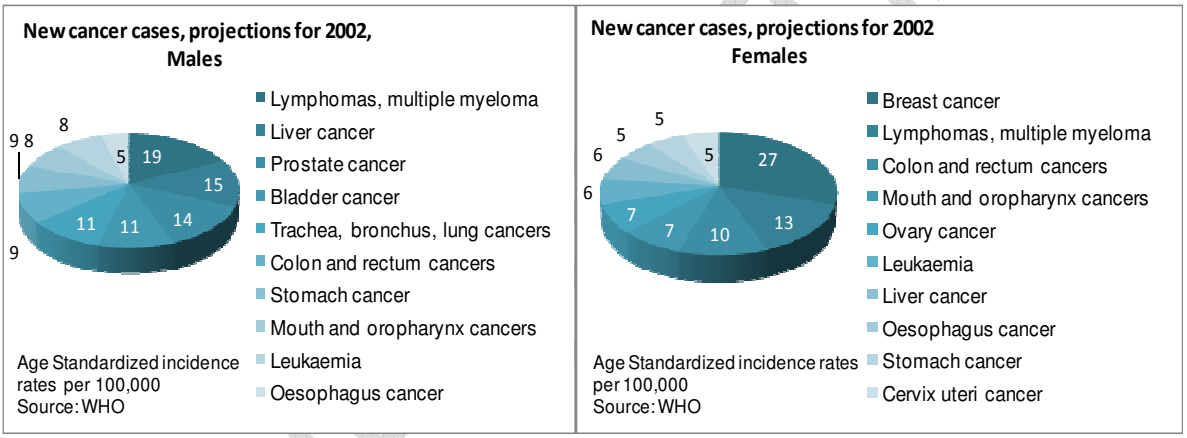
Table 2-9: Composition of Population by age group, Saudi Arabia, 2007-2015

Age group	% population 2007	% population 2015
45-49	2.7	3.2
50-54	2.0	2.3
55-59	1.4	1.7
60-64	1.1	1.2
65-69	0.9	0.8
70-74	0.7	0.7
Total	8.8	9.9

Source: US Census Bureau, IDB

Figures no. 2-8 and 2-9 illustrate the ten most common new cancer cases registered in Saudi Arabia during 2002, by gender, as reported by the WHO's cancer statistics. In men, lymphomas and multiple myeloma was reported to have the highest incidence, with 18 cases at every 100,000 men, while breast cancer had the highest incidence in Saudi women, with 27 cases among every 100,000 women.

Figure 2-8 and 2-9: Top 10 cancer sites, by gender, Saudi Arabia, 2002



According to MonoJo's business plan, the Saudi Arabian market for mAbs (for the types produced by MonoJo) is estimated at JD 580,000-700,000 per year. The same source estimates that the mAb diagnostics market in the Saudi market will register a 20% growth during 2008 (the estimation is based on factors such as the increase in cancer cases, the increase in population and the development of medical technology).

Egypt

Based on the US Census 2008 midyear estimates, Egypt's population is 81.7 million, and will reach 91 million by 2015, and 103.6 by 2025.Table 2-9 shows the composition of the population according to the cancer risk age groups:

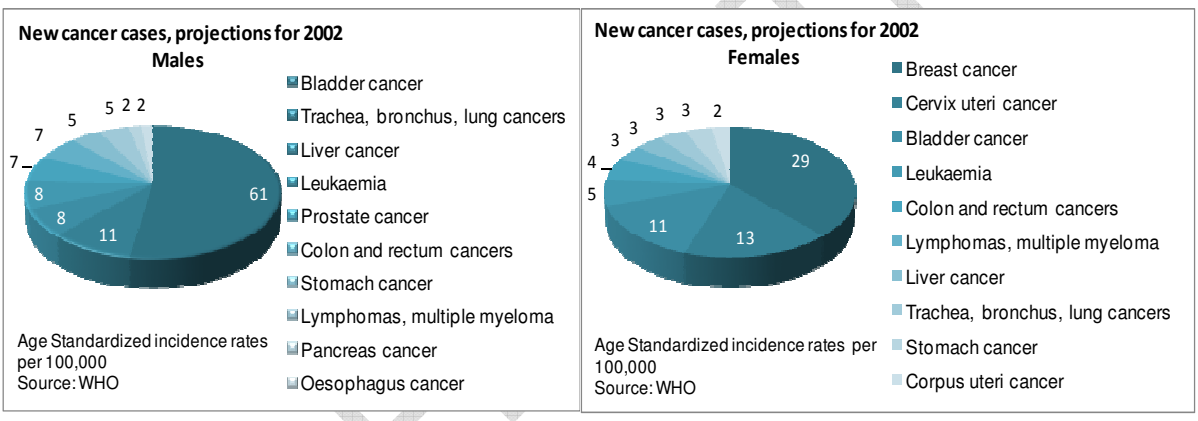
Table 2-10: Composition of population, by age group, Egypt 2007 -2015

Age group	% population 2007	% population 2015
45-49	4.9	5.5
50-54	4.2	4.6
55-59	3.5	3.9
60-64	2.6	3.2
65-69	1.9	2.4
70-74	1.4	1.6
Total	18.5	21.2

Source: US Census Bureau, IDB

The most common type of cancer in Egyptian males in 2002 was bladder cancer, followed by lung and liver cancer; in females, the most common types were breast cancer, cervix and bladder cancer. Figures no 2-10 and 2-11 illustrate the ten most common new cancer cases registered in Egypt in 2002, by gender, as reported by the WHO's cancer statistics.

Figure 2-10 and 2-11: Ten most common types of cancer in Egypt, by gender, 2002



Jordan

The Jordanian population is estimated at 6.1 million currently (midyear 2008), and expected to reach 7.2 million 2015 and 8.6 million by 2025. By year 2015, 18.6 percent of the population will be concentrated within the higher cancer rate groups.

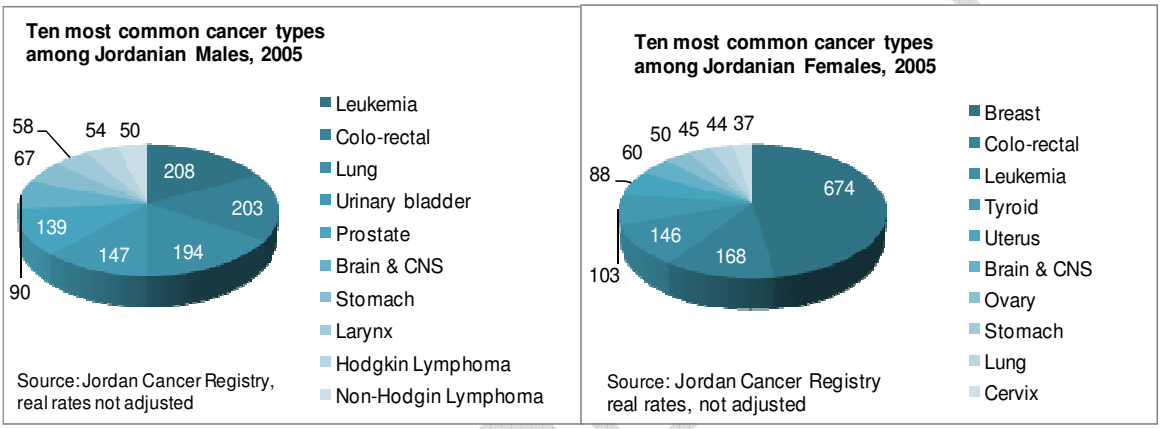
Table 2-11: Composition of Population, by selected age groups, Jordan, 2007-2015

Age group	% population 2007	% population 2015
45-49	4.2	6.1
50-54	2.8	4.4
55-59	2.3	3.0
60-64	2.0	2.1
65-69	1.5	1.7
70-74	1.2	1.3
Total	14	18.6

Source: US Census Bureau, IDB

Consumption of mAbs for cancer diagnostics is expected to increase at a pace similar to the cancer incidence growth. The latest available official data on cancer incidence in Jordan is from 2005: according to the Jordan Cancer Registry's newly published *"Cancer Incidence in Jordan 2005"*, 3,678 new cancer cases were registered in Jordan during 2005, an increase of 2.4 percent from 2004. By age distribution, cancer incidence is the highest in the 60 and above age group representing 38.9% of total cases, followed by the 45-59 age groups. The overall median age at diagnosis was 55 years, with variations according to cancer type and gender (51 years for females and 58 years for males). The most frequent type of cancer in Jordan, by gender, was breast cancer in women (36.2% of all cancer incidence in women) and leukemia in men (11.4% of cancer cases in men), closely followed by colon cancer in men. The figures below illustrate the ten most common cases of cancer in Jordan, by gender, during 2005.

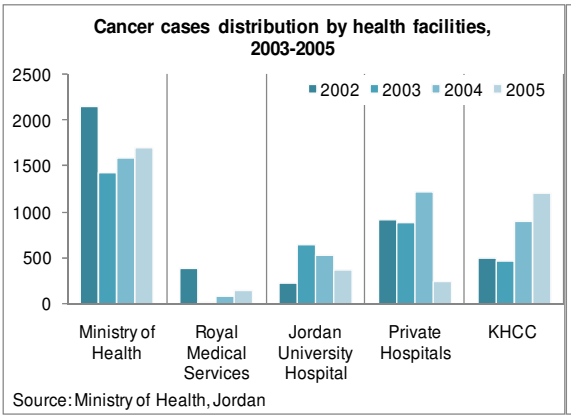
Figure 2-12 and 2-13: Ten most common types of cancer in Jordan, by gender, 2005

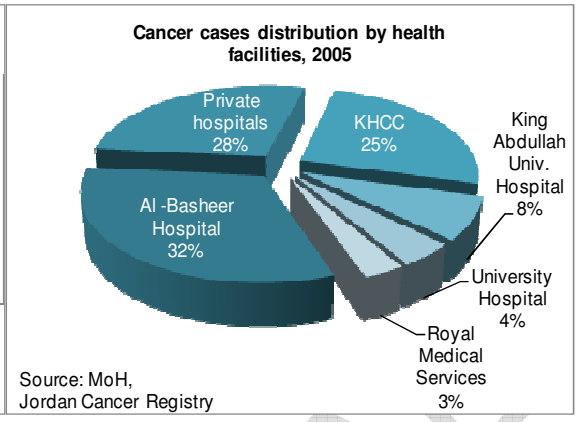


By buyers of cancer diagnostic monoclonal antibody products, the Jordanian market has several distinct customer segments, according on their size, buying patterns, and purchasing decisions.

- Public sector hospitals:
  - Al-Basheer Hospital (Ministry of Health)
  - the Royal Medical Services
  - Public University Hospitals such as the University Hospital and the King Abdullah University Hospital
- King Hussein Cancer Center (KHCC)
- Private Sector:
  - Private hospitals: the Islamic Hospital, Jordan Hospital, Al Amal, and Specialty Hospital
  - Private Medical laboratories: Med Labs and Bio Labs.
- Research Centres affiliated with universities and/or biotech centers

Figure 2-14 and 2-15: Cancer distribution in Jordan, by health facilities, 2002-2005





Data on cancer cases distribution by health facilities in Jordan (figures 2-14 and 2-15), shows that – while the number of cancer cases and distribution among the medical facilities vary each year, the largest number of cancer patients are treated in the Ministry of Health's Al-Basheer Hospital, some private sector hospitals and the King Hussein Cancer Center (KHCC). As such, we concluded that the bulk demand for mAbs cancer diagnostics would come from those institutions, in addition to some smaller-scale users such as university hospitals and the Royal Medical Service Hospital, as well as private sector labs. Given the above, there are two main potential institutional buyers that MonoJo could target: Al-Basheer Hospital and the KHCC which shows a constant increase in the number of cancer patients treated.

In terms of the market size, only some limited information could be obtained about the consumption of mAbs for cancer diagnostic, due to the reluctance of large customers such as the King Hussein Cancer Center- to provide such information. Al Basheer Hospital (which is representative of the Ministry of Health hospitals as it uses the bulk of these products) reported that the most frequent cancer type diagnosed/treated at Al-Basheer is breast cancer, and the most common types of cancer diagnostic mAbs are Estrogen receptor and Progesterone receptor, and HER2neu. The hospital reportedly purchased the following amounts of mAbs:

Table 2-12: Quantity of cancer diagnostic Abs at Al-Basheer Hospital, 2006-2007

Antbodies	Quantity in Vials		% change	Average price in JD/ \Vial	Value in JDs	
	2006	2007			2006	2007
Diagnostics mAbs	108	112	3.7	175	18,900	19,600
Therapeutic mAbs	24	24	-	n/a	n/a	n/a

Source: Al-Basheer Hospital

MonoJo's business plan reports that the demand for diagnostics mAbs in the private sector hospitals is highest in the Islamic Hospital, which (according to the PCG) represents 73.1 of the private sector market. Information obtained from MonoJo suggests that the local market value of monoclonal antibodies for cancer diagnostic is around JD250,000-300,000 per year, with an estimated 10% annual growth. However, these figures may be not accurate, given indications from historical data of cancer incidence rate, purchasing data, population growth, the number of potential foreign cancer patients treated in local hospitals etc., and therefore, the company must conduct a thorough analysis to closely estimate the potential future market potential.

2.3.4 MARKET TRENDS AND CHARACTERISTICS

The specific nature of mAbs (antibodies that are identical, each derived from one type of immune cell and each a clone of a single parent cell), makes possible their use in wide and potentially revolutionary applications. A major development in the mAb market came when the partially or fully humanized antibodies were developed, which are safer and more effective, and allowed mAbs to gain wider usage among patients. Also, many current mAb therapies are effective for a large number of diseases, making them even more attractive to drug developers.

Reported advances in new technologies are increasing competition in the market, but at the same time they provide growing opportunities for product discovery and development. New technologies produce more efficient approaches to manufacturing of monoclonal antibodies and biomarkers, and, in general open more opportunities for joint-ventures.

The industry is characterized by a rapid rise of offshoring and globalization, which contributes to the movement of research, development and clinical trials away from the U.S., U.K. and other developed countries into lower cost technology centers in India, and elsewhere in developing markets. In fact, our research identified that biotech firms are rising rapidly in India, China, Singapore and South Korea which, is believed, will provide serious future competition to older companies in the developed world.

It is estimated that clinical outsourcing associated with the need for faster development times and cost pressures increased by 15 percent between 2001 and 2005, outpacing the 11% rate for overall spending on development. Demand for contract research organization (CRO) services will likely grow by 16% annually over the next three years as larger companies seek assistance in managing large, complex global projects without adding to their in-house human resources ((In 2004, contract research companies, CROs managed 23,000 phase I-IV clinical trials worldwide, monitored more than 150,000 clinical investigators, and enrolled more than 640,000 new subjects). The IMS believes that shift towards outsourcing of manufacturing is likely to be followed by other functions within pharmaceutical companies, including some elements of R&D. It could speed up time to market for new products, give multinationals an entry point into emerging pharmaceutical markets, and make it easier for companies to manage changes in product demand and "concentrate on differentiating competencies such as innovation and brand building," according to IMS. However, there is uneasiness about the quality and safety of some of the products sourced from emerging markets, as well s concerns about intellectual property protection as complex manufacturing and processing information is signed over to partners in emerging markets.

Datamonitor projects that the monoclonal antibodies market will register a 14 percent annual growth, representing the fastest-growing biotech segment of antibody drugs. mAbs currently generate global revenues of around $20 billion and include such blockbusters[7] as Avastin, Herceptin, Remicade, Rituxan, Humira and Erbitux. It is estimated that there are currently 132 mAb products in development. The growth of the market is predicted to be dominated by chimeric mAbs (Remicade and Rituxan) taking market share of almost 50% in 2008. The number of approved humanised and human antibodies will also significantly increase, with sales forecast to reach $5 billion (approximately 30% market share) for humanised mAbs and $2 billion (approximately 10% market share) for human mAbs by 2008.

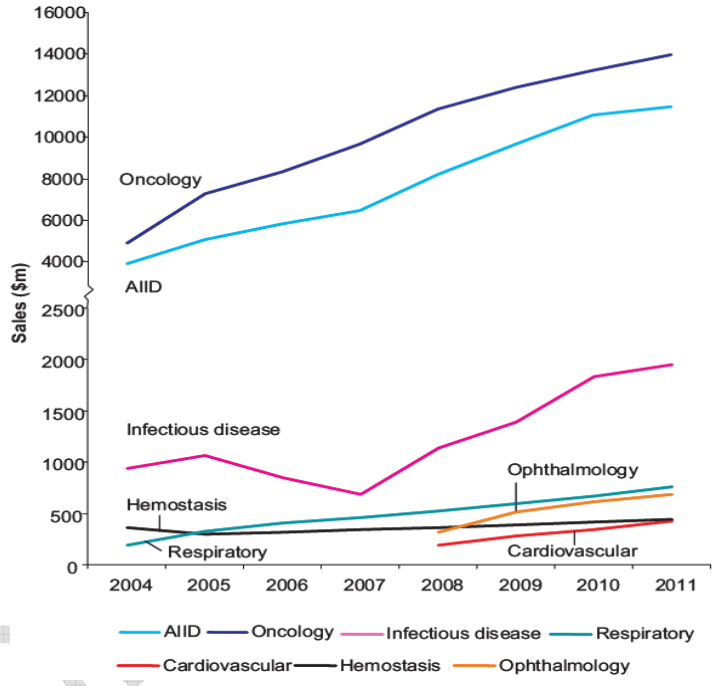
With recent US FDA approvals of Erbitux (colorectal cancer; Imclone Systems) and Avastin (colorectal cancer, Genentech), oncology will remain the driving income earner with forecast sales of around $14 billion by 2011. Arthritis, immune and inflammatory disorders (AIID)

[7] By some accounts, blockbusters are drugs with over $500 mil/ year in revenues, or, by some accounts >$1 billion/ annual revenues)

indication will be the next largest income earners, with sales reaching over $10 billion by 2011. The American Biotechnology Laboratory reported that there are a total of 22 therapeutic mAbs in the market. A list of mAbs approved for various disease indications by the US FDA and the European Regulatory Agencies is available in Annex 2.

Research indicates that companies will continue to increase their investments in the development of targeted therapies – or personalized drugs and biologics, designed to target specific molecules in tumor cells; this is believed to lead to an increased focus on diagnostic companies as potential partners and targets for take-over. To speed up development of new therapies and decrease in-house development costs, drug developers will seek closer alliances with academic institutions and scientists and rely on the development and acquisition of external technologies and drugs, and co-development alliances. In-licensing, acquisitions of smaller companies by larger ones and strategic alliances between companies are likely to increase.

Figure 2-16: Therapy area analysis of forecasted monoclonal antibody sales, in $ million, 2004-2011



Source: BusinessInsights

The monoclonal antibody technology has offered practical advantages for the *in vitro diagnostics* (IVD) industry to produce highly specific antibodies. Based on current trends, changes predicted for the IVD industry are: automated systems, smaller analyzers, the consolidation of hematology, chemistry, and immunochemistry assay platforms, an increase in the availability and use of point-of-care systems, increased involvement of the Internet for ordering tests and distributing information, and more noninvasive assays systems.

IMS Health reports that a number of emerging biotech and pharma companies are currently focused on developing next-generation mAb technologies[8], with the aim of producing more

[8] Ablynx, a Belgian biopharmaceutical company founded in 2002, has developed a novel class of therapeutic antibodies known as Nanobodies. These are comprised of the smallest functional fragment of naturally-occurring single-domain antibodies. Like conventional MAbs, they show high target specificity and low toxicity; however, like small molecules they can reach targets not easily recognised by currently marketed MAb therapies, including active sites of enzymes and receptors. Further advantages include ease of manufacture and high stability, enabling formulation for oral or topical delivery.

effective therapies that combine the advantages of mAbs with those of small molecule therapeutics.

In terms of medical devices, the U.S. FDA has become faster at approving applications from manufacturers: in 2007, the FDA said it cleared 2,640 devices for use under its so-called "510K" process, compared with 2,677 devices in fiscal year 2006.

2.3.5 MARKET ACCESS REQUIREMENTS

As a manufacturer that is considering exporting to foreign markets, MonoJo should be aware of the market access requirements of the countries targeted for export. These requirements refer to legislation based on consumer health and safety, environmental and labor concerns, in addition to non-legislative requirements that trading partners (i.e. importers, distributors, wholesalers, customers) in the target markets may request.

In the United States, the importance of regulatory compliance depends on the purpose of the product. All mAbs which MonoJo currently manufactures or has in development are *in vitro* diagnostic monoclonal antibodies, which are classified by the US FDA and the EMEA as "in vitro diagnostics" or IVDs. For marketing in the US and EU markets, these products are subject to regulations under the US Federal Food, Drug and Cosmetic Act and the EMEA, respectively.

According to the US FDA, the IVDs are medical devices that analyze human body fluids, such as blood or urine, to provide information for the diagnosis, prevention, or treatment of a disease. Medical devices are subject to the general controls of the Federal Food Drug & Cosmetic (FD&C) Act which are contained in the final procedural regulations in Title 21 Code of Federal Regulations Part 800-1200 (21 CFR Parts 800 - 1299). These controls are the baseline requirements that apply to all medical devices necessary for marketing, proper labeling and monitoring its performance once the device is on the market. (Annex 6 contains the summary of the US FDA's premarketing requirements for in vitro diagnostic products for human use: premarket approval of medical devices- CFR Title 21).

In the European Union, the in vitro diagnostics are governed by Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 and require that in vitro diagnostic medical devices offered for sale in EU countries conform with the Directive requirements and be CE marked. Directive 98/79/EC is available at http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31998L0079&model=guichett[9].

Quality management standards that international manufacturers of in-vitro diagnostics apply are the ISO 9001:2000 and ISO 13485:2003 for 'The design, development, manufacture and supply of high quality immunological reagents including custom specific products for the diagnostic and research markets.' These certifications allow for the manufacture of antibodies for commercial use, including *in vitro* diagnostic applications. The ISO 9001 and ISO 13485 quality certifications allow producers to offer antibodies and antibody manufacturing facilities to laboratories around the world, in particular those requiring registration with regulatory bodies (including research laboratories, diagnostics manufacturers and antibody suppliers). A growing number of medical device manufacturers are now requiring suppliers to comply with the ISO 13485 standard. In addition, for products commercialized in the US and EU markets, the manufacturing facilities are subject to

[9] The CBI (Centre for Promotion of Imports from Developing Countries) has available on its website a detailed guide of EU legislation on CE-marking: In vitro diagnostic medical devices , which contains a detailed description of the CE marking process according to Directive 98/79/EC, in addition to national legislation of each EU member country on the Directive's implementation (http://www.cbi.eu/marketinfo/cbi/docs/eu_legislation_on_ce_marking_in_vitro_diagnostic_medical_devices

compliance in all material aspects with the requirements of the FDA's Quality System Regulation, QSR[10] (formerly known as Good Manufacturing Practices). Materials used in development and testing activities may also be subject to the Controlled Substances Act, administered by the Drug Enforcement Agency (DEA).

Our research on leading diagnostics mAbs manufacturers shows that all these companies promote strong quality features and quality control procedures, such as the ISO 9001 quality systems for fully traceable procedures and products, the cGMP certification (for larger commercial manufacturers), and they comply with other regulations, such as the US 29 CFR 1910.1200, OSHA Hazard Communication Standard and EC Directive 91l155/EC which refer to the concentration of hazardous materials.

There are no official requirements for the commercialization of diagnostic mAbs for cancer in the Jordanian market, but institutional buyers in the medical sector (hospitals, cancer centers, labs, etc.) require that foreign suppliers have the CE mark or U.S. FDA approval for in vitro diagnostics (according to the regulator in the country of origin). In regional markets such as Egypt and Saudi Arabia, the situation is similar, buyers requesting the CE mark or US FDA approval. Some private buyers that use diagnostic mAbs for in-house research purposes would accept products without these certifications, but the products will be subject to their approval.

In terms of customs tariffs, Jordan exports to the world benefit from various bilateral and regional trade agreements, such as the Jordan-US FA the Pan-Euro Mediterranean Agreement between Jordan and the EU, the Jordan-Singapore FTA as well as the Great Arab Free Trade Agreement between Arab countries. Under the Jordan-US FTA, tariffs for monoclonal antibodies are zero, provided the products comply with rules of origin requirements (of country of origin, 35 percent added value and direct shipment). The Pan-Euro Mediterranean Agreement is aimed at establishing a free trade area over a period of twelve years, and provides good opportunities for Jordanian companies wishing to access the EU market.

2.3.6 COMPETITION ANALYSIS

Developments within both biotechnology and medical devices are becoming more complementary over time, as medical devices are increasingly being used to deliver new pharmaceutical and biotechnology products, and, as a result, the distinction between diagnostic and therapeutic monoclonal antibody companies is quite blurred, most are identified as producing both.

Companies which are looking to compete in the bio-generics mAbs markets will need significant financial resources to overcome the substantial expenses associated with bringing a bio-generic product to market. Successful players will need to develop and validate complex biopharmaceutical manufacturing processes, perform state-of-the-art bioanalytical comparisons, collect clinical safety and efficacy data, and deal with a difficult regulatory system in order to obtain marketing approval. Expenditures related to these factors are estimated to reach up to $40 million, with not guarantee for success. In addition, expenditures to support the product will continue even after regulatory approval.

[10] Because some of the in vitro diagnostic antibodies are used in the manufacturing process for drugs and medical device products, such end products are regulated by the FDA under Quality System Regulations (QSR). Although the customer is ultimately responsible for QSR compliance for their products, it is also the customer's expectation that the materials sold to them will meet QSR requirements. Therefore, manufacturers must make sure that their products comply with the QSR requirements, even after obtaining the certification. Failure to comply with these standards can cause customers to shift to other suppliers.

Industry news regularly report on the fact that larger biopharma companies are consolidating by building and acquiring smaller companies with experience in biopharmaceutical product development or forming strategic alliances. While this industry consolidation poses a significant threat to small players who cannot match the financial, technological or marketing strength of the big companies, the same conditions can be regarded as opportunities to the extent of which a small antibody maker such as MonoJo can provide contract manufacturing services to either larger biopharma firms, or research labs.

The global market for cancer detection products is dominated by large diagnostic product companies like Abbott Diagnostics, Johnson & Johnson, Diagnostic Products, Roche Diagnostics, Bayer Diagnostics, Dade, Tosoh and bioMerieux. These are matched by hundreds of small companies with a few products in the market. In addition, there are hundreds of contract manufacturing antibody suppliers who specialize both in the development and large scale production of monoclonal (and polyclonal) antibodies, usually GMP and cGMP compliant, or hundreds of others who specialize in the custom production of research-scale qualities of antibodies (Annex 4 provides links to mAbs manufacturers' directories). Many of these entered the antibody market as a spin-off from the national biotech or research institutions and through the years have managed to establish a good position in the manufacturing and commercialization of mAbs. In the United States for example, research centers located at academic institutions offer a good alternative for researchers needing small mAb amounts. These are not-for-profit, centralized facilities that offer specialized laboratory services to investigators on a fee-for-service basis. Many are at least partially funded by the National Institutes of Health.

The leading international manufacturers have significant financial, operational, sales and marketing resources, and experience in research and development. These and other companies have developed or could in the future develop new technologies that compete with products in the market. The market research conducted suggests that a competitive position for a mAbs manufacturer is determined by the following attributes:

- product function
- product quality
- technical support
- price
- the extent of product portfolio diversification
- capabilities for fast product development
- product marketing

Various customers may rank these above attributes differently, and therefore, MonoJo should position itself to compete in a market segment where it can leverage its core competencies and can offer specialized type of products to meet its target customers' needs, preferably not met by other players.

Globally and regionally, including Jordan, competition in the regional mAbs diagnostics market – is made up in general by the same international players. According to MonoJo, competition for their products in the local and regional markets is represented by: Biogenex, DAKO, Roche, Ventana, Abbott and Becton, Dickinson and Company (BD) (MonoJo presentation). According to our research of the Jordanian market, top players supplying Governement Hospitals are DAKO, Biogenex, Ventana, and BioCare.

To date, there are no Jordanian manufacturers of diagnostics mAbs to compete with MonoJo, however, the presence of the foreign competitors poses a challenge for MonoJo.These companies have substantially greater financial, technical (R&D) and human resource capabilities than MonoJo has, in addition to having a broad range of products, worldwide subsidiaries, several production facilities in various regions and worldwide commercial distribution networks. DAKO, Biogene, Ventana and BD have had long-term supply contracts in the local market for the past years, have proven product performance,

are competitive in terms of quality and price and are all characterized by a very diverse product portfolio. All these companies have distribution and/or technical offices in the Middle East. BD has offices in Egypt, UAE and Saudi Arabia (technical, scientific office), and BioGenex, DAKO and others have distributors in those countries. Customers in Jordan may show to have preferences towards purchasing from these established suppliers, and therefore, penetrating the local hospitals market could prove not an easy job for MonoJo.

In terms of therapeutics, only five monoclonal antibody products – Avastin, Herceptin, Humira, Remicade and Rituxan – accounted for 80% of total mAb revenues in 2006 (at a total of $3.1 billion, while product revenues for all other marketed mAbs were at $261million in 2006). These same products have revenues forecast to account for 70% of all mAb revenues until 2012. Datamonitor expect that Genentech/Roche will retain their stranglehold over the mAb market out to 2012, due to ownership of three of the 'big five' products. Oncology and AIID will remain the mAb segment therapeutic focus because they are the disease areas addressed by the 'big five'.

Four 'established' companies are ranked at the top end of the market – Genentech, Roche, Abbott and Johnson & Johnson – each of which generated mAb revenues in excess of $2 billion in 2006, and there is also the additional tier of four 'emergent' players – Biogen IDEC, Amgen, Novartis and UCB Pharma. Datamonitor expects this 'second tier' to expand their market presence out to 2012, with each forecast to record absolute annual mAb sales growth in excess of $1 billion over the period 2006-2012.

2.3.7 INDUSTRY ANALYSIS

The diagnostic products segment is subject to competition in technological innovation, price, and convenience of use, service, product performance, long-term supply contracts, and product potential for overall cost-effectiveness and productivity gains. Some products in this segment can be subject to rapid product obsolescence.

According to international industry reports, the biopharma industry in general presents strong barriers to entry in the face of newcomers: high R&D costs, patent limitation, the lengthy clinical trial time, the regulating agencies pre-marketing and post-marketing regulations to approve the drug, access to distribution channels, and huge marketing and sales costs. There is not much data available about the diagnostics monoclonal antibody industry in particular, but we believe that the factors that characterize the therapeutics antibody industry also apply largely to the diagnostics manufacturers.

Buyers and payers are very powerful in most markets, when it comes specially to putting pressure in prices. Because this industry is strongly driven by innovation and cost pressures from customers and payers, significant public and private resources are dedicated for R&D to develop new technologies, novel antibodies, and increased product safety and efficacy, which leads to constant challenges for manufacturers. The high costs of developing antibody drugs, plus the costs associated with the combined treatments where antibody drugs are used in combination with chemotherapy and radiotherapy, make the national healthcare providers may be reluctant to pay for the high cost of antibody drugs.

While industry competition is strong, collaboration between players of various sizes, nationalities and competencies is seen as a necessary development to broaden product pipeline; larger pharma companies are looking to partner with smaller biotech developers, in order to develop new technologies, and ultimately increase their capacity and product portfolio and returns. Our research shows that in order to produce more value, companies are looking to provide integrated solutions; separate divisions of the same company are

today working together, while others are forming partnerships to develop new products, by integrating the development and commercialization capabilities of the partners[11].

In Jordan, established players are those that also operate in regional and international markets and compete intensely on price and on quality, as well as on the diversification of product offering. During our research, we understood that not only information is very difficult to get and the industry is surrounded by a cloud of confidentiality, but that there is little or no cooperation between those identified as belonging to the group of local players, whether manufacturers, potentially interested in monoclonal antibody products development, existing and future potential customers, or research institutions.

Table 2-13: Competitive forces within the global mAbs for cancer diagnostics industry

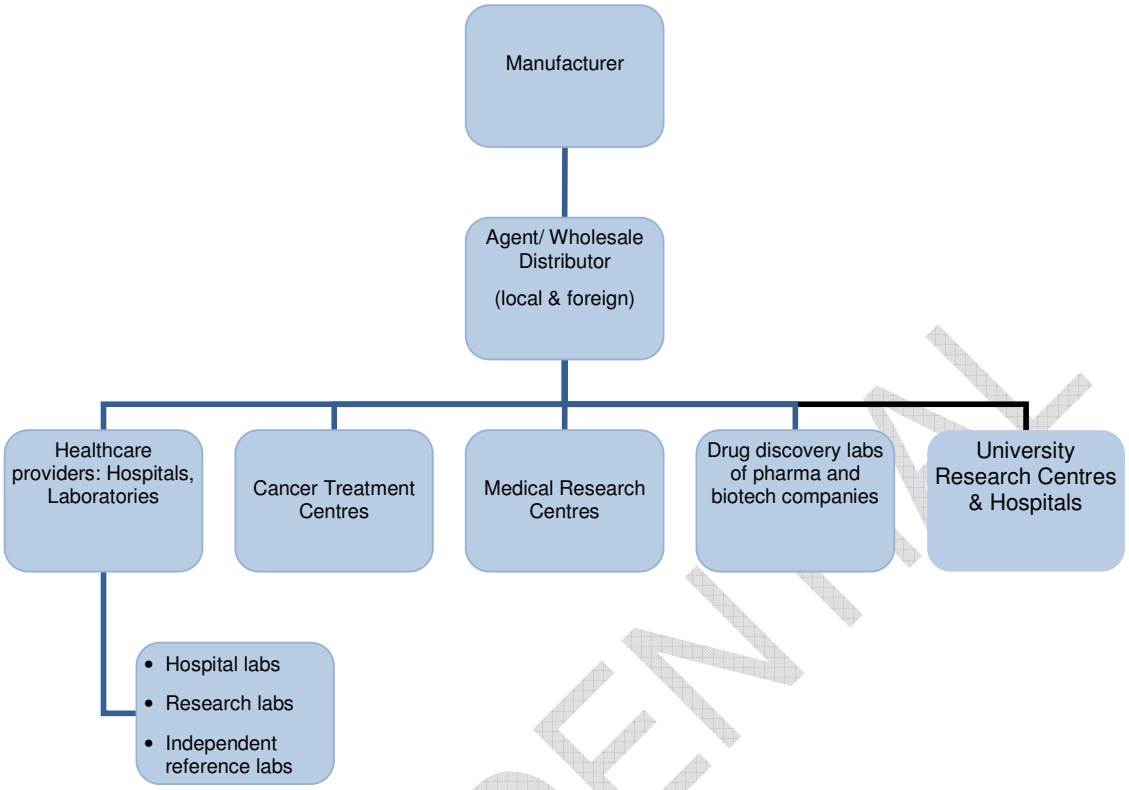
Threat	Characteristics
Growing internal industry rivalry, competition	- Innovation represents the highest competitive pressure due to demand for better technologies to develop higher performance products - Exiting firms competing in the market are similar in size and capabilities - Growing industry consolidation and strong alliances with academia, other biotech companies and pharmaceuticals - High market potential for new diagnostics, thus diversified product portfolios - Price, quality pressures - Increased globalization, reduced trade barriers, open-investment policies especially in Jordan and the region - High entry barriers in foreign markets (entry regulations, high capital requirements, customers loyalty towards established suppliers)
Threat of potential new entries	- Better access to new, specialized technologies - New investments influenced by positive national policies to provide support for the biotech industry (encourage investments) - Threat from the pharma industry in developing potentially cheaper substitutes - Threat from new entrants coming from emerging markets - Ease of access to strong global distribution networks
Buyers and payers strong bargaining power	- Buyers (hospitals, medical centers, insurance companies) are very cost-minded and demand reduced prices, better product quality, proof of high added-value and higher product performance - Customers looking for more targeted and customized treatments - Customers loyalty to initial suppliers - Purchasing trends characterized by the reduction of number of suppliers to lower costs
Government and Industry Regulations	- Strict worldwide regulatory environment due to consumers health and safety issues - Industry self-imposed standards - Governments support for biotech R&D, global and regional policies to promote biotech startups and investments in biotech parks (appealing to foreign investors)

2.3.8 TRADE CHANNELS

The international distribution channels for biotech products, including diagnostic mAbs are represented by agents and wholesale distributors of pharmaceutical products distributing the products to healthcare providers, such as hospitals, laboratories, etc. Customers of the diagnostic mAbs include research laboratories, hospital laboratories, independent reference labs, cancer treatment centers, medical and university research centers, individual scientists,

[11] the development of the PegaSys/ HCV test system represented the first time that Roche's therapeutic and diagnostic divisions worked together to deliver an integrated solution; traditionally, these divisions had operated independently and targeted different markets… When Genentech delivered the Herceptin/Her2 test solution, it moved beyond simple drug development by forming a partnership with a diagnostic company to develop the Her2 test. (Deloitte Research) (see Annex 5 for an example on the variety of alliances that Millenium biopharma company has formed)

and drug discovery laboratories of pharmaceutical and biotechnology firms involved in research of drug development.



In Jordan, as well as in regional and international markets, purchases of medical devices are not made directly by hospitals from foreign companies but through dealers and distributors. In general, suppliers need to go through a tender process. In terms of delivery, just like in the case of deliveries of other bulky products, the concept of just-in-time delivery direct to hospital departments is strongly preferred. Purchasing by the Ministry of Health hospitals in Jordan as well as other public sector hospitals, such as the Royal Medical Services, the University Hospital, etc. is done through an annual tendering process.

2.3.9 PRICING

Setting the price for a cancer diagnostics or treatment mAbs requires taking into consideration both the manufacturing costs and the capacity of the healthcare systems in the target markets to absorb such costs. In general, reports show that there is an increased price pressure from the customers and payers all over the world. The governments and insurance companies demand strong evidence of the product's value, in order to reimburse the product.

Information about prices of cancer diagnostic mAbs in the Jordanian market is available from MonoJo's business plan. The following table includes prices of leading suppliers, and the projected prices for MonoJo.

Table 2-14: Local prices of cancer diagnostic mAbs

Antibody	MonoJo*	BioGenex	DAKO/ BioGenex	Abbott, Roche, Ventana	BD
Cytokeratin (CK)	80	120-180/ vial	184-235 / vial	n/a	n/a
Progesterone Receptor (PR)	200	267/ vial	120/ vial; 265/ vial	160-200/ kit	n/a
S100	86	115/ vial	n/a	n/a	n/a
CEA	57	76/ vial; 175/ kit	150-165 / vial	200 avg. price/ kit	n/a
Anti-CD8	170	226/ vial	n/a	n/a	280-330/ kit
Estrogen Receptor (ER)	202	269/ vial	300-320 / vial ; 220-260/ vial	160-200 / kit	n/a
Actin	173	230 / vial	300/ vial ; 80/ vial	n/a	n/a
CD20	89	119/ vial	57 /vial	n/a	280-330/ kit
β-HCG	131	180/ vial ; 175/ kit	160 / vial	130-160-190/ kit	n/a
Anti-CD4	190	n/a	n/a	n/a	280-330/ kit
Anti-CD5	132	176 /vial	n/a	n/a	280-330/ kit
Anti-CD3	225	n/a	300 / vial	n/a	280-330/ kit
Anti-Kappa Chain	45	n/a	210-240 / vial; 200-300 / kit	n/a	n/a
Anti-Lambda Light	45	n/a	200-300/kit	n/a	n/a
BCL2	87	n/a	n/a	n/a	n/a
HMB-45	173	230 / vial	85-95/ vial	n/a	n/a
Desmin	86	115/ vial	57 / vial	n/a	n/a
KI-65	157	n/a	n/a	n/a	n/a

*Projected
Source: MonoJo's business plan

These prices show some big variances, possibly because of the products' concentration, the quantities purchased concentration, and supplier. For example, in one instance products from Dako, BioGenex and Ventana are listed at an average price for all products between JD105-340 for ready to use vials. When inquiring about prices of cancer diagnostic mAbs purchased by Al-Baseer Hospital, we obtained an average price of 175 for two products: Progesterone and Estrogene Receptor (PR, ER). The table shows that the planned prices of MonoJo's products are indeed less than those of the current suppliers.

2.3.10 COMPETITIVE ADVANTAGE

Based on the company audit and on the information available through the market research conducted, it appears that MonoJo's competitive advantage in Jordan and the MENA region is in having:

- Competitive prices (based on company claims that prices are 25-30% lower than competitors in the local and regional markets)
- Short lead time for local delivery – having product stock that can be delivered immediately
- Strategic agreements with scientists from local universities for R&D
- Being the only manufacturer of similar products in Jordan and the possibly in the Gulf region
- In-house sales experience and good local market knowledge

- Good contacts with stakeholders, such as the HCST, NBRC, KHCC, universities, clinical trial hospitals.

2.3.11 KEY INDUSTRY SUCCESS FACTORS

Studies suggest that the success of new monoclonal antibody products will depend on the continuous development and introduction of new products that address the needs of the customers, with the following factors considered as key to the success of mAb products:

- innovative molecular engineering
- shorter development times
- higher success rates
- strong and efficient intellectual property protection
- development of cost-effective manufacturing

Based on interviews with the company and given the local, regional and international market characteristic and industry variables, we concluded that the following are critical success factors for MonoJo:

- obtain relevant ISO and CE mark certification, and maintain a rigorous quality control system
- the ability to focus on product development in order to introduce new products that are demanded in the market and diversify the product line (according to future market demands)
- the capabilities to diversify the product pipeline
- the ability to either develop, license or acquire new technologies
- build strong marketing capabilities to be able to constantly screen the markets, indentify unmet needs and future trends to use for the development of new products or uses.
- build a good brand and company image in the market
- build knowledge assets and the financial resources to support and sustain in-house R&D capabilities
- the ability to form alliances and collaboration partnerships with industry and the scientific community
- ability to partner with sales and marketing companies with good distribution systems in the target market
- ability to obtain the support of the government to promote the industry and support R&D activities

2.4 SWOT ANALYSIS

In the SWOT analysis we use two sets of internal and external factors in order to design the company's strategy. From the company audit we identified the company strengths and weaknesses in relation to the industry in which it operates, and we used extensive market research and analysis to indentify the issues that characterize the monoclonal antibody markets, and the factors that influence the industry. The four lists below comprise the issues that were identified as most important to be considered when developing MonoJo's growth strategies for future market success and its integrated management system for future sustainability of its operations activities.

SWOT Matrix

Strengths	Weaknesses
- Competitive price - Good collaboration with local universities, clinical trial hospitals, foreign experts, researchers - Good regional positioning possibility - Good local sales expertise - Access to foreign research consultants - Willingness and thrive for development from all employees	- Poor product diversification, dependence on few mAbs for cancer diagnostic - Poor financial position- limited financial resources - Dependent of foreign technology - Challenges with brand image and identity - Weak in-house R&D capabilities, and limited skills and expertise in scientific research - Inadequate market research resources - Lack of Standard Operating Procedures that governs the operational activities at all functions - No clear key performance indicators have been set and no clear objectives are set for individuals thus poor performance evaluation system - Weak in-house safety regulations for handling chemicals - Poor security management system - Weak in-house communication channels
Opportunities	**Threats**
- Take advantage of Governments' efforts to contain or reduce costs of healthcare - Move into contract manufacturing operations (private label antibody manufacturing) - Utilize regional distributors with experience in pharmaceutical products of Jordanian origin - Expand into therapeutic areas (as an early stage developer) - in bio-generics, or new application areas for mAbs - Expand into other products that could provide the cash necessary for supporting the mAb line - Attractive local intellectual property protection - Easy regulations in the mAbs research market - Foreign currency exchange rate fluctuations (devaluation of dollar against the Euro is a positive development, rendering imports from countries other than the US too expensive, and Jordanian export prices becoming more competitive in foreign markets).	- Potential increased costs associated with R&D, staffing and compliance with regulations and industry standards - Potential for new entrants from emerging markets - Potential of new competing products entering the markets - The preference of buyers to purchase from long-term foreign) suppliers - Unexpected barriers in regional markets - Problems with channels of distribution in regional markets

3.0 OBJECTIVES

The short and medium-term growth objectives for the business, as identified together with MonoJo's management, are:

- Obtain ISO 900:2000 and 13485:2003 certification and CE mark by the first quarter of 2009.
- Achieve first five products' market readiness (in terms of purity and stability) by end of Q1 2009.
- Introduce the first five products into the market by end of 2009.
- Introduce a total of 17 products into the market by end of 2011, by developing at least four new products annually during 2008-2011.
- Achieve financial sustainability by the beginning of 2010.
- Build a strong regional position as a provider of monoclonal antibodies for cancer diagnostics: penetrate the Saudi and Egyptian markets by end of 2010.
- Achieve 20% market share in Jordan by end of 2010.
- Reach sales growth in the regional markets in line with those markets' growth rates.
- Generate the funds needed to develop antibodies for therapeutical use.
- Obtain GMP certification for antibody production by end of 2012.
- Make sales to international buyers no later than beginning of 2013.

4.0 GROWTH STRATEGY

MonoJo will position itself as a reliable and flexible producer offering high quality diagnostic monoclonal antibodies to customers in Jordan, the Middle East region and international markets at competitive prices. The company will target local and regional hospitals and clinical labs as well as regional international research institutions and larger biotech or pharmaceutical companies.

Based on discussions with the Company's management and the results of the situation analysis, we believe that MonoJo's best option is to pursue a diversification strategy, whereby the Company will develop new products and extend to new markets. MonoJo cannot rely only on the Jordanian market to sell its products, because, in the long term, the local market will prove to be too small to be profitable, and therefore, MonoJo will need to look for other markets with significant potential for growth, starting from the regional ones with highest potential - such as the Saudi and Egyptian - and later moving into international markets. Also, because the industry is strongly driven by innovation, developing new products, new product attributes or new applications for existing products will be the only way to compete with the major players in the market.

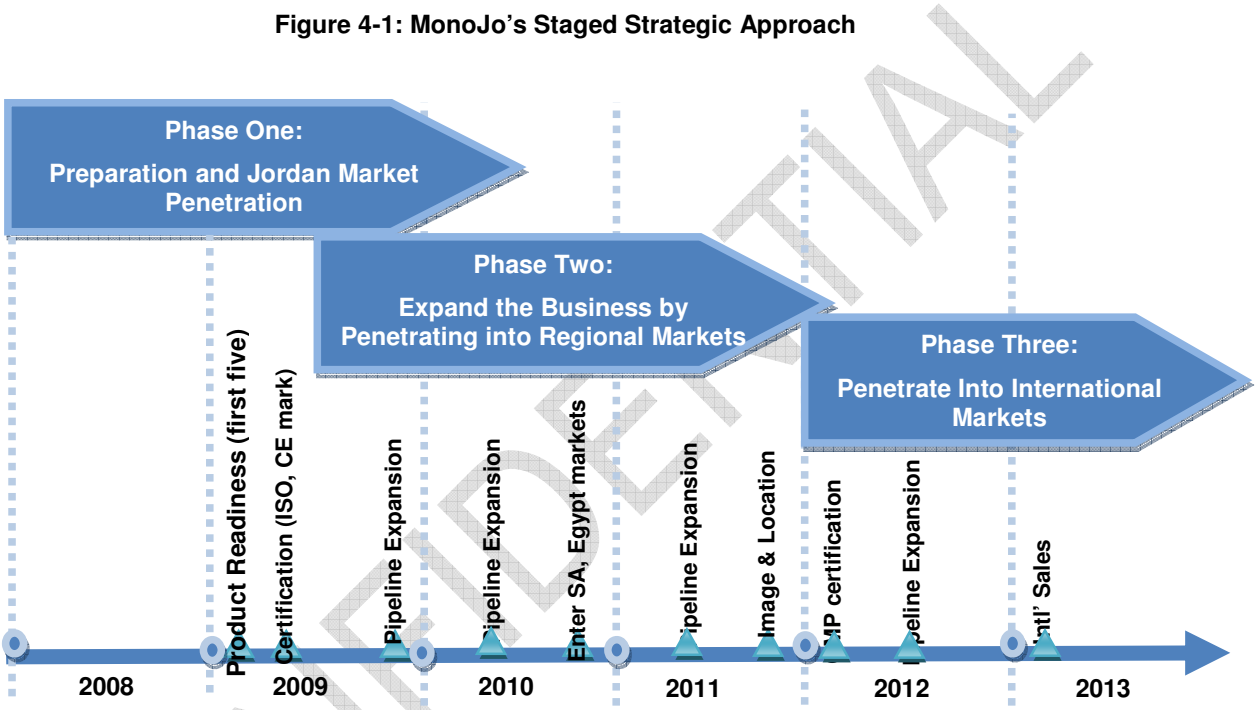
The Company can only achieve sustainable long-term growth if it can diversify its pipeline to balance its product portfolio across several therapy areas, leverage its assets (e.g. cost/price) and skills (e.g. sales and marketing), acquire and allocate resources efficiently across products and departments and functions (e.g. R&D, marketing), and adjust to a changing market environment by constantly benchmarking its products against future industry factors and market environment. As part of its product strategy, we recommend that MonoJo diversifies its product portfolio to include - in addition to the cancer diagnostics line - also new indications or therapeutic areas that look promising for the future (e.g. AIID or a niche area), particularly in the MENA region.

The Company should ensure that product packaging and labeling is in line with industry standards and requirements. At the same time, MonoJo should ensure that the product packaging and labeling is aligned with its brand identity and consistency is maintained across all its communicational and promotional materials and tools.

Also as part of its diversification strategy, MonoJo should establish a strategic business unit, which would operate as the commercial arm of the business, possibly under a different name. MonoJo should manufacture or assemble diagnostic products under license from foreign partners and distribute them – through the commercial unit - in the local and regional diagnostics markets. This will provide good financial resources to sustain the in-house product development process. At a later stage, the Company should start various commercial collaboration alternatives such as in-licensing products, co-marketing (for regional distribution of international products), etc.

The diversification strategy will follow a three-stage path starting from penetrating into the Jordanian market, expanding into regional markets and then moving into international markets. The process is illustrated in the following figure (4-1):

Figure 4-1: MonoJo's Staged Strategic Approach



Phase One: Preparation and Jordan market penetration

In this phase, the focus will be on building its capabilities and capacity to be able to enter the Jordanian market by focusing on product differentiation. MonoJo will position itself as a local producer of diagnostics antibodies that provides high quality products, customer service and flexibility in providing the product attributes that customers require. MonoJo will offer the diagnostic antibodies to local hospitals, and clinical labs at competitive prices.

The preparatory part is very important. In order to compete in the Jordanian market and to attract the customers of its competitors, MonoJo will have to build its necessary internal capabilities and capacity: it will have to obtain the necessary quality certifications, make solid progress in improving and managing the quality of its products, build brand identity, diversify its product pipeline and develop the resources necessary for sustainable research and product development activities.

- Improve the quality of the products and company image through obtaining the relevant ISO certifications (9001:2000 and 13845:2003) and the CE mark and by introducing effective quality management systems to be able to tender for local public sector purchasing contracts.
- Accelerate product research and development and diversify product pipeline, by gaining access to new technology through establishing collaborations with international biotech companies and researchers.

- Create brand identify and build brand awareness among all potential customer segments.
- Provide the most competitive pricing in the domestic market, by applying scientific product costing system and a cost-plus approach in calculating the price, while keeping in mind what customers are willing to pay and what competitors are offering.
- Strengthen relationships with local customers to gain their loyalty through well-planned awareness and promotional campaigns, and raise company's profile among local institutional buyers.
- Work closely with customers to understand what they need in order to provide better products and services and develop products or offers targeting particular uses.
- Apply for tenders and negotiate to ensure long-term contracts with institutional buyers.
- Develop the sales department capabilities to use direct selling to customers in the local market.
- Provide customers with just-in-time delivery, by building in-house storing capacities, adequate to cater for local demand.
- Promote the company in Government circles, and ask for financial support, as part of the Government's national policy to promote and support science and technology in Jordan, R&D activities and the biotechnology industry in Jordan.
- Build partnerships with those in the academia (in Jordan and beyond) to complement the in-house research activities.
- Build alliances with local and international firms for product development, technology licensing, and product distribution in regional markets.
- Establish a new business unit that will be dedicated to marketing and sales operations in the local and regional markets. The unit will act as the trade body or arm of MonoJo and it could operate under different name.

Phase Two: Business growth through expanding into regional markets

In order to overcome the limited growth opportunities afforded by the relatively small size of the domestic market, and to ensure the company's growth, MonoJo should expand to regional markets with highest potential such as Saudi Arabia and Egypt. This phase will begin during 2009, once the company has obtained the necessary certification and in parallel with the development and introduction of new products into the local market. Following are tactical strategies for expanding into regional markets:

- Invest in new product development within the antibody diagnostics segment, to diversify the product pipeline.
- Improve R&D, marketing, HR capabilities and financial resources to be able to expand into the bio-generics business.
- Adapt the product development plan to match the market need in terms of types of monoclonal diagnostic products.
- Identify key potential distribution partners, including building partnerships with local pharma companies with strong regional presence in the target markets, in order the leverage their distribution channels.
- Conduct promotional campaigns in the target markets.
- As pricing is probably the second most important variable in purchasing decisions, MonoJo will price its products at a cost-plus pricing, while considering the prices that customers in the target market are ready to pay and what buyers are offering.
- Participate in regional exhibitions such as Arab Health and Arab Lab.

- Conduct extensive market research in each target country to understand the market access requirements and market structure.
- Develop the website to e-commerce level and build the related resources needed to be able to do worldwide e-transactions.

Phase Three: Penetrate into international markets

Expanding into international markets entitles increased efforts and risks. We believe that the best entry strategy in international markets for MonoJo is to provide research quality customized antibodies at competitive prices, targeting US and European medical research market (research centers, scientists) and commercial biopharma companies. To succeed in the international market, MonoJo will adopt a strategy of targeting potential partners for alliances on collaborative research and product development, technology licensing and marketing arrangements[12].

At a later stage, MonoJo should pursue strategic alliances to leverage the resources and capabilities of potential partners for the development of bio-generics and for their marketing in international markets.

This phase should also include relocation of R&D and production to new and modern facilities - not only to accommodate for the physical expansion of production capacity, but also to upgrade the company's image to customers and partners. The physical aspect of the company and its location is as important as the promotional and communication materials and tools to conveying a positive image to customers, partners and suppliers.

Following are tactical strategies for penetrating into international markets:

- Pursue alliances and joint venture partnerships with foreign biopharma companies and research centres.
- Form partnerships with local pharma manufacturers which are interested in expanding into the biotech business and have presence in foreign markets.
- Improve R&D spending and efficiency.
- Build production capacity.
- Become Good Manufacturing Practices (GMP) certified by the USFDA and EMEA (this should be an important strategic matter pursued by MonoJo if intends to enhance its long-term competitive position and promote itself as a qualified partner to be considered for research and production partnerships or other forms of cooperation with foreign biotech and pharmaceutical companies)
- Move into therapeutic antibodies as an early-stage antibody drug developer company.
- Pursue alliances and joint ventures with international biotech companies.
- Participate in international exhibitions such as the Medica Expo in Germany.
- Develop export plans to Europe and the United States to find the best market entry strategies.

[12] During our research, we came across numerous announcements of biotech companies that have established collaboration partnerships for the purpose of research, product development, technology licensing and marketing. for example, BD Ventures – the $million venture capital fund owned by Becton Dickinson and Company seeks early-stage investment opportunities from companies that match the strategic interests of BD. Similarly, BioGenex has announced that it is interested to partner with firs that have the infrastructure to accelerate the commercialization of the company's in-house research efforts.

ANNEXES

ANNEX 1: BIOTECH INDUSTRY STATISTICS

Global	Amount	Units	Year	Source
Public & Private Biotech Companies	4,275	Companies	2006	E&Y
Public Biotech Companies	710	Companies	2006	E&Y
Revenues	73.5	Bil. US$	2006	E&Y
Increase from 2005	14	%	2006	E&Y
R&D Expenses	27.8	Bil. US$	2006	E&Y
Net Income	-5.4	Bil. US$	2006	E&Y
Number of Employees	190.5	Thousand	2006	E&Y
Total Pharmaceutical Sales, Worldwide	643.0	Bil. US$	2006	IMS
Total R&D Expenses, PhRMA Member Companies	43.0	Bil. US$	2006	PhRMA
Total R&D Expenses, All Pharmaceutical Companies	55.2	Bil. US$	2006	Burrill
U.S.				
Public & Private Biotech Companies	1,452	Companies	2006	E&Y
Public Biotech Companies	336	Companies	2006	E&Y
Revenues	55.5	Bil. US$	2006	E&Y
R&D Expenses	22.9	Bil. US$	2006	E&Y
Net Income	-3.5	Bil. US$	2006	E&Y
Number of Employees	130.6	Thousand	2006	E&Y
Total Biotech Company Financing	20.3	Bil. US$	2006	E&Y
Pharmaceutical Sales1, Domestic	174.7	Bil. US$	2006	PhRMA
% Generic (by volume)	58	%	2007	PhRMA
Pharmaceutical Sales1, Foreign2	71.1	Bil. US$	2006	PhRMA
Branded Biotech Drug Sales, U.S.	40.3	Bil. US$	2006	IMS
Prescriptions Filled, U.S., 12 month period ending Sept.	3.6	Bil.	2005	PhRMA
Total Pharmaceutical Company Spending on R&D[1]	43.0	Bil. US$	2006	PhRMA
as a Percentage of All Sales1	16.9	%	2005	PhRMA
Share of R&D Spending by Function:				
Prehuman/Preclinical	25.7	%	2005	PhRMA
Phase I	5.8	%	2005	PhRMA
Phase II	11.7	%	2005	PhRMA
Phase III	25.5	%	2005	PhRMA
Approval	6.9	%	2005	PhRMA
Phase IV	13.3	%	2005	PhRMA
Uncategorized	11.0	%	2005	PhRMA
Average Time Required for Clinical Trials, from Discovery through Phase IV	16	Years	2007	PhRMA
Average Cost of Developing a Biologic Drug	1.2	Bil. US$	2005	Tufts
Number of FDA Approvals for New Drugs (NDAs)	101	Approvals	2006	FDA
Number of Approvals for New Molecular Entities (NMEs)	22	Approvals	2006	FDA
Patents Granted for "Multicellular Living Organisms and Unmodified Parts Thereof" Since 1970	5,644	Patents	2005	USPTO
Total Requested Proposed for Biological Science Research, U.S. National Science Foundation	633.0	Mil. US$	2008	NSF
Average Annual Salary for Biochemists & Biophysicists	80,900	US$	May-06	BLS

[1] PhRMA Member Companies. [2] Not including foreign divisions of foreign companies.

E&Y = Ernst & Young; PhRMA = Pharmaceutical Research and Manufacturers Association; Burrill = Burrill & Company; IMS = IMS Health; Tufts = Tufts Center for the Study of Drug Development; FDA = U.S. Food & Drug Administration; USPTO = U.S. Patent & Trademark Office; NSF = U.S. National Science Foundation; BLS = U.S. Bureau of Labor Statistics

Source: Plunkett Research, Ltd

ANNEX 2: THERAPEUTIC MONOCLONAL ANTIBODIES APPROVED FOR MARKETING BY THE US FDA AND THE EUROPEAN REGULATORY AGENCIES

Trade name	Company	Initial disease approval	Approval date	Additional disease approval	Approval date
Orthoclone OKT3®	**Johnson & Johnson (J&J)** (Raritan, NJ)	Acute kidney transplant rejection	1986	Heart and liver transplant rejection	1993
ReoPro®	**Centocor** (Horsham, PA)	Stroke, acute ischemic stroke	1994	Refractory unstable angina	1997
Panorex® (Germany only)	**GlaxoSmithKline** (Middlesex, U.K.), **Centocor** (Malvern, PA)	Colon cancer	1995	None	—
Rituxan®	**Genentech** (South San Francisco, CA)	Advanced treatments for non-Hodgkin's lymphoma (NHL)	1997	Moderate-to-severe rheumatoid arthritis	2006
				In association with chemotherapy for diffuse large B-cell NHL	2006
Zanapax®	**Roche** (Nutley, NJ)	Relapsing-remitting and secondary-progressive multiple sclerosis (MS) not responsive to other therapies	1997	None	—
Simulect®	**Novartis** (Basel, Switzerland)	Acute organ rejection in patients receiving renal transplantation	1998	None	—
Synagis®	**MedImmune** (Gaithersburg, MD)	Respiratory syncytial virus	1998	None	—
Remicade®	**Centocor** (Malvern, PA)	Crohn's disease	1998	Rheumatoid arthritis	1999
				Inflammatory bowel disease (IBD)	2003
				Ankylosing spondylitis (AS)	2004
				Psoriatic arthritis	2006
Herceptin®	**Genentech**	Breast cancer, possibly other cancers	1998	Early-stage Her2-positive breast cancer	2006
Campath-1H®	**Genzyme** (Cambridge, MA)	B-cell chronic lymphocytic leukemia (B-CLL)	2001	None	—
Mylotarg®	**Wyeth Pharmaceuticals** (Collegeville, PA)	Bone marrow cancer (CD33 positive acute myeloid leukemia)	2002	None	—
Zevalin™	**Biogen Idec** (Cambridge, MA)	Relapsed or refractory low-grade, follicular, or transformed B-cell NHL	2002	None	—
Humira™	**Abbott** (Abbott Park, IL)	Moderate to severe rheumatoid arthritis	2002	Psoriatic arthritis	2005
				Crohn's disease	2007
Xolair™	**Genentech**	Asthma	2003	None	—
Bexxar®	**Corixa** (Seattle, WA)	First-line therapy for low-grade NHL	2003	None	—
Raptiva™	**Genentech**	Chronic moderate to severe plaque psoriasis	2003	None	—
Erbitux™	**ImClone** (New York, NY)	Advanced colorectal cancer	2004	Head and neck cancer	2006
Avastin™	**Genentech**	Metastatic colorectal cancer	2004	Advanced lung cancer	2007
Tysabri®	**Biogen Idec, Elan** (Dublin, Ireland)	Relapsing form of MS	2004, 2006*	None	—
Lucentis™	**Genentech** and **Novartis**	Wet form of AMD (age-related macular degeneration)	2006	None	—
Vectibix™	**Amgen** (Thousand Oaks, CA)	Colorectal cancer	2006	None	—
Soliris™ (eculizumab)	**Alexion** (Cheshire, CT)	Paroxysmal nocturnal hemoglobinuria (PNH)			

*Market reintroduction following withdrawal in 2005.

Source: the American Biotechnology Laboratory

ANNEX 3: HIGH-COST CANCER DRUGS LIKELY TO BE APPROVED BY THE US FDA AND THE EMEA, 2007-2010

Small molecules	Monoclonal antibodies
Sorafenib	Bevacizumab
Sunitinib	Pertuzumab
Axitinib	Nimotuzomab
Lapatinib	Galiximab
Tipifarnib	Catumaxomab
Cediranib	Eculizamab
Erlotinib	Tositumomab
Gefitinib	Nimotuzumab
Imatinib	Alemtuzumab
Ipsinemib	Apomab
Motesanib	Volociximab
Vandetanib	Panitumomab
Bosutinib	Adecatumumab
Lestaurtinib	Lexatumumab
Nilotinib	Lumiliximab
Fulotinib	Ipilimumab
Brivanib	
Dasatinib	
Pazopanib	
Everolimus	
Selicilib	

ANNEX 4: RECOMMENDED WEB RESOURCES FOR INFORMATION FOR THE BIOTECH INDUSTRY:

1. GEN, the Genetic Engineering & Biotechnology News - one of the largest biotech resource website, with links to hundreds of biotechnology industry sources such as international biotech associations, trade associations research resources, regulatory links etc: http://www.genengnews.com/weblinks.aspx

2. Advanced Medical Technology Association: http://www.advamed.org/MemberPortal/Membership/member_company_listing.htm

3. Global Medical Technology Network Worldwide - Cooperative Medical Device Associations: http://www.advamed.org/MemberPortal/Issues/International/globalorg.htm

4. European Medical Manufacturing Suppliers Directory: In Vitro Diagnostics: Monoclonal antibodies: http://www.devicelink.com/company/emdm/category/In_Vitro_Diagnostics/Monoclonal_antibodies.index.html

5. A database of all USFDA cleared/approved 510(k) IVD products is available for search at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

6. Search for 510 (k) approved devices in US FDA classification database: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm

7. The Antibody Resource Website: http://www.antibodyresource.com/

ANNEX 5: EXAMPLE OF STRATEGIC ALLIANCES AND BUSINESS PARTNERSHIPS IN THE BIOPHARMA INDUSTRY

Millennium is a biopharmaceutical company with strategic alliances and business partnerships with some of the world's leading pharmaceutical and biotechnology firms. The relationships range from disease-oriented therapeutic collaborations and technology-transfer arrangements, to marketing and licensing agreements.

THE COMPANY'S KEY ALLIANCES, PAST AND PRESENT

Year	Collaborator	Alliance Type	Therapeutic Area/ Molecule
2006	Ortho Biotech, Inc.	Co-promotion	VELCADE® (bortezomib) for Injection
2004	GlaxoSmithKline	Marketing	INTEGRILIN® (eptifibatide) Injection
2003	Ortho Biotech Products, LP	Marketing	VELCADE® (bortezomib) for Injection
2001	Abbott Laboratories	50/50 disease-focused, technology exchange and development	Metabolic diseases, technology
2001	Schering-Plough Corporation	Marketing	INTEGRILIN® (eptifibatide) Injection
2000	Roche Diagnostics	Disease-focused	Rheumatoid arthritis diagnostics
2000	Becton Dickinson	Disease-focused	Colon cancer diagnostics
2000	Aventis Pharma	50/50* disease-focused, technology transfer and technology development	Inflammation, technology
2000	Taisho Pharmaceutical	Product development	MLN977 for asthma
1999	Schering AG/Berlex Laboratories	Product distribution	Campath® (alemtuzumab)– monoclonal antibody
1999	Bristol-Myers Squibb	Disease-focused	Cancer pharmacogenomics
1999	Becton Dickinson	Disease-focused	Cancer diagnostics
1998	Bayer	Disease-focused	Cardiovascular diseases, cancer, pain, blood diseases and viral infections
1997	Monsanto	Technology transfer	Agriculture
1997	Genentech	Product development	MLN02
1996	American Home Products	Disease-focused	Bacterial diseases
1996	ILEX Products, Inc.	Product development	Campath– monoclonal antibody
1996	Roche Bioscience	Target-specific discovery	CCR3 chemokine receptor
1996	American Home Products	Disease-focused and technology transfer	Central nervous system diseases, technology
1996	Eli Lilly	Disease-focused	Cancer
1995	Aventis	Target-specific discovery	NF-KB Inflammation
1995	Eli Lilly	Disease-focused and technology transfer	Cardiovascular diseases, technology

ANNEX 6: THE US CODE OF FEDERAL REGULATIONS, TITLE 21, VOL. 8, REVISED AS OF APRIL 1, 2007

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 809

IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

Authority: 21 U.S.C. 331, 351, 352, 355, 360b, 360c, 360d, 360h, 360i, 360j, 371, 372, 374, 381.

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER H--MEDICAL DEVICES

PART 814

PREMARKET APPROVAL OF MEDICAL DEVICES

Subpart D--Administrative Review [Reserved]

Subparts F-G [Reserved]

ANNEX 7: PRODUCTION AREA STANDARD OPERATING PROCEDURES

#	Name of SOP	Objectives
1	Personnel self preparation and cleanliness before entering the production area	This SOP describes the procedures to be followed by all production personnel for self preparation and cleanliness.
2	End of day procedure	This SOP describes the procedures to be followed by the technical supervisor to do a final check ensuring that everything is set in order prior to leaving the laboratory
3	Daily production planning procedure	It describes the daily distribution of roles and duties to the technical team taking into account the achieved level of activities that took place in the previous day
4	Equipment calibration procedure	This SOP describes the needed procedures to ensure proper calibration of all equipments to ensure accurate results of data obtained for the experiments
5	Protocols for running new equipment	This SOP describes the instructions and procedures to use the equipment or run the experiments.
6	Checking room surroundings for sterile area	This SOP describes the procedures to be conducted to maintain the sterility of the sterile area to prevent any possible contamination
7	CO2 incubator operating procedure	This SOP describes the sequential steps of properly and safely operating the CO2 incubators available in the firm
8	Disposal of rejected finished products	This SOP outlines the steps to be followed for proper handling of rejected finished products taking into consideration the reason behind rejection.
9	Processing non conformities (contingency plan)	This SOP describes the actions to be conducted by the technical team for any nonconformance that may take place in the laboratory whether related to equipments, materials, experiments.
10	Coding raw materials, packaging materials	This SOP describes the instructions on how to code all materials (raw, packaging) used as per the set categories and classifications
11	Inventory handling procedure	This SOP describes the procedures for material picking, usage, reordering, and storing new procured materials
12	Water treatment system (RO system)	This SOP is developed to ensure that water used for the preparation of each product is of adequate quality and complies to specifications.

13	Filing of experiments testing results	This SOP describes the proper recording and filing of experiments testing results along with data interpretation and lessons learned
14	Autoclave operation, performance and validation	This SOP describes the sterilization procedure by autoclaving
15	Cleaning production area	This SOP describes the procedures to be followed in properly cleaning the production area
16	Fermenter operating procedure	This SOP describes the sequential procedure of properly and safely operating the two available fermenters in the firm
17	Laminar flow operating procedure	This SOP describes the sequential steps of properly and safely operating the laminar flow available in the firm.
18	Finished product quarantine and release	This SOP aims at ensuring that no intermix takes place under any circumstances between QC approved batches and those just released from the production department waiting for QC approval.
19	Waste product disposal	This SOP establishes compliance of the company with environment friendly practices.
20	Disposal of rejected finished products	This SOP outlines the steps to be followed for proper handling of rejected finished products taking into consideration the reason behind rejection.

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