



# SASB Standard for Biotechnology

## Example of Integrated Disclosure in Form 10-K

July 30, 2014

The information, text, and graphics in this publication (the "Content") is owned by Sustainability Accounting Standards Board. All rights reserved. You may use the Content only for non-commercial and scholarly use, provided that you keep intact all copyright and other proprietary notices related to the Content, and that you make no modifications to the Content. The Content may not be otherwise disseminated, distributed, republished, reproduced, or modified without the prior written permission of Sustainability Accounting Standards Board. To request permission, please contact us at [info@sasb.org](mailto:info@sasb.org).

## Introduction

The following is a mock excerpt from a Form 10-K for a biotechnology company, "Bay-DNA Inc.", that incorporates disclosure to the SASB Standard for Biotechnology into its Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A). This document serves as an example of one type of disclosure SASB envisions for its standards; it is not intended to provide a template for companies to follow. This is a working document on which SASB is actively soliciting feedback on the content, scope, and presentation format of disclosure to SASB Standards. Comments can be made via: [www.sasb.org/helpdesk](http://www.sasb.org/helpdesk)

---

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## Form 10-K

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2012

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

Commission file number 000-12477

### **Bay-DNA Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**One Bay-DNA Loop,  
Menlo Park, California**

(Address of principal executive offices)

**99-999999**

(I.R.S. Employer  
Identification No.)

**94025-1111**

(Zip Code)

...

## **Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

### **Sustainability Performance**

#### *Overview*

The Board of Directors has delegated to the Integrated Sustainability Review Committee matters relating to corporate governance and responsibility for promoting sustainable management of the Company's activities. The Committee reviews internal compliance with sustainability codes and principles across all business units, supervises compliance with environmental, health and safety matters, conducts scenario planning for impacts related to environmental and social trends and uncertainties, and assists the Board of Directors in determining material sustainability issues for disclosure herein.

The Company conducted an assessment to determine sustainability-related risks and opportunities it faces using the Sustainability Accounting Standards Board's (SASB) Sustainability Accounting Standard – Biotechnology (HC0101). We determined that all disclosure topics identified by SASB represent trends and uncertainties that may

have material impacts on the financial condition or operational performance of the Company. The following is a discussion and disclosure of our performance on 11 sustainability topics. For ease of interpretation Table 1, below, summarizes all quantitative metrics presented throughout this section.

### *Access to Medicines*

Improving access to medicines is a priority of the Company. The Company engages in a number of activities to increase access to its products, while taking a strategic approach that incorporates tiered pricing scheme based on level of economic development and health care needs in markets where our products are sold.

#### **Initiatives to promote access to healthcare products in priority countries as defined by the Access to Medicine Index**

The Company began a \$16 million global outreach program in 2011 to provide product donations and financial support to nonprofits helping patients in priority countries access treatments for various priority diseases, focusing primarily on HIV/AIDS, diarrheal disease, and tuberculosis, which are designated “Priority Diseases” according to the Access to Medicine Index. In 2012 we expanded our outreach program budget to \$23 million and began offering use of patented compounds to research institutions focusing on HIV/AIDS. We made a commitment to respect the right of the priority countries to use the TRIPS (trade-related aspects of intellectual property rights) flexibilities in-line with the Doha Declaration on the TRIPS Agreement and Public Health. The Company received a #4 ranking in the Access to Medicine Index in 2012. These strategic initiatives create opportunities for revenue growth and marketing, distribution, and sales partnerships. The Company will continue its initiatives to improve access to our products in priority countries.

#### **Products on the WHO List of Prequalified Medicinal Products**

We currently have eight (8) World Health Organization Prequalified Medicinal Products (PMPs) having received approval for one (1) additional drug, Stavudine, this year. Our WHO PMPs, all of which target HIV, are: Stavudine, Aciclovir, Ciprofloxacin, Diazepam, Efavirenz, Nevirapine, Lopinavir + Zidovudine, and Ritonavir. These WHO PMPs facilitate entry into developing nations, which present large potential sales growth, product innovation, and profit opportunities. We recently finalized an agreement with the largest health care delivery system in sub-Saharan Africa, and we anticipate that the resulting sales pipeline will contribute to our revenues for several years. We hope to increase our number of WHO PMPs.

Metric	Year Ended December 31,		
	2010	2011	2012
Number of WHO Prequalified Medicinal Products	5	7	8

### *Drug Safety & Side Effects*

The safety of our products at all stages – from clinical trials to the administration and use and through to safe disposal – is a key area of attention for the Company. We acknowledge, however, that there are inherent risks associated with the use of drug products. We attempt to minimize these through stringent adherence to quality control procedures and proactive recall processes whenever a safety concern is identified.

#### **Products in MedWatch’s Safety Alerts for Human Medical Products database**

One (1) product, Dalamide, was listed in MedWatch’s Safety Alerts for Human Medical Products database. No products are identified as having *potential safety issues* according to the FDA’s review of FAERS. The FDA has warned that Dalamide can cause viral infections and has approved changes to the labels of this drug to include this concern. The FDA is continuing to evaluate Dalamide to determine if the updated labeling is adequate. The Company has found that the listing of even one product in the MedWatch database can have a material adverse effect on consumer confidence and sales, cash flows, and profits. During 2012, the Company successfully addressed

concerns with another product, Zermcan, and this product is no longer listed in MedWatch. The Company intends to monitor products listed in the MedWatch database and those identified by the FDA as having potential safety issues and promptly address any safety issues with such products.

Metric	Year Ended December 31,		
	2010	2011	2012
Number of products in MedWatch's Safety Alerts for Human Medical Products database	3	2	1

#### Fatalities associated with products

No fatalities were associated with our products during 2012. Our experience shows any number of fatalities associated with our products can create litigation, liability, and negative revenue and reputational consequences. Because many of our products treat life threatening conditions, we expect that a certain number of fatalities will occur from time to time. The number of fatalities is connected to the effectiveness of our risk management procedures, drug labeling, and conversations with physicians about our products. We plan to monitor and investigate any fatalities associated with our products and minimize the number of fatalities in the future.

Metric	Year Ended December 31,		
	2010	2011	2012
Fatalities associated with the Company's products	1	1	0

#### Recalls and market withdrawals

We voluntarily issued a Class II recall for all unexpired lots of one (1) product, Gamorelin, due to quality control concerns identified by an FDA inspection of our San Diego, CA manufacturing facility. The recall resulted in a 30% decrease in sales of the product during 2012 and could affect our market share in the anti-heartburn market. Recalls and market withdrawals have a material adverse effect on cash flow, fines and settlement costs, and litigation. Consumer confidence in our products could be weakened, harming our ability to create value. We are committed to returning this important product to the market as quickly as possible, once the quality control issues are resolved. We intend to issue voluntary recalls and withdrawals in a timely manner when warranted by safety and quality concerns.

Metric	Year Ended December 31,		
	2010	2011	2012
Recalls and market withdrawals	3	1	1

#### Product stewardship initiatives for product end-of-life management

Expired, unused, and excess drugs products – including our own – may be sold on the black-market, abused, accidentally ingested, or released into the environment. In 2010, the Company formed a committee to explore possible take-back programs to manage these potential impacts associated with end-of-life management of our products. In May of 2012, we announced that we will support and participate in product take-back and disposal programs in communities where current, viable infrastructure exists. The budget allocated for these activities and amount of product reclaimed through these efforts will be determined by 2014. Effective product stewardship can reduce future liabilities and strengthen our brand reputation. As our product pipeline grows, the financial impact of our product end-of-life management will increase. The Company expects to maintain its commitment to supporting and executing effective take-back programs.

## *Safety of Clinical Trial Participants*

Safe clinical trials play a crucial role in the development of new products and the Company's continuing prosperity. The Company takes numerous steps to maximize the safety of its clinical trial participants.

### **Management process for clinical trials**

The health of patients in clinical trials is priority for the Company and we are committed to conducting clinical trials in all world regions – including those in developing countries in Central and Latin America, Africa, and Asia – according to uniformly high ethical standards. Furthermore, the Company aims to apply its standards to trials it has sponsored and conducts as well as those conducted on our behalf by clinical research organizations (CROs). The company conducts trials in accordance with the standards of the International Conference on Harmonization - Good Clinical Practices (ICH-GCP), the Council for International Organizations of Medical Public Policy Statement: Clinical Trial Ethics Sciences International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS, 2002), the Pharmaceutical Research and Manufacturers of America (PhRMA, 2009) Principles on Conduct of Clinical Trials, applicable local regulatory requirements and following the ethical principles that have their origin in the Declaration of Helsinki.

The Company requires that a three stage informed consent process be implemented in all trials to ensure that participants understand the risks and benefits of the procedures, how personal medical data is collected and used, and that participation in the trial is voluntary, among other information. The Company retains documentation that all participants in its trials or trials conducted on its behalf have provided informed consent.

The Company monitors clinical trials globally through audits and inspections conducted by the Company and by third-parties. These inspections verify that Company policies, GCPs, and applicable laws are being adhered to. During 2012 the Company or a third-party conducted an inspection at each of the 168 active studies we were conducting globally. One was terminated because the CRO conducting it failed to follow GCPs.

The Company's ability to ensure the safety of clinical trial participants is critical to securing regulatory approval and continued product development success. Further, the Company's inability to conduct safe and effective clinical trials could increase its cost of capital over time. The Company will continue to strengthen its oversight and management of clinical trials.

### **Voluntary Actions Indicated (VAI) and Official Actions Indicated (OAI)**

From time to time, during routine FDA inspection of the Company's clinical researchers the investigator will issue voluntary actions (VAI) and official actions (OAI). During 2012 we saw a decrease in OAI for the second consecutive year and a slight increase in VAI. These trends demonstrate the Company's commitment to proactively addressing VAI issued to clinical researchers we work with in our trial. An increase in the number of VAI or OAI could increase regulators' scrutiny of our clinical trials and increase the costs of conducting clinical trials. Through our clinical trial management process, we seek to understand and contain the occurrence of VAI and OAI.

Metric	Year Ended December 31,		
	2010	2011	2012
Voluntary Actions Indicated (VAI)	10	12	15
Official Actions Indicated (OAI)	12	9	5

### **Legal and regulatory fines and settlements in LICs and LMICs**

The Company paid a total of \$40 million in fines and settlements in 2012 due to administrative irregularities during the informed consent process for trials in Bangladesh and for underreporting of side-effects caused by a test drug in India. The Company might continue to incur fines and settlements in LICs and LMICs as it

expands into new markets and as the number of clinical trials in World Bank Low-income and Lowermiddle-income Countries (LIC and LMICs) grows. The trend towards more clinical trials in LICs and LMICs could have a material adverse effect on the Company's ability to successfully and cost effectively bring new products to market. The Company plans to take steps to improve the management of and training regarding clinical trials in LICs and LMICs. Creating an open and transparent process for clinical trials is a priority for the Company, particularly in LIC and LMICs. In 2012, we joined the Open Trials campaign, an initiative that promotes the registration of clinical trials and public disclosure of our design, methods and results of clinical trials, both positive and negative, minimizing safety and economic risks.

Metric	Year Ended December 31,		
	2010	2011	2012
Legal and regulatory fines and settlements (dollars in millions)	\$10	\$25	\$40

### *Affordability & Fair Pricing*

The Company is committed to discovering and developing innovative, cost-effective products that serve unmet medical needs. In addition, we allocate \$10 million each fiscal year toward sponsoring programs to address patient affordability and access barriers, as we strive to support and advance solutions for better health care. However, generic competition is one of the Company's leading challenges, and continues to affect our financial statements. See "Item 7. "Results of Operations" for further information.

#### **Settlements linked to Abbreviated New Drug (ANDA) litigation**

In 2012, generics manufacturers filed ANDAs seeking approval to market generic versions of one (1) product, OROGEN, the Company's once-daily treatment for type 2 diabetes. In settlements, PNP Labs and Trax-DNA received payments and agreed to delay the release of their generic versions of the drug for 18 months. These types of settlements help the Company maintain profit margins, but could cause the Company to forego large revenue opportunities from expanded access through generic versions. The Company will continue to balance external price containment pressures against the profit and revenue implications of expanding access to our drugs.

Metric	Year Ended December 31,		
	2010	2011	2012
Settlements linked to ANDA litigation	8	5	2

#### **Ratio of price increases to increases in Consumer Price Index**

The Company has achieved a 1:1 ratio of our price increases as compared to increases in the US CPI through reductions in manufacturing costs. This ratio affects sales, profits, and consumer perceptions of the Company's commitment to access to medicines. Whether the ratio can continue to be near 1:1 depends on the Company's ability to keep manufacturing costs proportionate to increases in the CPI. The Company will maintain the ratio at a level that permits us to continue to produce profits and maintain a healthy financial condition on an ongoing basis.

Metric	Year Ended December 31,		
	2010	2011	2012
Ratio of weighted average of net price increases to annual increase in U.S Consumer Price Index	1.18:1	1.15:1	1:1

### *Ethical Marketing*

The Company enforces its Policies on Business Conduct and Code of Ethics, which govern our employees, along with U.S. federal and state laws, and foreign laws pertaining to "fraud and abuse". We are committed to protecting the health and well-being of patients by ensuring that medically sound knowledge of the benefits and risks of our medicines is understood and communicated thoroughly and accurately to patients, physicians and global

health authorities. The Company is an industry leader in evolving our interactions with health care professionals and our approaches to U.S. direct-to-consumer advertising.

### **Fines, settlements associated with false marketing claims**

In 2012, the Company paid a \$12 million fine to settle allegations that we violated the False Claims Act by marketing Refrex, an anti-seizure drug, for off-label uses. In response we enhanced our marketing policy, removed perceived ambiguities in our marketing materials for the product, and retrained all sales representatives. Fines and settlements associated with false marketing claims have a material adverse effect on the Company's reputation, sales, and profits. Global expansion might increase the incidence of false marketing claims and the dollar amount associated with such claims. We will continue our efforts to contain fines and settlements associated with false marketing claims.

Metric	Year Ended December 31,		
	2010	2011	2012
Fines, settlements associated with false marketing claims (dollars in millions)	\$35	\$20	\$12

### **Code of ethics governing off-label promotion**

The Company's code of ethics has a section discussing off-label promotion, which it defines according to the FDA guidance. All staff receive training upon hire, and sales staff receive annual training. Furthermore, we attempt to proactively identify instances of off-label promotion of our products through routinely monitoring outgoing sales calls. We attempt to identify trends and patterns in off-label use of our products through anonymous surveys of physicians. Any case where the Company promotes off-label use of its products has the potential to have a material adverse effect on the Company's reputation, sales, and liabilities. The Company expects that consistent enforcement of, and training on, the code of ethics should help us limit the incidence of off-label promotion.

### *Employee Recruitment, Development, & Retention*

The Company's human capital helps it develop and commercialize new products, conduct clinical trials, and navigate government regulations. Our ability to recruit, develop, and retain highly skilled talent is a significant determinant of our success.

### **Recruitment and retention**

The Company began an \$8 million program to recruit and retain qualified scientists and technicians, which includes an internship program in partnership with global universities, mentorship programs, conferences and workshops for professional development, and leadership programs for employees with management potential. In response to intense competition for personnel from our competitors, we increased our budget for salaries and benefits by a total of \$58 million in 2012. The budget will be adjusted as warranted by conditions in the labor market and how the program affects recruitment and retention. Our ability to recruit and retain top talent affects all aspects of our results of operations and financial condition, and whether we can successfully execute and innovate our strategy. We believe that the program will have a positive impact on our ability to conceive and bring new products to market.

### **Training and development expenditure**

Because of rapid changes in the industry, the Company makes the training and development of its personnel a priority. Training and development programs keep our personnel at the cutting edge of scientific, clinical, and managerial knowledge. Furthermore, employee satisfaction surveys we conduct show a strong correlation between training and development and employee engagement, an indicator we believe affections retention of employees. We have increased our budget for professional qualifications to enhance the skills of our personnel in a highly competitive industry. Spending for other training has increased as the Company strengthens its

training in anti-bribery, anti-false claims marketing, clinical trial management, and risk management. The Company will evaluate and consider where it allocates training and development expenditures to optimize the use of its spending.

Metric	Year Ended December 31,		
	2010	2011	2012
Training and development expenditure, per FTE (dollars in thousands) – Professional qualifications and industry education	\$0.5	\$4	\$8.5
Training and development expenditure, per FTE (dollars in thousands) – Other training	\$0.5	\$1	\$1.5

### Employee Turnover

Employee turnover at all levels affects the Company's ability to execute on its strategic and operational plans, from new market entry, to safe clinical trials, to the commercialization of new products. A certain level of turnover is beneficial, as new talent can spur innovation and better execution. We set turnover goals by level and type of turnover (voluntary or involuntary). Patterns in turnover inform our recruitment and retention policies, as well as our training and development initiatives. Excessive turnover, especially involuntary turnover or turnover among Executive/Senior Managers and Professionals, can increase recruitment, development, and retention expenses and stifle product development and operational excellence. The Company will continue to monitor and manage employee turnover to balance the objectives of talent renewal and continuity.

Metric	Year Ended December 31,		
	2010	2011	2012
Executive/Senior Managers			
Voluntary turnover	4.1%	2.3%	1.7%
Involuntary turnover	1.0%	0.8%	0.9%
Mid-level Managers			
Voluntary turnover	8.2%	6.4%	9.1%
Involuntary turnover	2.3%	2.2%	3.9%
Professionals			
Voluntary turnover	11%	12.6%	9.8%
Involuntary turnover	3.4%	4.8%	2.1%
All Others			
Voluntary turnover	12.1%	13.3%	11.9%
Involuntary turnover	4.1%	2.9%	3.4%

### Employee Health & Safety Management

The Company has established processes to comply with governmental regulations regarding workplace safety. Hazardous materials, biological agents and byproducts, and radioactive material are inherent in our operations, and it is not possible to eliminate the risk of accidental exposure from our operations. Our success in providing a safe work environment can have an effect on costs of litigation, fines, penalties, and employee turnover. The increase in the Laboratory Acquired Infection Rate will be examined by our risk management committee, and appropriate changes in employee safety training and laboratory procedures will be considered. The Company will continue its efforts to ensure a high level of workplace safety.

Metric	Year Ended December 31,		
	2010	2011	2012
Total Injury Rate	5.2	4.4	2.1
DART Rate	3.5	2.5	1.2
Laboratory Acquired Infection Rate	No data available	0.5	1.1

## *Counterfeit Drugs*

Like many companies in the industry we have seen a rapid increase in the incidence and sophistication of counterfeit drugs operation in the past decade, and we are committed to creating processes to curb this trend. For example, in 2010 authorities from 50 countries seized almost 7 million tablets, capsules and vials of counterfeit versions of our drugs. Many of these raids were a result of leads from our Global Safety Enforcement Team. Counterfeit drugs in 2012 have led to a loss of \$50 million in revenue. See “Item 7. Results of Operations” for further information.

### **Traceability of products through supply chain**

The Company has put processes in place to address the problem of counterfeit medicines. In Pakistan, we implemented a “track and trace” technology, adding serial numbers to 40 products, which reduced the number of reports of counterfeit medicines. After this successful pilot, we are in the process of implementing similar initiatives globally. Additionally, we are evaluating the use of RFID tagging as well as several emerging technologies that enable advanced traceability. The growing contribution of the global supply chain to our operations could create the need to implement additional measures to trace products, which could result in significant increases in technology spending for several years. The Company will vigorously trace its products through the supply chain to mitigate against the effects on its brand and revenues.

### **Alert process for counterfeit products**

The Company works closely with the FDA in alerting the public when counterfeit drugs are identified. We issue press releases, as well as post additional information on our website, and numerous other public websites. A prompt and effective alert process will bolster consumer confidence in the safety and source of our branded products. We intend to remain vigilant in protecting consumers against dangerous counterfeit drugs.

### **Actions to alert authorities of counterfeit products**

A number of arrests and raids were made in 2012 in association with counterfeit versions of four (4) of our products: Orogen, Bipaxil, Litnovir, and Diazenil. These legal actions included the arrest of an owner of an online pharmacy in Canada, and raids in China and India resulting from leads from the Company’s Global Safety Enforcement Team. Counterfeit products have material negative effects on our brand, sales, and profits. As the Company’s expands its global operations, the Company plans to increase the number of personnel on its Global Safety Enforcement Team and to cooperate with law enforcement officials to reduce the volume of counterfeit products.

## *Energy, Water, and Waste Efficiency*

We are working to reduce the company’s resource consumption by identifying priority areas through lifecycle analyses of our best-selling products. By understanding our ecological impact, we hope to develop a strategy that will reduce our footprint and increase use of sustainable materials. Upon conclusion of these lifecycle analyses, we plan to set reduction targets and implement a strategy to achieve these targets. We anticipate that these actions will result in cost reductions in resource consumption, improved operational efficiencies in our manufacturing processes, and better hedging against likely increases in energy and water prices. We will continue to monitor the percentage of our water that comes from water stressed regions, as the highest increases in water prices tend to occur in water stressed regions. Opportunities for product innovation could emerge from improvements in energy, water, PMI, and waste efficiency.

## Energy, Water, Process Mass Intensity (PMI), and Waste

Metric	Year Ended December 31,		
	2010	2011	2012
<b>Energy</b>			
Usage (gigajoules)	10,097,298	15,240,371	18,701,473
Renewables (% of total)	n/a	5.1%	14.8%
<b>Water</b>			
Consumption (m <sup>3</sup> )	68,137	73,224	56,952
Percent of total from water stressed regions (% of total )	9.8%	15.3%	22.4%
Percent recycled (% of total)	0%	0%	3.8%
<b>Process Mass Intensity (PMI)</b>			
Overall PMI (kg input/kg output)	-	-	180 kg input / 1 kg API output
Solvent PMI (kg input/kg output)	-	-	90 kg input / 1 kg API output
Water PMI (kg input/kg output)	-	-	75 kg input / 1 kg API output
<b>Waste</b>			
Total generated (metrics tons)	-	102,000	115,000
Recycled (% of total)	-	10%	20%
Landfilled (% of total)	-	65%	50%
Incinerated/waste to energy (% of total)	-	25%	30%

### Corruption & Bribery

The Company's Policies on Business Conduct and Code of Ethics include clear guidelines on anti-bribery and anti-corruption practices. However, as we continue to expand our work around the world, we acknowledge that certain regions in which we operate pose a higher risk for corrupt practices. We have created a more robust training program on the U.S. Foreign Corrupt Practices Act and international anti-bribery laws for employees who conduct work in foreign countries.

### Fines and settlements associated with bribery, corruption, or other unethical practices

In 2012, the Company agreed to pay \$3 million to settle allegations that our subsidiary acted improperly in the marketing, promotion and sale of the anticonvulsant drug Dopaden. Extensive training on anti-bribery and anti-corruption policies was conducted and is ongoing among employees of that site, and across the company. These types of settlements have a material impact on the Company's profits, liabilities, and brand. The occurrence of unethical practices may become more frequent as the Company expands globally. The Company intends to continue its training programs on anti-bribery, anti-corruption, and other unethical practices to reduce the risk and size of fines and settlements.

Metric	Year Ended December 31,		
	2010	2011	2012
Fines and settlements associated with bribery, corruption, unethical practices (dollars in millions)	\$20	\$8	\$3

### **Code of ethics for interactions with healthcare professionals**

Bribing healthcare professionals to use or recommend the Company's products can create adverse publicity and damage the Company's ability to productively use a critical channel of influence. The Company has adopted and implemented PhRMA's Code on Interactions with Healthcare Professionals. The Company believes that training on, and enforcement of, the PhRMA's Code will limit the incidence of unethical interactions between Company personnel and healthcare professionals.

### *Manufacturing & Supply Chain Quality*

Our manufacturing and supply chain contributes to the successful execution of our corporate strategy. We are committed to operating a manufacturing and supply chain that protects consumer health and strengthens our ability to create value. The Company faces the potential for large fines, lost revenues from disruptions to manufacturing, higher cost of capital, and injury to consumers if we do not manage the quality of our manufacturing and supply chain. Global expansion creates new challenges to the effective management of the manufacturing and supply chain. We are in the process of implementing heightened processes and controls to maintain a high level of quality in our management system.

### **FDA enforcement actions for violations of cGMP**

During 2012 there were no incidents of FDA enforcement associated with current good manufacturing practices (cGMP) violations. The Company successfully addressed issues raised in an FDA Warning Letter about cGMP violations at our Texarkana, TX facility. FDA enforcement actions hurt the reputation and brand of the Company, result in liabilities, and adversely affect product quality and patient safety. The Company will continue to be vigilant in monitoring, reporting, and correcting any violations of cGMP.

### **Facilities and Tier 1 suppliers participating in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program**

The Company is committed to ensuring product quality and patient safety by using a secure global supply chain that delivers authentic, high quality, safe materials. In 2009, we became a founding member of Rx-360 to further this goal, and in 2011 we hosted a two-day Rx-360 conference to broaden membership throughout the industry. All of the Company's facilities and 98% its Tier 1 suppliers participate in the program. Two new Tier 1 suppliers aim to have Rx-360-compliant audits conducted by mid-2013. As the Company's supply chain expands in size and complexity, audits can bring potential product quality and patient safety issues to management's attention in a timely manner. Product quality and patient safety have material adverse effects on profits, liabilities, and the cost of capital. The Company plans to include future facilities and Tier 1 suppliers in the Rx-360 training program.

**Table 1. Summary of Quantitative Accounting Metrics**

Disclosure Topic	Metric	Year Ended December 31,		
		2010	2011	2012
Access to Medicines	Number of WHO Prequalified Medicinal Products	5	7	8
	Number of products in MedWatch	3	2	1
Drug Safety and Side Effects	Fatalities associated with the Company's products	1	1	0
	Recalls and market withdrawals	3	1	1
Safety of Clinical Trial Participants	Voluntary Actions Indicated (VAI)	10	12	15
	Official Actions Indicated (OAI)	12	9	5
	Fines and settlements in LICs and LMICs (dollars in millions)	\$10	\$25	\$40
Affordability & Fair Pricing	Settlements linked to ANDA litigation	8	5	2
	Ratio of price increases to increase in U.S Consumer Price Index	1.18:1	1.15:1	1:1
Ethical Marketing	Fines and settlements associated with false marketing claims (dollars in millions)	\$35	\$20	\$12
	Professional qualifications and industry education training and expenditure, per FTE (dollars in thousands) –	\$0.5	\$4	\$8.5
Employee Recruitment, Development, & Retention	Other training expenditure, per FTE (dollars in thousands)	\$0.5	\$1	\$1.5
	Executive/Senior Managers			
	Voluntary turnover	4.1%	2.3%	1.7%
	Involuntary turnover	1.0%	0.8%	0.9%
	Mid-level Managers			
	Voluntary turnover	8.2%	6.4%	9.1%
	Involuntary turnover	2.3%	2.2%	3.9%
	Professionals			
	Voluntary turnover	11%	12.6%	9.8%
	Involuntary turnover	3.4%	4.8%	2.1%
	All Others			
	Voluntary turnover	12.1%	13.3%	11.9%
Involuntary turnover	4.1%	2.9%	3.4%	
Employee Health & Safety Management	Total Injury Rate	5.2	4.4	2.1
	DART Rate	3.5	2.5	1.2

**Table 1. Summary of Quantitative Accounting Metrics**

Disclosure Topic	Metric	Year Ended December 31,		
		2010	2011	2012
	Laboratory Acquired Infection Rate	-	0.5	1.1
Energy, Water, and Waste Efficiency	<b>Energy</b>			
	Usage (gigajoules)	10,097,298	15,240,371	18,701,473
	Renewables (% of total)	n/a	5.1%	14.8%
	<b>Water</b>			
	Consumption (m <sup>3</sup> )	68,137	73,224	56,952
	Percent of total from water stressed regions (% of total )	9.8%	15.3%	22.4%
	Percent recycled (% of total)	0%	0%	3.8%
	<b>Process Mass Intensity (PMI)</b>			
	Overall PMI (kg input/kg output)	-	-	180 kg input / 1 kg API output
	Solvent PMI (kg input/kg output)	-	-	90 kg input / 1 kg API output
	Water PMI (kg input/kg output)	-	-	75 kg input / 1 kg API output
	<b>Waste</b>			
	Total generated (metrics tons)	-	102,000	115,000
	Recycled (% of total)	-	10%	20%
	Landfilled (% of total)	-	65%	50%
Incinerated/waste to energy (% of total)	-	25%	30%	
Corruption and Bribery	Fines and settlements associated with bribery, corruption, unethical practices (dollars in millions)	\$20	\$8	\$3
Manufacturing & Supply Chain Quality Management	Percentage of facilities participating in Rx-360	-	-	100%
	Percentage of Tier 1 suppliers participating in Rx-360	-	-	98%