Internal Control

The Board of Directors has a supervisory duty and the Executive Management the overall responsibility for Lundbeck’s risk management and internal controls in relation to the financial reporting process, including compliance with relevant legislation and additional disclosure requirements pertaining to financial reporting.

The purpose of the risk management process and the internal controls is effectively to identify, manage and mitigate the risk of errors in the financial reporting process and to provide reasonable assurance that material misstatement and errors in relation to the financial reporting process are mitigated. Furthermore, the purpose is also to support a complex commercial business, focusing on quality, effectiveness and strong ethics in everyday transactions and decisions.

The Board of Directors has set up an Audit Committee, which has an advisory role in relation to the Board of Directors, including on matters such as internal controls in the financial reporting procedures, financial and accounting issues, evaluation of financial reporting and other financial information and risk management. The Audit Committee gathers independent advice and insights from the external auditors, who are present at the Audit Committee meetings. The external auditors present their audit strategy and findings to the Audit Committee.

Control environment
The Board of Directors approves the overall risk management policies presented by the Executive Management. These policies are incorporated in the internal control and risk management system, which comprises a clearly defined organizational structure, including roles and responsibilities. Based on this structure, Lundbeck has drawn up manuals describing the principal business procedures, internal controls, requirements on the segregation of functions and duties, reconciliations, approval and authorization as well as accounting policies. The compliance with the guidelines is verified in an ongoing process.

Lundbeck has set up a central controlling function to check the financial reporting from all business areas, including compliance with the accounting policies. Each business area has been allocated a business controlling function which reviews the validity of reported earnings and underlying activities of each business area.

Supervision of internal controls and management
The Executive Management regularly assesses the risks that Lundbeck is exposed to, in relation to financial reporting. Any changes that could affect Lundbeck’s risk environment, Executive Management will review and consider appropriate mitigating actions together with the Board of Directors. The Audit Committee assesses whether the internal controls related to the financial reporting process are effective in relation to the risks identified.

Once a year, and as needed, the Audit Committee reviews the accounting policies and any changes thereto as well as critical estimates and judgments related to the financial reporting. As part of the review, the committee discusses changes in accounting policies and the impact of critical estimates and judgments with the Executive Management. The Audit Committee reports the findings of these assessments to the Board of Directors, which approves the financial reporting process and the findings of the assessment.
Control activities

There are several control activities performed within Lundbeck. The control activities are based on a risk assessment and continuous risk control processes are in place. The objective of the control activities is to ensure compliance with strategies, policies, manuals, procedures etc. established by the Board of Directors and the Executive Management and each business area, respectively, and Lundbeck aims to prevent, detect and correct any misstatement, discrepancy and error.

One key element of the control activity is the Internal Control Framework covering the key-risks for Lundbeck. The purpose of the framework is to ensure an acceptable level of assurance to mitigate the risks of unintentional and intentional errors and fraud. At the same time, one global framework brings standardized controls across all entities increasing efficiency of site visits and making rotation between entities easier.

The requirements have been defined in respect of analyses, key figures, monthly financial data, etc. in the financial information that forms the basis of internal and external financial statements. The business areas have established reporting procedures that are consistent with Lundbeck’s reporting process and the special operational issues of each business area. Supplementary information is gathered on an ongoing basis to ensure compliance with any requirements regarding notes, other disclosure requirements and operational analyses.

Within Group Finance, Lundbeck has established a Financial Compliance area comprising general compliance subjects and Enterprise Risk Management. The department performs financial compliance site reviews where the scope is based on a risk assessment and includes review of financial processes and internal controls focusing on the Internal Control Framework among other general financial compliance subjects. The defined compliance site review plan is approved annually by the Audit Committee.

Information and communication

Lundbeck has established information and communication systems which, among other things, set out the general financial reporting requirements and external financial reporting requirements in accordance with current legislation and applicable regulations, including the International Financial Reporting Standards as adopted by the EU.

As a result of the ongoing work with business procedures, internal controls and changing financial reporting regulation, Lundbeck regularly updates the contents of the systems and manuals in respect of business procedures, internal controls, and requirements on the segregation of functions and duties, reconciliations, approval and authorization and accounting policies. The manuals are accessible on Lundbeck’s intranet.

Monitoring

The risk assessment and control activities are monitored in an ongoing process. The process includes entity wide controls to ensure the monitoring of the financial results, which are compared to budgets and estimates, analytical controls, reconciliations and management approvals based on the Authorization and Signing Policy. Major weaknesses and non-compliance with the internal guidelines are reported to the Audit Committee, who monitor all issues.

As part of their audit of the financial statements, the external auditors elected at the annual general meeting, report on major weaknesses in Lundbeck’s internal controls in the long-form audit report to the Board of Directors, whilst less significant weaknesses are addressed in a management letter to the CFO.

The Board of Directors ensures that the Executive Management follows up on any outstanding issues, and the Executive Management ensures that the subsidiaries follow up on any weaknesses. Once a year, the subsidiary managers and financial controllers declare that their reporting information is consistent with Lundbeck’s guidelines. In connection with the financial reporting process, the Executive Management makes a separate statement that the consolidated reporting is consistent with Lundbeck’s guidelines and policies.
The risk assessment and control activities are monitored in an ongoing process. These are used by the management and the persons who have ownership of processes, risks and control procedures. The process includes a review of the financial results, which are compared to budgets and estimates. An analytical control and ongoing assessments are performed of key figures. Major weaknesses and non-compliance with internal guidelines are reported to the Executive Management, who follows up on any issues.

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