Risk Factors Comparison 2025-02-20 to 2024-02-22 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

Increasing attention to environmental, social and governance matters may impact our business, financial results, stock price or reputation. We face increasing scrutiny from stakeholders related to our environmental, social and governance ~~(ESG)~~ practices and disclosures ~~, including practices and disclosures related to climate change, diversity and inclusion and governance standards~~ . Investor advocacy groups, certain institutional investors, lenders, investment funds and other influential investors are also increasingly focused on ~~ESG~~ **such** practices and **related** disclosures and in recent years have placed increasing importance on the implications and social cost of their investments. In addition, government organizations are enhancing or advancing legal and regulatory requirements specific to ~~ESG~~ **these** matters. The heightened stakeholder focus on ~~ESG~~ **sustainability** issues related to our business requires the continuous monitoring of various and evolving laws, regulations, standards and expectations and the associated reporting requirements. A failure to adequately meet evolving stakeholder expectations may result in noncompliance, the loss of business, reputational impacts, diluted market valuation, an inability to attract customers and an inability to attract and retain top talent. In addition, if legislation or regulations are enacted or promulgated in the U. S. or in any other jurisdiction in which we do business that impose more stringent restrictions and requirements than our current legal or regulatory obligations, we and companies in our supply chain may experience increased compliance burdens and costs to meet the regulatory obligations, which could cause disruption in the sourcing, manufacturing and distribution of our products and adversely affect our business, financial condition or results of operations. In addition, our adoption of certain standards or mandated compliance to certain requirements could necessitate additional investments that could impact our profitability. Legal, Quality and Regulatory Risks New governmental regulations or changes in existing governmental regulations may reduce demand for our products or increase our expenses. We compete in many markets in which we and our customers must comply with federal, state, local and international regulations, such as environmental, health and safety and food and drug regulations. We develop, configure and market our products to meet customer needs created by those regulations. Any significant change in regulations, such as the Inflation Reduction Act of 2022 (IRA), which contains drug price negotiation provisions, or change in the interpretation of existing regulations, could reduce demand for our products or increase our expenses. For example, we manufacture pharmaceuticals and many of our instruments are marketed to the pharmaceutical industry for use in discovering and developing drugs. Changes in the U. S. Food and Drug Administration' s (the FDA) regulation of the drug discovery and development process could have an adverse effect on the demand for these products, and increased FDA regulation of **THERMO FISHER SCIENTIFIC INC.** laboratory- developed tests could delay and add to the cost of commercialization of these products, as well as subject us to additional regulatory controls. We are subject to laws and regulations governing government contracts, and failure to address these laws and regulations or comply with government contracts could harm our business by leading to a reduction in revenues associated with these customers. We have agreements relating to the sale of our products to government entities and, as a result, we are subject to various statutes and regulations that apply to companies doing business with the government. The laws governing government contracts differ from the laws governing private contracts and government contracts may contain pricing terms and conditions that are not applicable to private contracts. We are also subject to investigation for compliance with the regulations governing government contracts. A failure to comply with these regulations could result in suspension of these contracts, criminal, civil and administrative penalties or debarment. Our pharma services offerings are highly complex, and if we are unable to provide quality and timely offerings to our customers, our business could suffer. Our pharma services offerings are highly exacting and complex, due in part to strict quality and regulatory requirements. Our operating results in this business depend on our ability to execute and, when necessary, improve our quality management strategy and systems, and our ability to effectively train and maintain our employee base with respect to quality management. A failure of our quality control systems could result in problems with facility operations or preparation or provision of products. In each case, such problems could arise for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials or environmental factors and damage to, or loss of, manufacturing operations. Such problems could affect production of a particular batch or series of batches of products, requiring the destruction of such products or a halt of facility production altogether. In addition, our failure to meet required quality standards may result in our failure to timely deliver products to our customers, which in turn could damage our reputation for quality and service. Any such failure could, among other things, lead to increased costs, lost revenues, reimbursement to customers for lost drug product, registered intermediates, registered starting materials, and active pharmaceutical ingredients, other customer claims, damage to and possibly termination of existing customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. Production problems in our drug and biologic manufacturing operations could be particularly ~~THERMO FISHER SCIENTIFIC INC.~~ significant because the cost of raw materials for such manufacturing is often high. If problems in preparation or manufacture of a product or failures to meet required quality standards for that product are not discovered before such product is released to the market, we may be subject to adverse regulatory actions, including product recalls, product seizures, injunctions to halt manufacture and distribution, restrictions on our operations, civil sanctions, including monetary sanctions, and criminal actions. In addition, such problems or failures could subject us to litigation claims, including claims from our customers for reimbursement for the cost of lost or damaged active pharmaceutical ingredients, the cost of which could be significant. **A violation of data privacy or data protection laws could adversely harm our operating results and financial condition, damage our reputation or otherwise materially harm our business. As a global organization, we are subject to data privacy and data protection laws, rules,**

and customer- imposed controls as a result of producing, collecting, processing, storing and transmitting confidential, personal and / or sensitive data in the course of our business. A significant number of countries where we operate have enacted privacy or data protection laws, rules and regulations, the majority of which have extraterritorial scope, creating significant compliance challenges as we seek to maintain our global reach, with significant penalties for non-compliance, based on total worldwide annual revenue from the preceding financial year. In some cases, there are restrictions on the transfer of personal data outside the home country. More recently, privacy and data protection regulators are paying special attention to emerging issues linked to new digital technologies, such as the use of artificial intelligence, biometrics, and surveillance technologies, which pose unique challenges to existing privacy and data protection paradigms. For example, in the U. S., individual states regulate data breach and security requirements, and multiple governmental bodies assert authority over aspects of the protection of personal privacy. European laws require us to have an approved legal mechanism to transfer personal data out of Europe, and the EU General Data Protection Regulation imposes significantly stricter requirements in how we collect and process personal data. Several countries, such as China, have passed laws that require personal data relating to their citizens to be maintained on local servers and impose additional data transfer restrictions. Any actual or perceived noncompliance with these laws, rules and regulations, our internal policies and procedures or our contracts governing the processing of personal data could result in significant consequences, including, among other things, business interruption, sanctions and significant pecuniary fines, regulatory inquiries and investigations, adverse publicity, loss of competitive advantage and customer trust, as well as privacy litigation and civil lawsuits with damages, any of which may adversely affect our business, reputation and financial statements. The importance of privacy and data protection laws, rules and regulations for our industry specifically is constantly growing, as personal data is an integral part of doing business in our sectors, and the legal standards are evolving and becoming more complex worldwide. We are subject to product and other liability risks for which we may not have adequate insurance coverage. We may be named as a defendant in product liability or errors and omissions lawsuits, which may allege that products or services we have provided have resulted or could result in an unsafe condition, property damage or injury to end users or financial loss for consumers. Additionally, products currently or previously sold by our environmental and process instruments and radiation measurement and security instruments businesses include fixed and portable instruments used for chemical, radiation and trace explosives detection. These products are used in airports, embassies, cargo facilities, border crossings and other high- threat facilities for the detection and prevention of terrorist acts. If any of these products were to malfunction, it is possible that explosive or radioactive material could fail to be detected by our product, which could lead to product liability claims. In addition, patients involved in our clinical services trials conducted by our clinical development services business or taking drugs approved on the basis of those trials may also bring personal injury claims against us. There are also many other factors beyond our control that could lead to liability claims, such as the reliability and competence of the customers' operators and the training of such operators. Any such product liability claims brought against us could be significant and any adverse determination may result in liabilities subject to insurance policy exclusions where insurance would not respond or in excess of our insurance coverage. Although we carry product liability and errors and omissions insurance, we cannot be certain that our current insurance will be sufficient to cover these claims or that it can be maintained on acceptable terms, if at all. We are required to comply with a wide variety of laws and regulations, and are subject to regulation by various federal, state and foreign agencies. We are subject to various local, state, federal, foreign and transnational laws and regulations, which include the operating and security standards of the FDA, the U. S. Drug Enforcement Agency (the DEA), various state boards of pharmacy, state health departments, the U. S. Department of Health and Human Services (the DHHS), the European Medicines Agency (the EMA), the EU member states and other comparable agencies and, in the future, any changes to such laws and regulations could adversely affect us. In particular, we are subject to laws and regulations concerning current good manufacturing practices and drug safety. Our subsidiaries may be required to register for permits and / or licenses with, and may be required to comply with the laws and regulations of, the DEA, the FDA, the DHHS, foreign agencies including the EMA, and other various state boards of pharmacy, state health departments and / or comparable state agencies as well as certain accrediting bodies depending upon the type of operations and location of product distribution, manufacturing and sale. The manufacture, distribution and marketing of many of our products and services, including medical devices, and our pharma and clinical development services, are subject to extensive ongoing regulation by the FDA, the DEA, the EMA, and other equivalent local, state, federal and non- U. S. regulatory authorities. In addition, we are subject to inspections by these regulatory authorities. Failure by us or by our customers to comply with the requirements of these regulatory authorities, including without limitation, remediating any inspectional observations to the satisfaction of these regulatory authorities, could result in warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution, restrictions on our operations, civil or criminal sanctions, or withdrawal of existing or denial of pending approvals, including those relating to products or facilities. In addition, such a failure could expose us to contractual or product liability claims, contractual claims from our customers, including claims for reimbursement for lost or damaged active pharmaceutical ingredients or personal injury, as well as ongoing remediation and increased compliance costs, any or all of which could be significant. We are the sole manufacturer of a number of pharmaceuticals for many of our customers and a negative regulatory event could impact our customers' ability to provide products to their customers. We are also subject to a variety of federal, state, local and international laws and regulations that govern, among other things, the handling, transportation and manufacture of substances that could be classified as hazardous, and we are required to comply with various import laws and export control and economic sanctions laws, which may affect our transactions with certain customers. In certain circumstances, export control and economic sanctions regulations may prohibit the export of certain products, services and technologies. In other circumstances, we may be required to obtain an export license before exporting the controlled item. Compliance with the various import laws that apply to our businesses can restrict our access to, and increase the cost of

obtaining, certain products and at times can interrupt our supply of imported inventory. Any noncompliance by us with applicable laws and regulations or the failure to maintain, renew or obtain necessary permits and licenses could result in criminal, civil and administrative penalties and could have an adverse effect on our results of operations. Our reputation, ability to do business and financial statements may be impaired by improper conduct by any of our employees, agents, business partners or other third parties. We have internal controls and compliance systems to protect the company against acts committed by employees, agents or businesses that we acquire that would violate U. S. and / or non- U. S. laws, including the laws governing payments to government officials, bribery, fraud, kickbacks and false claims, pricing, sales and marketing practices, conflicts of interest, competition, employment practices and workplace behavior, export and import compliance, money laundering and data privacy, but these controls and systems may not be sufficient to prevent every such wrongful act. In particular, the U. S. Foreign Corrupt Practices Act, the U. K. Bribery Act 2010 and similar anti- bribery laws in other jurisdictions generally prohibit companies and their intermediaries from making improper payments to government officials for the purpose of obtaining or retaining business, and we operate in many parts of the world that have experienced governmental corruption to some degree. Any such improper actions or allegations of such acts could damage our reputation and subject us to civil or criminal investigations in the U. S. and in other jurisdictions and related shareholder lawsuits, could lead to substantial civil and criminal, monetary and nonmonetary penalties and could cause us to incur significant legal and investigatory fees. In addition, the government may seek to hold us liable for violations committed by companies which we acquire. We also rely on our suppliers to adhere to our supplier standards of conduct, and material violations of such standards of conduct could occur that could have a material effect on our business, reputation and financial statements. In addition, any allegations of issues resulting from the misuse of our products could, even if untrue, adversely affect our reputation and our customers' willingness to purchase products from us. Any such allegations could cause us to lose customers and divert our resources from other tasks, which could materially and adversely affect our business and operating results. Our inability to protect our intellectual property could have a material adverse effect on our business. In addition, third parties may claim that we infringe their intellectual property, and we could suffer significant litigation or licensing expense as a result. We place considerable emphasis on obtaining patent and trade secret protection for significant new technologies, products and processes because of the length of time and expense associated with bringing new products through the development process and into the marketplace. Our success depends in part on our ability to develop patentable products and obtain, defend and enforce patent protection for our products both in the U. S. and in other countries. We own numerous U. S. and foreign patents, and we intend to file additional applications, as appropriate, for patents covering our products. Patents may not be issued for any pending or future patent applications owned by or licensed to us, and the claims allowed under any issued patents may not be sufficiently broad to protect our technology. Any issued patents owned by or licensed to us may be challenged, invalidated or circumvented, and the rights under these patents may not provide us with competitive advantages. In addition, competitors may design around our technology or develop competing technologies. Intellectual property rights may also be unavailable or limited in some foreign countries, which could make it easier for competitors to capture increased market position. We could incur substantial costs to defend ourselves in suits brought against us or in suits in which we may assert our patent rights against others. An unfavorable outcome of any such litigation could materially adversely affect our business and results of operations. We also rely on trade secrets and proprietary know- how with which we seek to protect our products, in part, by confidentiality agreements with our collaborators, employees and consultants. These agreements may not adequately protect our trade secrets and other proprietary rights. These agreements may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently developed by our competitors. We also depend in part on our trademarks and the strength of our proprietary brands, which we consider important to our business. If we are unable to protect or preserve the value of our intellectual property rights for any reason, including our inability to successfully defend against counterfeit, knock offs, grey- market, infringing or otherwise unauthorized products, our brand and reputation could be damaged, and our business may be harmed. Third parties may assert claims against us to the effect that we are infringing on their intellectual property rights. In the event that a claim relating to intellectual property is asserted against us, or third parties not affiliated with us hold pending or issued patents that relate to our products or technology, we may seek licenses to such intellectual property or challenge those patents. However, we may be unable to obtain these licenses on commercially reasonable terms, if at all, and our challenge of the patents may be unsuccessful. Our failure to obtain the necessary licenses or other rights could prevent the sale, manufacture, or distribution of our products and, therefore, could have a material adverse effect on our business, financial condition and results of operations. Risks Relating to Financial Profile Fluctuations in our effective tax rate may adversely affect our results of operations and cash flows. As a global company, we are subject to taxation in numerous countries, states and other jurisdictions. In preparing our financial statements, we record the amount of tax that is payable in each of the countries, states and other jurisdictions in which we operate. Our future effective tax rate, however, may be lower or higher than experienced in the past due to numerous factors, including a change in the mix of our profitability from country to country, changes in accounting for income taxes, the results of examinations and audits of our tax filings and recently enacted and future changes in tax laws in jurisdictions in which we operate. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations, which could have an adverse effect on our business, results of operations and cash flows. In December 2021, the Organization for Economic Cooperation and Development (" OECD ") published a proposal for the establishment of a global minimum tax rate of 15 % (the " Pillar Two rule "). ~~The OECD has recommended that~~ **While it is uncertain whether the United States will enact legislation to adopt** the Pillar Two rule ~~become~~ **, numerous countries have enacted legislation, or have indicated their intent to adopt legislation, to implement certain aspects of the Pillar Two rules** effective ~~for fiscal years beginning after~~ January 1, 2024 ~~. To date~~ , ~~member states~~ **with general implementation of the remaining global minimum tax rules by January 1, 2025. The OECD and implementing countries** are **expected to** ~~in various stages of implementation and the OECD continues~~ **continue** to ~~refine technical~~ **make further revisions to their**

legislation and release additional guidance. We are closely monitoring developments of the Pillar Two rule and are currently evaluating the potential impacts in each of the countries in which we operate; however, we currently do not expect the Pillar Two rule to have a material impact on our effective tax rate. Our existing and future indebtedness may restrict our investment opportunities or limit our activities and negatively impact our credit ratings. As of December 31, ~~2023~~ **2024**, we had approximately $ ~~34~~ **31**. ~~92~~ **27** billion in outstanding indebtedness. In addition, we have availability to borrow under a revolving credit facility that provides for up to $ 5. 00 billion of unsecured multi- currency revolving credit (the Facility). We may also obtain additional long- term debt and lines of credit to meet future financing needs, which would have the effect of increasing our total leverage. Our leverage could have negative consequences, including increasing our vulnerability to adverse economic and industry conditions, limiting our ability to obtain additional financing and limiting our ability to acquire new products and technologies through strategic acquisitions. Our ability to make scheduled payments, refinance our obligations or obtain additional financing will depend on our future operating performance and on economic, financial, competitive and other factors beyond our control. Our business may not generate sufficient cash flow to meet our obligations. If we are unable to service our debt, refinance our existing debt or obtain additional financing, we may be forced to delay strategic acquisitions, capital expenditures or research and development expenditures. Additionally, the agreements governing our debt require that we maintain a financial ratio, and contain affirmative and negative covenants that restrict our activities by, among other limitations, limiting our ability to incur additional indebtedness, merge or consolidate with other entities and create liens. The covenants in the Facility include a Consolidated Net Interest Coverage Ratio (Consolidated EBITDA to Consolidated Net Interest Expense), as such terms are defined in the Facility. Specifically, the company has agreed that, so long as any lender has any commitment under the Facility, any letter of credit is outstanding under the Facility, or any loan or other obligation is outstanding under the Facility, it will maintain a minimum Consolidated Net Interest Coverage Ratio of 3. 5: 1. 0 as of the last day of any fiscal quarter. Our ability to comply with these financial restrictions and covenants is dependent on our future performance, which is subject to prevailing economic conditions and other factors, including factors that are beyond our control such as the impact of foreign exchange rates and interest rates. Our failure to comply with any of these restrictions or covenants may result in an event of default under the applicable debt instrument, which could permit acceleration of the debt under that instrument and require us to prepay that debt before its scheduled due date. Also, an acceleration of the debt under certain of our debt instruments would trigger an event of default under other of our debt instruments.