SASB Standard for Biotechnology

Example of Integrated Disclosure in Form 10-K

July 30, 2013

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

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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	**99-999999**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One Bay-DNA Loop, Menlo Park, California	**94025-1111**
(Address of principal executive offices)	(Zip Code)

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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

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. 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.

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 are: Stavudine, Aciclovir, Ciprofloxacin, Diazepam, Efavirenz, Nevirapine, Lopinavir + Zidovudine, and Ritonavir.

	Year Ended December 31,		
Metric	**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, Dalomide, was listed in MedWatch's Safety Alerts for Human Medical Products database. The FDA has warned that Dalomide can cause viral infections and has approved changes to the labels of this drug to include this concern. The FDA is continuing to evaluate Dalomide to determine if the updated labeling is adequate.

	Year Ended December 31,		
Metric	**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.

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.

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

Product stewardship initiatives for product end-of-life management

In 2001, the Company formed a committee to explore possible take-back programs. In May of 2012, we announced that we will participate in product take-back programs in regions where current, viable infrastructure exists. The budget allocated for these activities and amount of product reclaimed through these efforts will be determined by 2014.

Safety of Clinical Trial Participants

The Company's success is tied to the success of our clinical trials. We are committed to ensuring the safety and legal rights of participants through a transparent process that adheres to FDA regulations and various other national and international protocols. However, we acknowledge that there are inherent risks associated with the use of drug products used in clinical trials. We attempt to minimize these through proactively monitoring the safety of participants in clinical trials for our products.

Management process for clinical trials

The health of patients in clinical trials is priority for the Company. With every clinical trial, we submit extensive regulatory commitments to various authorities, and committees, and we do not hesitate to terminate trials if there are safety concerns. For example, a $1.1 billion impairment charge was recognized when the development of BDNA-X4856, a compound that we acquired as part of our acquisition of Cellorvix to treat HIV/AIDS, was discontinued in the interest of patient safety. See "Item 1. Financial Statements —Note 4. Goodwill and Other Intangible Assets" for further information.

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

Though we ultimately determined the incident was isolated, after FDA Clinical Investigator Inspections identified objectionable conditions at our clinical study site in Texas in May of 2012, we took steps to improve our clinical trial processes. We strengthened our informed consent process and increased the frequency and quality of monitoring participants during trials.

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

Creating an open and transparent process for clinical trials is a priority for the Company, particularly in World Bank Low-income and Lowermiddle-income Countries (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. For example, 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.

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.

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.

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	4:1	3:1	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.

	Year Ended December 31,		
Metric	**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. 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 proactively identify instances of instances of off-label use of our products through anonymous surveys of physicians.

Employee Recruitment, Development, & Retention

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 $20 million in 2012.

Training and development expenditure

	Year Ended December 31,		
Metric	**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

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

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

The Company has seen a rapid increase in counterfeit drugs in the past several years, 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.

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.

Legal actions related to 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.

Energy, Water, and Waste Efficiency

We are working with an NGO (PharmaFootprints) to reduce the company's resource consumption by undergoing a lifecycle analysis. 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 our lifecycle analysis, we will be creating an official corporate sustainability strategy and hiring a Chief Sustainability Officer to lead these efforts.

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

Metric	Year Ended December 31, 2010	2011	2012
Energy			
Usage (gigajoules)	10,097,298	15,240,371	18,701,473
Renewables (% of total)	n/a	5.1%	14.8%
Water			
Consumption (m^3)	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%
Process Mass Intensity (PMI)			
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
Waste			
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.

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

The Company has adopted and implemented PhRMA's Code on Interactions with Healthcare Professionals.

Manufacturing & Supply Chain Quality

FDA enforcement actions for violations of cGMP

There were no incidents of FDA enforcement associated with current good manufacturing practices (cGMP) violations.

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 materials that we can trust. 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. 100% of the Company's facilities and its Tier 1 suppliers participate in the 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
Drug Safety and Side Effects	Number of products in MedWatch's Safety Alerts for Human Medical Products database	3	2	1
	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
	Legal and regulatory 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 weighted average of net price increases to annual increase in U.S Consumer Price Index	4:1	3:1	1:1
Ethical Marketing	Fines, settlements associated with false marketing claims (dollars in millions)	$35	$20	$12
Employee Recruitment, Development, & Retention	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
	Executive/Senior Managers			
	Voluntary turnover	4.1%	2.3%	1.7%
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Table 1. Summary of Quantitative Accounting Metrics

Disclosure Topic	Metric	Year Ended December 31, 2010	2011	2012
Employee Health & Safety Management	Total Injury Rate	5.2	4.4	2.1
	DART Rate	3.5	2.5	1.2
	Laboratory Acquired Infection Rate	-	0.5	1.1
Energy, Water, and Waste Efficiency	Energy			
	Usage (gigajoules)	10,097,298	15,240,371	18,701,473
	Renewables (% of total)	n/a	5.1%	14.8%
	Water			
	Consumption (m^3)	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%
	Process Mass Intensity (PMI)			
	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
	Waste			
	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	-	-	100%