QTVascular







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SUSTAINABILITY REPORT 2017

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Board Statement

QT Vascular Ltd ("QT Vascular" or "Company", and together with its subsidiaries, the "Group") specialises in the design, assembly and distribution of advanced therapeutic solutions for the minimally invasive treatment of complex vascular diseases. The Company is listed on the Catalist Board of Singapore Exchange Securities Trading Limited ("SGX-ST"). In line with the Group's aspiration to create positive impacts for the wider community, the Board of the Company ("Board") recognises the importance of sustainability and considers environmental, social and governance ("ESG") issues in decision-makings.

The Board believes that trust is the most important of sustainability areas on which to focus, as trust is fundamental to the success of our business. Through the materiality assessment process, QT Vascular identified three material ESG factors, namely, product quality, business ethics and regulatory compliance, as the Group's sustainability priorities. These material factors are essential for QT Vascular to build trust among its customers and investors. The Board has considered sustainability issues as part of its strategic formation, concurred with the management on the material ESG factors identified, overseen the management and monitoring of these material ESG factors and approved this Sustainability Report.

This is QT Vascular's inaugural Sustainability Report, encapsulating the Group's sustainability policies, practices and performance for the financial year ended 31 December 2017 ("2017"). This report is aligned with the "Sustainability Reporting Guide" in Practice Note 7F of the SGX-ST Listing Manual Section B: Rules of Catalist ("Catalist Rules"). This report is also prepared with reference to the Global Reporting Initiative ("GRI") Standards, as it is a globally recognised reporting framework on sustainability reporting.

2017 Sustainability Highlights

100% product categories assessed for health and safety impacts

Zero non-compliance concerning health and safety of products

Zero product recall for any of QT Vascular's products

Zero significant findings in audit with regard to business ethics and independence

Zero confirmed cases of corruption

Zero non-compliance with relevant laws and regulation

About This Report

This Sustainability Report encapsulates QT Vascular's sustainability policies, practices and performance from 1 January 2017 to 31 December 2017. The report covers the listed entity, QT Vascular Ltd and all its wholly-owned subsidiaries, including TriReme Medical, LLC., TriReme Medical (Singapore) Pte Ltd and Quattro Vascular Pte Ltd.

The report is prepared in accordance with the requirements of Practice Note 7F: "Sustainability Reporting Guide" of the Catalist Rules. The report also makes reference to the Global Reporting Initiative (GRI) Standards, a globally recognised framework to report on ESG issues. The report references the following topic-specific disclosures:

- Disclosure 205-3 from GRI 205: Anti-corruption 2016
- Disclosure 416-1 and 416-2 from GRI 416: Customer Health and Safety 2016
- Disclosure 417-2 and 417-3 from GRI 417: Marketing and Labelling 2016
- Disclosure 419-1 from GRI 419: Socioeconomic Compliance 2016

No external assurance has been sought for this report. Please forward any enquiries or feedback to info@triremedical.com.

Materiality Assessment

To identify ESG factors important to our business and key stakeholders, QT Vascular conducted a materiality assessment workshop under the facilitation of an external consultant. The materiality assessment process was guided by the GRI Principles of Materiality and Stakeholder Engagement, and considered the following aspects:

- Global and local emerging sustainability trends;
- Industrial hot topics and future challenges for medical device industry, as identified by peers; and
- Insights gained from interactions with internal and external stakeholders

Three material factors were identified from the process:

1 Product Quality
2 Business Ethics
3 Regulatory Compliance

Product Quality

QT Vascular is a medical device company specialising in the minimally invasive treatment of vascular diseases. Committed to developing and offering safe and reliable medical devices, QT Vascular places top priority on product quality. We exercise strong governance regarding quality control throughout our value chain to build consumer and investor confidence.

Coronary artery disease ("CAD") and peripheral artery disease ("PAD") happen in the arteries surrounding the heart and periphery parts of the body (especially of the pelvis and legs), respectively. They are primarily caused by lesions consisting of plaque, which narrows or blocks arteries, thus obstructing normal blood flow. CAD and PAD can be treated by percutaneous transluminal coronary angioplasty ("PTCA") and percutaneous transluminal angioplasty ("PTA") respectively.

Our main products include both minimally invasive balloon catheters for PTCA and for PTA. By collaborating with industry specialists and physicians who are key opinion leaders, we develop and offer new and differentiated tools for physicians to improve the outcomes in complex peripheral and coronary interventions.

Our products are used in either PTCA or PTA. During the angioplasty procedure, a small incision is made and our balloon catheter is inserted on a steerable "guide wire" to reach the narrowed section of the affected artery. The balloon catheter is then inflated temporarily to push outward on the plaque and the wall of the vessel, thus improving blood flow at the narrowing. At the end of the procedure, the balloon is deflated and removed so no balloon catheter is left behind in the artery. In this way, our balloon catheters provide minimally invasive alternatives to permanent implants such as stents, offering a range of medical and cost benefits[1]. We are proud that these benefits ultimately lead to a better quality of life for patients.

[1] For more details, please visit QT Vascular website https://qtvascular.com/us/about-us/ on "Why is it important to avoid the use of permanent implants such as stents?"

Get to know our Chocolate® products

In 2010, we commenced the development of a second generation balloon catheter for treating peripheral vascular diseases named Chocolate® PTA. Designed to provide atraumatic dilation in the treatment of blocked arteries, Chocolate® PTA incorporates a unique nitinol constraining structure to allow controlled balloon expansion. This design helps to reduce the shear stress placed on the vessel during inflation, which in turn ensures uniform balloon expansion and prevents distortions and over-stretching of the vessel. To date, our unique constraining structure for Chocolate® PTA and Chocolate XD® is the first and remains the only balloon catheters in the world with this design, protected by strong intellectual property portfolio and offering unique treatment options for peripheral and coronary artery disease. Those products are now owned by large multinational companies namely Medtronic, Inc. and Teleflex, Inc. and continue to improve life around the globe.

To date, the Group have also received CE mark clearance for its unique peripheral Drug Coated balloon, Chocolate® Touch and coronary Drug Coated balloon, Chocolate Touch®. Drug Coated balloons represent a new category of device that combines the mechanical dilatation of a balloon catheter with the biological effect of a drug to treat occluded arteries. These categories of devices have been available for several years in Europe and were recently approved in the United States. QT Vascular is in the process of obtaining US regulatory approval for the Drug Coated Balloons.

Research and Development

To offer better treatment of vascular disease, we continue to invest in research and development. In 2017, we made progress on several of our critical, high-value development programmes. We commenced on our pivotal study of the Drug Coated Chocolate Touch® Balloon, one of the very few Drug Coated Peripheral Balloon to receive approval to conduct clinical studies in the U.S. by FDA. Furthermore, we have obtained positive 24-month outcomes of the Chocolate Heart® First-in-Human study, adding significantly to the body of evidence supporting the unique and distinguished benefits of the Chocolate® platform. Going forward, we will stay committed in research and continuously seek to develop new products with improved performance.

QT Vascular establishes a robust quality management system (“QMS”) in line with ISO 13485:2016 Quality Management for Medical Devices, U.S. Food and Drug Administration (“FDA”) Quality System Regulation (“QSR”) and other worldwide healthcare regulatory requirements. An effective QMS helps us to consistently provide safe and effective products to fulfil customer expectations and maintain compliance with laws and regulations. Our QMS is externally audited on a regular basis.

What is a quality management system (QMS)? And what is ISO 13485?

A QMS is a set of policies, processes and procedures to govern product quality. It is based on the Plan-Do-Check-Act cycle, a four-step management method used in business for the control and continual improvement of processes and products. In the medical device industry, a QMS is required by regulators in most countries.

ISO 13485, *Medical devices – Quality management systems - Requirements for regulatory purposes*, is an internationally agreed standard that sets out the requirements for a QMS specific to the medical device industry. Since laws and regulations vary from country to country, ISO 13485 does not set detailed requirements, but instead provides guidance on how to identify those regulatory requirements and how to incorporate them into QMS, thus offering flexibility.

Our QMS outlines a comprehensive set of policies and standard operating procedures ("SOPs") governing the management and monitoring of product quality. Multiple layers of tests and control points are set up at different stages of the product life cycle, beginning from the initial stage of product design, to production in progress and all the way to the finished product distribution. To ensure the consistency of quality throughout the value chain, we vigorously check incoming materials, parts and products. We also conduct our audit of all critical suppliers. Examples of key policies and SOPs on quality management include but are not limited to the following:

Product life cycle	Key policies and SOPs on quality management
Design	• Design Control Procedure • Equipment Specifications, Qualification, Maintenance and Calibration • Risk Management
Test	• Conduct of Clinical Investigation • Procedure Clinical Investigation Monitoring
Assembly	• Supplier Management • First Article Inspection • Controlled Manufacturing Environment • Receiving and Inspection • Material and Product Control • Non-conforming Materials Programme
Distribution	• Packaging and Shipping • Field Sales Product Handling Requirements
After sale	• Customer Feedback Procedure • Compliant Management • Handling of Out-of-Specification and Out-of-Trend Results • Corrective and Preventive Action ("CAPA") • Product Recall Field Corrections and Removals • Vigilance Reporting

Product life cycle	Key policies and SOPs on quality management
All stages	• Management Review • Quality Management System Manual • Records Management and Retention • Training • Internal Quality Audits

To inculcate a strong quality culture, the Regulatory Affairs and Quality Assurance Department provides mandatory Quality Awareness Training for all employees on a regular basis. The Quality Awareness Training covers key points on our QMS, and related policies and practices.

In 2017, we have assessed 100% of our significant product categories for health and safety impacts. There were zero non-compliance concerning the health and safety impacts of products and services. As a testament to our stringent quality control processes, there were no product recalls for any of QT Vascular's products during the year. In the coming year, we aim to maintain our record of zero product recall due to quality reasons. We are routinely audited by European CE notified bodies, Medtronic, Inc. and Teleflex, Inc.. We have been audited by FDA and are one of a small number of companies selected to participate in a pilot quality programme with FDA.

Business Ethics

In the medical device industry, business ethics and independence are shared concerns for many of our stakeholders. Operating ethically is fundamental in building trust with QT Vascular's business partners, regulators, investors and clients. At QT Vascular, we are committed to upholding high levels of business ethics in all areas of our business practices.

QT Vascular takes a strong stance against all forms of corruption. Employees are required to abide by the Employee Code of Conduct, which gives guidance on issues like prohibition of bribery, management of conflict of interest and anti-corruption. New employees are required to consent with all anti-corruption related policies by acknowledging via a declaration form.

We are committed to maintaining independence and high levels of business ethics in our interactions with healthcare professionals in all business settings, including research or development, and marketing and sales. Following section 6002 of the U.S. Affordable Care Act, also known as the "Sunshine Act" we set clear policies on the provision of gift, entertainment or anything of value, to healthcare professionals, thus preventing any perceived or actual breach of independence issues. All interactions are properly recorded and verified in accordance with regulatory requirements. These independence precautions help us to safeguard the impartiality of research results and the provision of healthcare services, which is essential in maintaining public trust and protecting our brand reputation.

More about Section 6002 of the U.S. Affordable Care Act

Section 6002 of the U.S. Affordable Care Act, also known as the "Sunshine Act", requires manufacturers of drugs and medical devices to report annually to the Secretary of Health and Human Services on the payments or other transfer of value to physicians and teaching hospitals. Reportable items include, but are not limited to, cash, gift, entertainment and other items of values. The Act also requires declaration of ownership or investment interests held by physicians or the immediate family members of physicians in applicable manufacturers and group purchasing organizations. This Act facilitates transparency into the financial relationship between the industry and healthcare personnel/institutions, helping to reduce the potential for conflicts of interest that physicians or teaching hospitals could face as a result of their relationships with manufacturers. This Act ultimately aspires to empower informed decision-making for consumers of health care.

To ensure independence in clinical trials, the Group appoints independent consultants and committees to collect, analyse and evaluate clinical data received from clinical trial sites. Clinical investigators are selected objectively based on a balanced consideration of expertise, history of compliance, interest in the study, availability for the study, adequate facility and staff resources, adequate enrolment potential, influence within the targeted medical

community, and potential conflicts with the study. At the same time, as clinical trials involve human subjects, we also place strong emphasis on research ethics throughout our engagement with independent investigators, covering issues such as informed consent from subjects, data privacy and security, and other ethical issues.

As part of our business ethics monitoring and assurance process, the Group has established a whistle-blowing channel for employees to report any suspected ethical issues in good faith. Information on the whistle blowing policy was formalised as part of our Corporate Governance Manual and made accessible to all employees. The Independent Directors of the Group have been listed as the contact points, with their contact details disclosed to all. Since the establishment of the whistle-blowing channel in 2014, to date, the Group has not received any whistle blowing reporting.

In 2017, there were no confirmed incidents of corruption. No issues were noted in relation to business ethics and independence in both internal and external audits. Going forward, we target to maintain the same high levels of business ethics and zero confirmed incidents of corruption in 2018.

Regulatory Compliance

The medical device industry is heavily regulated by the US FDA, EU and worldwide healthcare regulatory bodies. Regulatory compliance is the baseline for our continued operation. We are committed to strengthening our internal control and adhering to relevant laws and regulations.

QT Vascular actively identifies and manages its enterprise risks, with a particularly strong focus on product safety risks, which is also the most heavily regulated and closely monitored issue by the regulators. Having established a risk management system in accordance with ISO 14971:2012 Risk Management for Medical Devices, QT Vascular has set out SOPs to address all essential elements of risk management, including:

- The development of a risk management plan
- Risk assessment (including hazard identification and analysis, risk estimation, and risk evaluation/acceptability)
- Risk minimization and risk control
- Risk based decision-making
- Risk information monitoring
- Risk review and reporting

In case of any non-conformance relating to the health and safety impacts of QT Vascular's products and services, or inaccurate or unfair marketing and labelling information, QT Vascular will duly report to relevant government agencies in compliance with its corresponding reporting obligations under various jurisdictions. At the same time, QT Vascular also will conduct an internal investigation to find out the root cause of non-conformance and develop risk controls for the future.

We seek to adhere to all relevant socioeconomic laws concerning issues like customer health and safety, independence and anti-corruption, marketing and labelling, taxation, product pricing, as well as a range of audit and reporting requirements. In 2017, across the Group, there were zero incidents of non-compliance with socioeconomic laws and regulations, including laws concerning marketing communications as well as product information and labelling, which resulted in significant fines or non-monetary sanctions.

Meanwhile, we acknowledge the changing regulatory environment and seek to stay abreast with new areas of law. The Regulatory Affairs team communicates regularly with regulators and industry associations for updates. In turn, our policies and procedures are modified accordingly to ensure compliance. The Group also maintains very strict documentation control over its policies and procedures documents. To communicate promptly on changes in internal policies and procedures or regulatory requirements, each employee is required to read up on the changes and sign off as evidence of review.

In the coming year, we aim to maintain zero non-compliance with all laws and regulations which result in significant fines or non-monetary sanctions.