QT VASCULAR LTD

SUSTAINABILITY REPORT 2019

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Board Statement

QT Vascular Ltd ("QT Vascular" or "Company", and together with its subsidiaries, the "Group") is pleased to present its third Sustainability Report, which has been approved by the Board.

As a medical device company, we aspire to improve the quality of lives for patients through the products we offer. To realise this vision, we believe comprehensive considerations for relevant environmental, social and governance ("ESG") risks and opportunities is fundamental to ensure the quality of our products, as well as the long-term reliability of our operations.

In 2019, we continue to uphold the upmost standards of integrity, responsibility and accountability in our business practices and met all of our 2019 targets set for our material ESG factors, namely product quality, business ethics and regulatory compliance. We strive to maintain the same record of zero product recall due to quality issues and zero non-compliant incidents concerning product quality, business ethics and regulatory compliance in the forthcoming year.

The Board oversees and is supported by the Sustainability Steering Committee ("SSC") and the Sustainability Task Force ("STF") in its continuous efforts to integrate sustainability issues into QT Vascular's strategic formulation and oversee sustainability performance and reporting. The SSC, composed of the senior management team, develops sustainability objectives and strategy based on the Board's directions, manages QT Vascular's overall sustainability performance, and reports to the Board regularly. The STF, consisted of senior management representatives from different business functions, implements sustainability practices and action plans across QT Vascular based on the sustainability objectives and strategy formulated.

We look forward to sharing our sustainability progress with you in this Sustainability Report.

Board of Directors
QT Vascular Ltd

About QT Vascular

QT Vascular is a medical device company specialising in the minimally invasive treatment of vascular diseases.

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 drug coated 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.

During an 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 blood 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. ("Medtronic") and Teleflex, Inc. ("Teleflex") and continue to improve life around the globe.

To date, the Group has also received CE marking clearance for its unique peripheral drug-coated balloon, Chocolate® Touch and coronary drug-coated balloon, Chocolate® Heart. 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 ("US"). 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. Patient enrollment continued in our pivotal study of the Drug Coated Chocolate Touch® Balloon, one of the few drug-coated peripheral balloons to receive approval to conduct clinical studies in the US by the US Food and Drug Administration ("FDA").

K. Katsanos, in early December 2018 published a meta-analysis regarding increased mortality for subjects treated with paclitaxel-coated devices*. This analysis led to a wide-spread review by the regulators, prompting two physician letters from FDA on 17 January and 15 March 2019, followed by multiple enrollment challenges. While enrollment continues in 2020, the Coronavirus ("COVID-19") pandemic has impacted all industries around the globe. Currently, US hospitals are focusing on support and recovery for COVID-19 patients and US clinical studies are impacted as a result. Our clinical team is working closely with all US sites to ensure the safety of our clinical trial participants and integrity of the study data.

*Katsanos, K., Spiliopoulos, S., Kitrou, P., et al (2018). Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. JAHA; 7:e0112452019 Sustainability Highlights

2019 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 summarises QT Vascular's sustainability policies, practices and performance from 1 January 2019 to 31 December 2019, with a focus on its material ESG factors. 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 SGX Catalist Rules 711A and 711B, as well as SGX Catalist Rules Practice Note 7F: Sustainability Reporting Guide. The report also makes reference to the Global Reporting Initiative (GRI) Standards, a globally recognised framework to report on ESG issues. This report references the following GRI Standards and topic-specific Disclosures:

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

All information is disclosed in good faith and to the best of our knowledge. No external assurance has been sought for this report. Please forward any enquiries or feedback to info@triremedical.com.

Materiality Assessment

To determine ESG factors of significant interests to our business and key stakeholders, QT Vascular conducted a materiality assessment guided by the GRI Principles of Materiality and Stakeholder Engagement workshop. We considered the following in identifying potential material ESG factors:

- Global and local key sustainability trends;
- Hot topics and future challenges for our industry, as identified by our peers; and
- Insights gained from interactions with internal and external stakeholders.

Three material ESG factors were identified from the assessment process:



QT Vascular reviewed the above material ESG factors in 2019 and found that they continue to be relevant. QT Vascular will regularly review and assess its material ESG factors to ensure their pertinence.

Product Quality

QT Vascular is committed to developing and offering medical devices that are safe and reliable for the patients. We view product quality as top priority and have built a rigorous governance structure focused on quality control throughout our value chain to ensure consumer and investor confidence.

QT Vascular has established a robust quality management system ("QMS") in accordance with ISO 13485:2016 Quality Management System for Medical Devices, FDA Quality System Regulation ("QSR"), and other worldwide healthcare regulatory requirements. Our QMS is regularly audited by external parties to ensure its effectiveness in guaranteeing the quality of our products and our compliance with relevant laws and regulations.

Our QMS outlines a comprehensive set of policies and standard operating procedures ("SOPs") governing the monitoring and management and of product quality. Multiple layers of tests and control points are set up at each stage of the product life cycle to confirm that the policies and SOPs are properly observed and implemented. We also conduct audits of all critical suppliers and vigorously check incoming materials, parts and products to ensure quality consistency across our value chain.

Our 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
Operations	• Supplier Management • First Article Inspection • Process Validation • 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 • Medical Device Reporting (MDR) • Vigilance Reporting
All stages	• Management Review

Product life cycle	Key policies and SOPs on quality management
	• Quality Management System Manual • Document Change Control • Records Management and Retention • Training • Internal Quality Audits

In addition to auditing our QMS and critical suppliers, we are routinely audited by European CE notified bodies, as well as Medtronic and Teleflex for product quality. We have also been audited by the FDA.

We believe it is vital to cultivate a strong quality culture for our QMS to be effective. Our Regulatory Affairs and Quality Assurance Department holds regular, mandatory Quality Awareness Training for all employees, which covers key points on our QMS, and related policies and practices.

Performance Measures	2018	2019	2020 Target
Percentage of significant product and service categories assessed for health and safety impacts	100%	100%	Maintain zero product recall due to quality reasons
Number of non-compliant incidents concerning the health and safety impacts of products and services	0	0	
Percentage of products recalled due to quality problems	0%	0%	

Business Ethics

Operating fairly and ethically is fundamental in maintaining our stakeholders' trust in us. At QT Vascular, we uphold high standards of business ethics and independence in all areas of our business practices.

QT Vascular takes a zero-tolerance approach towards corruption. All employees are required to abide by the Employee Code of Conduct, which provides guidance on prohibition of fraud and bribery and management of conflict of interest. New employees are required to consent to all anti-corruption related policies by signing a declaration form.

We are committed to maintaining our independence 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[2], we set clear policies on the provision of gift, entertainment or anything of value, to healthcare professionals. All interactions with healthcare professionals are properly recorded and verified in accordance with regulatory requirements. These independence precautions help us prevent any perceived or actual breach of independence, as well as safeguard the impartiality of research results and the provision of healthcare services.

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, adequate facility, staff resources and enrolment potential, influence within the targeted medical community, as well as interest in, availability for and potential conflicts with the study. Furthermore, as clinical trials involve human subjects, we strictly monitor ethical issues such as informed consent from and HHPA requirements related to subjects and data privacy and security throughout our engagement with independent investigators to ensure research ethics.

As part of our business ethics monitoring and assurance process, the Group has established a whistle-blowing policy, which stipulates clear channels for employees to anonymously report any suspected ethical issues. The Independent Directors of the Group have been listed as the contact points, with their contact details disclosed to all employees.

Performance Measures	2018	2019	2020 Target
Number of confirmed incidents of corruption	0	0	Maintain the same high levels of business ethics and zero confirmed incidents of corruption
Significant findings of internal and external audits conducted in relation to business ethics and independence	0	0	

[2] 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. 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 organisations to enhance transparency in existing financial relationships between the industry and healthcare personnel and institutions.

Regulatory Compliance

We believe our reputation is built by being responsible and accountable. We view regulatory compliance as the baseline for our continued operation, and we are committed to adhering to all relevant laws and regulations, including those concerning customer health and safety, independence and anti-corruption, marketing and labelling, taxation, product pricing, as well as a range of audit and reporting requirements.

The medical device industry is heavily regulated by the FDA, the European Union ("EU") and worldwide healthcare regulatory bodies. The Group is audited every 2 years by the FDA and once a year by EU notified body, and no material non-compliance issues have arisen from the audit to date. The Group has also never paid any fine or penalties for non-compliance of any regulatory audit to date.

In addition to regulatory audits, we strive to continuously strengthen our internal controls. QT Vascular actively identifies and manages its enterprise risks, with a particularly strong focus on product safety risks, which is the most heavily regulated and closely monitored issue by the regulators. We have established a risk management system in accordance with ISO 14971:2012 Risk Management for Medical Devices, as well as a suite of 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 evaluation of risk acceptability)
- Risk minimisation and risk control
- Risk-based decision making
- Risk monitoring, review and reporting

To ensure that we stay abreast with new developments of relevant laws and regulations, our Regulatory Affairs team communicates regularly with regulators and industry associations for updates. When changes occur, we modify our policies and procedures accordingly, maintain strict documentation control, and promptly communicate changes in internal policies and procedures or regulatory requirements with our employees. Each employee is required to read up on the changes and sign off as evidence of review.

In case of any non-conformance with relevant laws and regulations, QT Vascular will duly report to relevant government agencies in compliance with its corresponding reporting obligations under various jurisdictions. QT Vascular will also conduct an internal investigation to identify root causes of non-conformance and develop corresponding risk controls.

Performance Measures	2018	2019	2020 Target
Number of non-compliant incidents concerning product and service information labelling	0	0	Maintain zero non-compliance with all laws and regulations which result in significant fines or non-monetary sanctions
Number of non-compliant incidents concerning marketing communications	0	0	
Number of non-compliant incidents with laws and regulations in the social and economic area that results in significant fines and non-monetary sanctions	0	0	