# Risk Information (As of July 6, 2020)

The business performances of the Olympus Group may be materially influenced by various factors which may occur in the future. Olympus has established "The Policy of Risk Management and Crisis Response" and related rules based on which we develop global risk management systems to mitigate business risks.

In particular, the Olympus Group applies uniform process and standard to identify and evaluate risk factors that may prevent it from achieving corporate strategy, fiscal year strategy, and fiscal year targets so that it may prioritize the risk factors and formulate efficient and effective measures based on the degree of importance of each risk factor. Those measures are discussed and formulated as Olympus Group level issues, and the Olympus Group has further established a system to track and periodically monitor progress of the said measures. The Group has also started to standardize risk management processes globally so that uniform risk management processes will apply when monitoring the achievement of business targets at each region. We believe these initiatives will enhance the achievement of our strategies and fiscal year targets.

Set out below are our principal business risk factors, aside from managerial decisions made by the Olympus Group, which may affect Olympus Group's business performances.

The future outlooks described below are based on the forecasts of the Olympus Group made as of the end of the fiscal year ended March 31, 2020.



# Risks Associated with Changes in Policy of Medical Administration and Strengthening of Reprocessing Regulations

In the medical business, medical system reforms aimed at curbing healthcare expenditures and improving quality of life (QOL) are ongoing both in Japan and overseas, and regulatory requirements for medical device applications and registrations in all over the world, such as European Medical Device Regulation (EU-MDR), are increasing year by year. In addition, the requirements concerning reprocessing (i.e., cleaning, disinfection, and sterilization) are becoming more complex.

The Olympus Group's earnings may be adversely affected if: (i) amendments to healthcare laws and regulations or related administrative policies, or other unexpected environmental changes occur; and (ii)-a Olympus Group fails to launch new products or services in a timely manner or (ii)-b Olympus Group otherwise needs to take certain actions corresponding to such amendments or changes.

In March 2018, the U.S. Food and Drug Administration (FDA) has issued warning letters to duodenal endoscopy manufacturers including Olympus group, due to incompliance with the mandatory post-marketing surveillance studies relating to the cleaning and disinfection of such products. Although we have since performed the post-marketing surveillance research requirements with having dialogues with the FDA, further regulatory actions may be taken by the FDA depending on the future progress.

#### **Risks Associated with Market Competition**

In the business fields where the Olympus Group relates to, there are risks that: (i) severe competitions with our competitors may cause decline in the unit price of our products or in our market shares; and that (ii) the alternative technologies or products may emerge.

In addition to the research and development activities we have engaged in in the past, we will conduct both research and development activities and marketing and sales activities utilizing the technologies which we will acquire through alliances and open innovations. However, depending on the outcome, the Olympus Group's earnings may be adversely affected.

### **Risks Associated with Selling Activities**

As government-sponsored healthcare systems are widely developed around the world in the field of the medical business, the Olympus Group and many of the distributors and suppliers engages in business with government-affiliated companies, healthcare providers and officials. The Olympus Group and the distributors and suppliers operate in countries or jurisdictions where there has been governmental corruption in the past, and we are working to educate employees to carry out proper transactions. On the other hand, there are a wide range of laws and regulations that cover fraud and misconduct in the healthcare industry; if such laws and regulations or their application change in the future, that may adversely affect the Olympus Group's sales or marketing activities.

In the Scientific Solutions Business, system provision to research activities funded by national budgets of countries accounts for a high proportion of earnings of the Olympus Group. Therefore, if such national budgets are curtailed in the wake of unfavorable macroeconomic fluctuations, the Olympus Group's ability to secure its earnings may be adversely affected.

In the digital camera field of the Imaging business, if the market contracts more sharply than anticipated, the Olympus Group may be unable to adequately counter the resulting sales decline with the restructuring measures currently implementing, and this may adversely affect the Olympus Group's earnings.

#### Risks Associated with Production/ Development Activities

For products and parts that depend on certain suppliers, if the procurement are restrained by such suppliers, the Olympus Group's ability to produce and supply products may be adversely affected. In addition, if we are unable to appropriately respond to sudden changes in market conditions, the Olympus Group's earnings as well as our supply chain may be adversely affected.

The Olympus Group and its manufacturing contractors manufacture products in accordance with strict quality standards. However, if any product deficiency, malfunction, etc., occurs, not only substantial costs including those of a recall would be incurred but also the Olympus Group's reputation from the market would be undermined, which may adversely affect the Olympus Group's earnings.

The Olympus Group is continuing to advance development of products adopting cutting-edge technologies. However, if a technological innovation causes unexpected change in market environment, and the Olympus Group fails to develop new products which adequately meets customers' needs in a timely manner, the Olympus Group's earnings may be adversely affected. In addition, if Olympus Group suffers cost increase due to the extension of development period and impairment loss of capitalized R&D assets, the Olympus Group's earnings may be adversely affected.

#### Risks Associated with Foreign Currency Exchange Rate Fluctuations

The Olympus Group provides products and services in various markets all over the world, and the overseas sales ratio on a consolidated basis accounts for approximately 82% in the fiscal year ended March 31, 2020. Also, some of our production bases are located overseas.

Olympus mainly uses forward exchange contracts to reduce the risk of foreign exchange fluctuations. However, if (i) sudden fluctuations in foreign currency exchange rates occur or (ii) the amounts of accounts receivable or payable covered by such contracts significantly differ than expected, then the Olympus Group's business performance may be adversely affected.

# Risks Associated with Business Collaborations and Corporate Acquisitions

The Olympus Group has built long-term strategic partnerships with leading enterprises in connection with technologies, product development, sales and marketing. If we fail to maintain such partnerships due to reasons such as occurrence of financial or any other business-related issues or change of our or their strategies, our business activities may be adversely affected.

The Olympus Group may acquire a business enterprise in order to expand its business. If the Olympus Group fails to integrate the acquired business in line with its corporate strategy or to utilize the existing business or the acquired business in an efficient manner, Olympus Group's business may be adversely affected, or its business performances and financial position may be adversely affected due to impairment of goodwill, loss on sale of business or liquidation or other related expenses.

The Olympus Group holds investment securities for business purposes which include facilitating business

alliances. As such, our business performance and financial position could be adversely affected under some situations involving considerable volatility with respect to stock prices and valuations of such investments brought about by developments that include market fluctuations and changes in the financial position of entities targeted for investment.

The Olympus Group has been attempting to transfer of all the equity interests in Olympus (Shenzhen) Industrial Ltd., a consolidated subsidiary in Shenzhen, China and owned by Olympus (China) Co., Ltd., another consolidated subsidiary. However, depending on the future outcomes, the Olympus Group's business performance and financial position may be adversely affected.

# **Risks Associated with Overall Investment**

The Olympus Group is investing in various areas related to its business, and upon making investments, we make assessments from various aspects. However, in the event of an unexpected change in circumstances, such as a sudden change in the external environment, the Olympus Group's business performance and financial position may be adversely affected.

# **Risks Associated with Leakage of Information**

The Olympus Group possesses important confidential information such as technology information, as well as the personal information of its customers and other related parties. In order to prevent external leakages of this information, we take various countermeasures including the establishment of internal regulations, the provision of training programs to our employees widely and thoroughly, and the strengthening of security systems. Nevertheless, in case of unauthorized leakage of such information, the Olympus Group may suffer damage to its corporate value, loss of social credibility, and indemnity obligations to customers and related parties affected by such information leakage, which may in turn cause adverse effect to its business performances and financial position.

#### **Risks Associated with Internal Control System**

The Olympus Group has developed and is maintaining and continuously improving a system to ensure appropriate and reliable financial reporting. However, no matter how effective the internal control system is, there is a potential risk that it may not properly operate for reasons such as any actions made by willful misconduct or gross negligence or our employees or other persons. If the Olympus Group fails to properly respond to such a situation, of the Olympus Group may breach the laws and regulations, which may result in payment of fines under administrative action, penalties under criminal proceedings, or indemnity civil lawsuits. Moreover, in such case, we may suffer an adverse impact on our business from a loss of our social trust, which in turn may cause an adverse impact on our operating results.

In addition, The Olympus Group has developed, and is operating and continuously improving a system to ensure valid and efficient work processes. However, there is a potential risk that the said system may not properly work due

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to reasons such as unexpected changes in the business and social environment which invalidates the system, or mishandlings by internal organizations or functions. If the Olympus Group fails to properly respond to such situations, the Olympus Group's business performance and financial position may be adversely affected.

#### **Risks Associated with Laws and Regulations**

We globally operate our businesses, including the Medical Business, which is a regulated business. We are subject to various laws, including the healthcare-related laws, antimonopoly laws both in Japan and other jurisdictions, as well as the anti-bribery provisions of the U.S. Foreign Corrupt Practices Act of 1977 (FCPA), the UK. Anti-Bribery Act and other anti-bribery laws in other jurisdictions. We are also subject to various laws targeting fraud and misconduct in the healthcare industry, including the Act against Unjustifiable Premiums and Misleading Representations in Japan, and the Anti-Kickback Statute and the False Claims Act in the United States.

Violations of these laws may be punishable by criminal or civil fines, imprisonment and/or exclusion from participation in certain national healthcare programs. Furthermore, since many of our customers rely on reimbursement from public health insurance and other government programs to subsidize their medical expenditures, if our participation in such programs is restricted as a result of a violation of these laws, that could adversely affect the demand for our products and the number of surgical procedures performed with our devices.

The plea agreement, which we executed on December 3, 2018 with the U.S. Department of Justice, requires our subsidiary, Olympus Medical Systems, Corp. (OMSC), to "undertake steps to enhance its regulatory compliance processes and procedures, and to regularly make certain certifications that OMSC is meeting the expectations of the settlement." Depending on OMSC's performance of the said obligation, it may be subject to additional measures by the U.S. Department of Justice.

We strive to fully comply with these laws, however, if we violate any of them, regardless such violation is intentional or not, it may affect our business, financial condition, results of operations and cash flows as well as the price of shares of our common stock.

#### **Risks Associated with Litigation**

The Olympus Group may be subject to lawsuits, disputes and other legal proceedings in connection with our domestic and international businesses. If a material lawsuit such as indemnity claim or injunction is filed by a third party, the Olympus Group's business performance and financial position may be adversely affected.

The Olympus Group uses various intellectual property rights in the course of its R&D and production activities, and although it believes that Olympus Group lawfully own or are licensed to use such rights, if any third party asserts that we have unknowingly infringed any of these intellectual property rights and files litigation, the Olympus Group's earnings may be adversely affected. Civil litigations have been filed in the United States alleging that plaintiffs have suffered damages with respect to the duodenoscopes that our group manufactures and markets. Considering the current status of these cases, we believe they will not give a significant impact on our business results and financial situation.

Olympus (Shenzhen) Industrial Ltd., a consolidated subsidiary in Shenzhen, China and owned by Olympus (China) Co., Ltd., another consolidated subsidiary had been sued by Shenzhen Anping Tai Investment and Development Co., Ltd. on December 23, 2016, and its judgment was handled down on July 30, 2018. We objected to this judgment and filed an appeal on August 17, 2018, but it may affect the Olympus Group's business performance and financial position depending on the future progress.

#### **Risks Associated with Financing**

The Olympus Group finances itself by, amongst others, loans from financial institutions as well as issuance of bonds. Changes in the financial markets may have an impact on our financing capacities.

Furthermore, if our financing costs rise due to reasons such as deterioration in our business performances, this may also have an adverse impact on our financing capacities.

#### **Risks Associated with Business Structure Reform**

In November 2019, the Olympus Group announced the corporate strategy aiming as a truly global medtech company to achieve sustainable growth of the Olympus Group.

In this corporate strategy, the Endoscopic Solutions Division aims to expand its portfolio with single-use endoscopes, and the Therapeutic Solutions Division seeks to achieve sales growth by introducing new products in its focus areas. In addition, we expect to implement large-scale efficiency improvements in the areas of products (cost of sales and R&D), commercials (sales and marketing, and maintenance services), and corporate (indirect expenses for corporate functions), as a company-wide efficiency improvement program.

If this program does not progress as scheduled, the Olympus Group's business performance and financial position may be adversely affected.

#### **Other Comprehensive Risks**

Through its domestic and overseas subsidiaries and affiliates, we operate our businesses globally. Our businesses may be subject to investigations by domestic and overseas authorities; or we may have consultations with or report to authorities pursuant to laws and regulations (such as responding to the examinations under the antimonopoly acts or those related to pharmaceutical and medical device related laws, or voluntary disclosure to the U.S. Department of Justice under the Foreign Corrupt Practices Act). Our earnings may be adversely affected depending on the results of such investigations and consultations.

In addition, we are expanding our business globally, and our tax burden may be increased due to changes in applicable tax laws or changes in their interpretations and application guidelines in each jurisdiction. The valuation allowance for deferred tax assets may need to be increased as a result of recoverability reassessment due to changes in business conditions or the implementation of organizational restructuring. If such situations occur, it may adversely affect the financial condition and business performance of the Group.

Moreover, occurrence of natural disaster, disease, war, or terrorist attack may adversely affect Olympus Group's earnings.

#### **Risks Associated with COVID-19**

Since the repeatedly reported outbreaks of COVID-19 infections in Wuhan, Hubei Province, China in December 2019, and the outbreaks have been reported all over the world. As a result, the economic downturn caused by the lockdown to prevent the spread of infection and the self-restraint of economic activity has led to a global recession.

Due to the outbreak, in our business activities, visits to medical institutions are restricted, and there are some restrictions on sales activities as well. In addition, the Olympus Group is requesting the domestic and overseas employees to work from home, etc. with the purpose of preventing the infections and the spread of the COVID-19, which causes some restrictions and delays not only in sales activities but also other business activities such as the announcement of financial results for fiscal year 2020 and convocation of the 152nd General Meeting of Shareholders.

If medical institutions will be compelled to prioritize the responsive measures to COVID-19, the number of medical treatments related to our business may decrease, in which case, our sales activities may be further adversely affected. In addition, if the spread of the infection continues for a long period, (i) the procurement of specific products and parts will be restricted and the production and supply capacity of the Olympus Group may be affected, and (ii) business activities such as the announcement of financial results and the General Meeting of Shareholders may delay.

We have set up a global task force to ensure business continuity and to prevent infection. Specifically, we take measures such as ensuring physical distance at work, thorough wearing of masks, ventilation of facilities, and refraining of business trips and events. It should be noted that while the state of emergency in Japan was lifted from the end of March 2020, working from home measures remained in effect, in principle, until June 2020. Since that time, these measures have been lightened, but restrictions still remain in order to keep attendance rates low. We will continue to take every measure to maintain stable supply of our products and services to our customers, while maintaining the top priority of protecting the health and safety of our employees, healthcare professionals, patients, and communities.

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