Tat CAPITAL
Corporate Finance & FX Advisory

Explore India's Medical Device potential with Tat Capital

Sulakshana Badri

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Healthcare is one of the important industry fields all around the world, playing a pivotal role in nurturing an individual and in turn the world at large. Under this industry, the highly innovative Medical Device Market holds a key position, as the state-of-the-art technologies tremendously improve an economy's healthcare offering.

India is among the top-20 markets for medical devices in the world and 4th largest in Asia (after Japan, China and South Korea), wherein the Market size is expected to reach $50 billion by 2025.

As per government estimates, India's medical devices industry is pegged at a $5.2 billion, and as per a Deloitte report, its 15.8% growth rate is more than double of the global industry growth rate of 4-6%

MEDICAL DEVICE SEGMENTS:

BY APPLICATION

CONSUMABLES & DISPOSABLES

needles, staples, packaging, medical gloves, sutures, tubing, syringes, catheters, medical gloves, gowns, adhesives, masks, and sealants for wound dressing and a whole lot of other instruments and tools used within a hospital or surgical environment

I-V DIAGNOSTIC

in-vitro examination of specimens derived from the human body solely to provide information for diagnostic, monitoring or compatibility purposes

DIAGNOSTIC IMAGING

Imaging that gives hints about a medical state: X-rays, CT scans, nuclear medicine scan, MRI scan, ultrasound

ORTHOTICS AND PROSTHETICS

Orthotics: accuracy in the fabrication involving the lower and upper limbs, spine or cranium / Prosthetics: use of artificial limbs (prostheses) to increase the function and lifestyle of persons with limb loss

DENTAL PRODUCTS

To improve oral hygiene

PATIENT AIDS

Pacemakers and hearing aids

EQUIPMENT AND INSTRUMENTS

Used in Healthcare delivery system: includes patient monitors, ECG, oxygenators etc.

Key points:

- India's market is highly fragmented (~800 manufacturers of Medical devices), much of whom are SMEs, wherein Average investment = $2.7 to 3.1 million / Average turnover = $7.09 to 7.87 million.
- The Indian medical device sector has received an investment of $505 million from 27 M&A transactions and around 43 venture capital / private equity investment in last five years.
- There are 6 major segments for medical devices in India: The equipment and instrument segment is currently dominating at a rate of 53-56%, and is projected to maintain its dominance, followed by medical implants.
- Orthopedics and Prosthetics & Patient Aids segments are expected to be the two fastest-growing verticals by 2020 and are projected to grow at a CAGR of 9.6% and 8.8% respectively.
- Diagnostic imaging, Dental products, and Consumables are expected to grow at a CAGR of 7.1%, 7.4% & 7.1%, respectively, during 2015-20 & Surgical robotics market to expand at 20% CAGR during 2017-25
- The estimated market size of the consumer and durable segment is $1404 million.

TAT & MedTech:

Tat Capital is pleased to introduce Andhra Pradesh MedTech Zone (AMTZ), which provides capital intensive scientific facilities required by most medical device manufacturers, and 200+ modern state of the art independent manufacturing units.

TAT partnered with AMTZ and conducted an event & roadshow on the Medical Device opportunities in the sub-continent, which became an exceptionally well received event. It was oversubscribed and over 40 medical device stakeholders, distributors in the industry attended the closed event, showing strong interest to explore the Indian opportunity.

Here are some of the TAT-AMTZ MedTech event pics:


AMTZ
सिद्धिर्भवति कर्मजा
Dr. Jitendar Sharma
Managing Director & CEO- AP Med Tech Zone
Executive Director- Kalam Institute of Health Technology

1c. TAT's Co-founders/Directors Ram Gorlamandala & Pras Indrakumar with AMTZ MD/CEO Dr. Jitendar Sharma

The AMTZ story:

AMTZ is India's 1st Integrated Medical Devices Manufacturing Park, and is an enterprise under the Government of Andhra Pradesh, a one of its kind 270 Acre zone, dedicated for Medical Device and Component Manufacturers.

The objective behind this 'One-Stop-Solution' is not only to reduce the cost of manufacturing up to 40% but also to simplify the end-to-end operations, and AMTZ is inviting Medical Devices manufacturers to set up their units at the AMTZ site in Visakhapatnam, India.

Salient Features

- Prebuilt manufacturing units in plots measuring 0.25 acres / 0.5 acres / 1.0 acres / 2.0 acres provided to interested manufacturers.
- Office space for interested government / private organisations for facilitation of Zone functioning
- Exclusive World class scientific facilities needed for medical devices manufacture, highly capital intensive, in Public Private Partnership (PPP) mode.
- Empanelled partners across technology transfer, human resources, quality / regulatory compliance, project management, financial support. Manufacturer has option to choose from these bouquet of service providers for any business requirements.
- Partnership with Global Medical Device Nomenclature (GMDN) Agency for enabling export and global market access.
- Close interaction with industry and Government to suggest and pursue policy and process interventions needed for growth of the industry.
- Authorization by Ministry of Health and Family Welfare, Govt. of India to setup dedicated help desk for understanding and smooth implementation of Medical Device Rules, 2017.

In fact, AMTZ's Common Scientific Facilities (CSF) for MD Testing is the USP of the industrial park, as it aids manufacturers to test products as per global norms and standards. Its first phase of CSF include:

- Centre for Biomaterial Testing
- Centre for Electro-Magnetic Interference and Electrical Safety Testing
- Centre for Radiation Testing
- X-Ray/CT Scan Tube Manufacturing
- Centre for MedTech Innovation & Rapid Prototyping

The below visual by AMTZ further shows those Medical Device segments that offer a high potential:

High Potential Segments in India

Key Segment	Sub-segment	% of Import dependency	Share of the overall Medical Device market	Overall attractiveness for Indian Manufacturers to invest in this segment
Consumables	Cardiac Catheter, Other needle, Syringe, Lab reagent, Suture, Strips & cartridge, Dialysers and Filters, cannula	35%	16%	High
Dental Product	Dental Implant, Artificial teeth, Dental instruments	60%	3%	Medium
Diagnostic Imaging	X-Ray tubes, USG Probe, Radiation beam delivery system, Radiation generator unit, CT Scan, MRI, PET Scan, ALPHA, BTA/GMA Radiation for other use in radiography equipment	52%	30%	Very High
IV Diagnostics	Lab reagent & accessories	67%	10%	High
Orthopaedic & Prosthetics	Artificial joints & joint implants	62%	8%	High
Others	Artificial dialysis apparatus & haemodialyser, defibrillator, Lithotripsy equipment ,ECHO,EEG, ECG, anesthesia equipments, Laparoscope, endoscope	83%	24%	Very High
Patient Aids	Pacemaker, Hearing aid, Cochlear implant, Stents	50%	9%	Medium

Table : High Potential *Segments in India*

4th WHO Global Medical Device Forum:

AMTZ will be hosting the most esteemed 4th WHO Global Medical Device Forum in December 2018 in partnership with WHO, wherein close to 2000 delegates from 194 UN Nations including India are expected to attend.

It is in fact the first time in the history of WHO that this conference is being hosted in India! The 4th Global Forum will build upon the work that was accomplished at the 1st Global Forum in Bangkok in 2010, the 2nd in Geneva in 2013, and the 3rd also in Geneva in 2017. AMTZ had also received the coveted recognition from WHO to host the South-east Asia's First Prequalification Cell for IVD on 22.11.2017.

What are the 4th Forum Objectives:

- To define methods of increasing and measuring access to essential and priority medical devices under Universal Health Coverage in compliance with the Sustainable Development Goals
- To share country evidence of best practices in regulating, assessment and management of medical devices
- To demonstrate development and use of innovative appropriate affordable technologies to respond to global health priorities
- To share WHO tools and guidelines on medical devices for better implementation

Special topics to be addressed: Nomenclature of medical devices, essential in vitro diagnostic tests, Oxygen supply system.

What's more?

Tat Capital will be leading a delegation team to this forum, which will be held in the AMTZ campus at Visakhapatnam (Vizag) from 13th-15th December 2018.

Not only that, TAT is also putting together a team of medical companies, wherein we will accompany the delegates to India early next year and give a taste of the multiple ways in which they can benefit from the 'India' collaboration.

Write to us to register your interest in these events and know more about how we can help you to explore this potential!

The WHO Forum & its journey so far:

Along with other global initiatives, the First WHO Global Forum on Medical Devices had been instrumental in raising awareness of the need for affordable, appropriate, accessible and available medical devices – with the need for a robust accountability process.

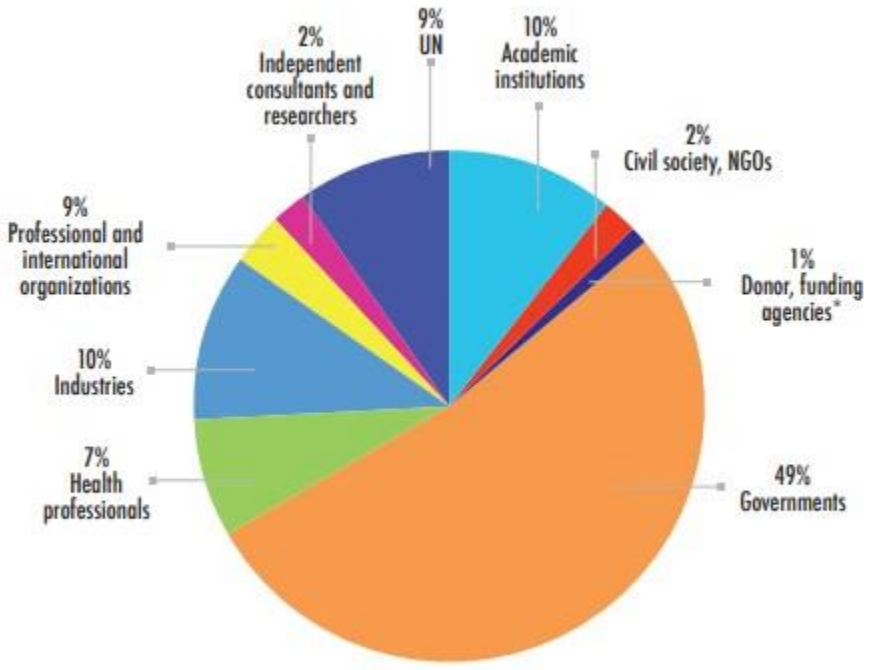
First forum - expected outcomes:

Identification of actions that can be taken for the improvement in availability, accessibility, appropriate selection, assessment, regulation, management, safety and use of medical devices;

Compilation of best practices, available resources, tools and guidelines on medical devices for integration into national health plans;

Establishment of a network of interdisciplinary professionals who will continue to support the role of medical devices in health systems.

The below pie chart shows the different background of the 380 participants -

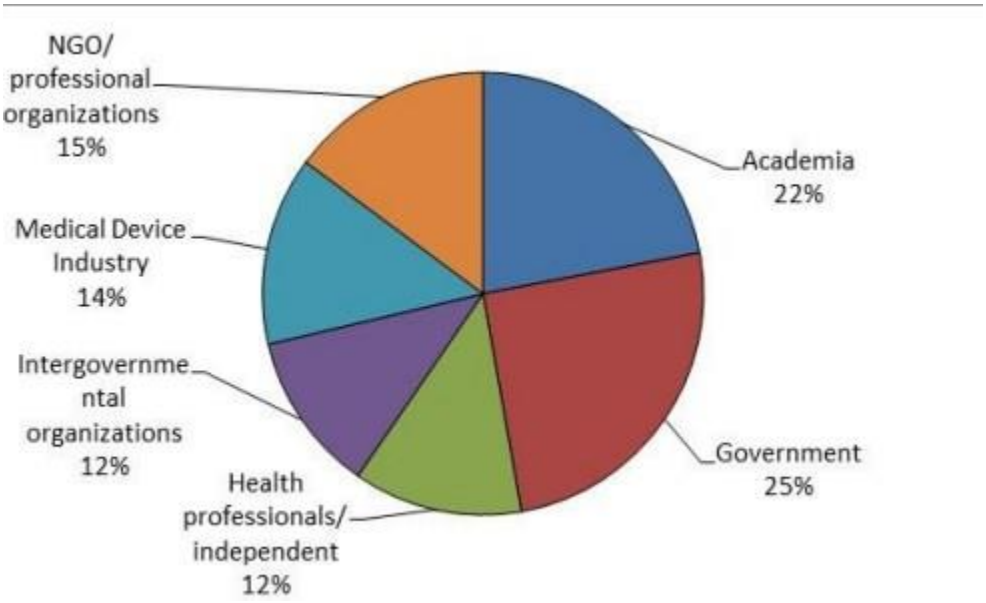


Second forum - expected outcomes:

- To define methods of increasing access to priority medical devices under the Universal Health Coverage initiative.
- To share evidence on best practices in health technology assessment, management and regulation of medical devices, wherein there were requests from low to middle income countries to pass on information on how to proceed with their ministries or organizations to define the tech role.
- To demonstrate the development and use of appropriate and innovative technologies that respond to global health priorities.
- To present the outcomes of the implementation of the World Health Assembly resolution on health technologies (WHA60.29) and the status of actions resulting from the First Global Forum on Medical Devices.

- While most of them have been completed or are being addressed, continuous work is needed on health technology assessment, innovations, regulations of medical devices and especially on the free access to a global nomenclature of medical devices.

The below pie chart shows the different background of the 572 participants –

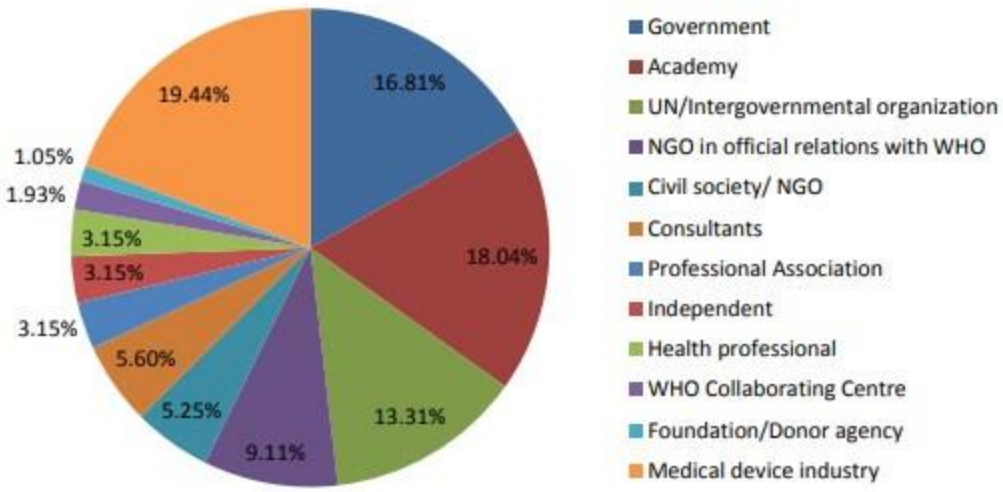


Third forum - expected outcomes:

During the Third WHO Global Forum, the planned objectives were met, there was exchange of information on the areas of innovation, regulation, selection, assessment, management including procurement, donations, technical specifications, lists and safe use.

- Availability of a global nomenclature, classification and coding of medical devices, that can serve the Unique Device Identification (UDI) system, procurement, regulations and safe use of devices.
- Information on prices of medical devices, through databases.
- Information on decommissioning and disinvestment of medical devices.
- Increase availability of appropriate, affordable, priority medical devices for primary health care.
- Develop lists of priority medical devices for emergency and trauma, cardiovascular diseases, diabetes and respiratory diseases, among others.

The below pie chart shows the different background of the 570 participants –



Why is the Indian market important?

The advancement in the medical sector has yielded huge success in the treatment and eradication of some illnesses in India.

At current times, due to an increasing demand for medtech products, marketers are looking for opportunities to manufacture / source medtech products in Asia. While China has been an attractive point for Medtech sourcing and manufacturing, the costs have risen over the last few years, making it much relevant for manufacturers to explore India. This can be attributed to the country's growing middle class, an increase in the number of hospitals, and a greater need for sophisticated medical devices and better healthcare.

The subcontinent, as a key player in the global pharmaceuticals industry, offers an attractive market opportunity for global medical device manufacturers, which has so far been heavily import driven. Why?

- Inexpensive, yet highly skilled labor base + reduced production costs (be it rent, utilities, raw materials) + local manufacturing advantages + economic market potential
- Large population = Rapid Urbanisation = Rise in middle class = Rise in Private Healthcare spending = Rising awareness & demand for better healthcare
    - According to the United Nations, India's population is set to touch 1.45 billion by 2028, making it the world's most populous nation
- With a boom in health & wellness centric society, rise in penetration of medical insurance & healthcare affordability is increasing like never before

- Rising innovations to cater to unique domestic market demands
    - Medical tourism and luxury healthcare markets are among India's fastest-growing industries
    - Few Indian companies have upped their offering by designing and developing specialty devices at a lower cost, which are on par with global quality standards, gaining a niche market in many regions globally
- Local manufacturing expansion due to "Make In India" initiative = a possibility of reduced import dependency = rise in private set up
- The Medical Electronics Devices Sector (a sub-sector of Medical Devices, which is relatively small with <6% contribution) has constantly been growing in recent years and is expected to reach $7 billion by 2020, becoming more attractive for domestic as well as international manufacturers
- Consistent demand for surgical instruments, cancer diagnostics, orthopedic and prosthetic equipment, imaging, orthodontic and dental implants, and electro medical equipment

As we earlier saw, Medical devices in India hold a market share worth $5.2 billion, contributing around 4 to 5% to the $96.7 billion healthcare industry in the country, which shows how there is much untapped potential. In the last year, the industry saw growth in both - a) core manufacturing sector & b) technology start-ups, who are disrupting the diagnostics and wearable space. One can see how medtech will continue to provide a fantastic platform for disruptive innovation, providing out-of-the box, innovative and cost-effective solutions for all consumers.

With a large number of private players coming in, there is a growth in the number of hospitals, diagnostic centres and specialised facilities. Most of these hospitals have their quality and accreditation at par with international standards.

◆ Did you know? ◆
393 hospitals have already received the National Accreditation Board for Hospitals & Healthcare Providers (NABH) accreditation in the last decade.

⇒ An article in MedTech Intelligence states that Asian manufacturers have become increasingly more compliant with international standards such as ISO or good manufacturing practice (GMP), as well as FDA and European quality standards. Local Asian manufacturers have also been improving infrastructure in order to keep up with advances in medical technology, and how the quality standards and production capabilities in Asia are oftentimes able to meet Western expectations.

⇒ Another MedTech Intelligence case study article highlighted how all the manufacturers that they had visited in India met basic requirements such as ISO 13485 certification, in-house cleanrooms, in-house EtO sterilization and in-house quality testing laboratories, and how the subcontinent presents itself as a good low-cost production center. It reported that more and more device commodity products are being made and sourced in India as well as Vietnam, wherein India still remains one of the top countries for medical sourcing and manufacturing, with the additional boon of being close to the growing Asian medical markets.

⇒ A bwdisrupt article states how several start-ups and SMEs selling specialty surgical devices such as stents, catheter to high-end devices and equipment like the ones used in Intervention Radiology are gearing up to meet pent-up demand.

Technological advancement/expertise coupled with government support has no doubt been advantageous. Additionally, here are few other key elements that every new player in this market needs to be aware of:

- India boasts of strong patent, trademark, and copyright protection with its Trade-related conditions of Intellectual Property Rights.
- No import duty on some medical equipment.
- Individual life-saving medical equipment is exempted from payment of excise duty.
- Government has incentivized scientific investigation and development by catering weight deduction.
- The GST factor has allowed a concession from the earlier rates of 6% central excise duty + 5% VAT + CST, octroi, entry tax etc., which amounted to >13%.
    - The new 12% rate will aid in achieving lower manufacturing costs, thereby benefiting even end consumers.

Foreign direct investment (FDI) & India:

The Healthcare Industry has grown to be one of the largest sectors in terms of both revenue and employment that the government had budgeted around $28 billion on public health spending for FY 2017-18. With both the industry / government spotlight on Medical Devices, it is looking towards foreign investments and technological innovations for advancement.

With the liberalising of government policies, foreign business now have more freedom to invest in India's medical devices industry than ever before. With a scope for the big India opportunity, an increasing number of MNCs are setting up their manufacturing bases here.

In January 2015, Government of India modified the FDI regulations allowing 100% FDI under automatic route in Greenfield and brownfield projects in medical device sector. It also clarified that medical devices will no longer be defined by the Drugs and Cosmetics Act, 1940, widening the range of items defined as 'medical devices' in the FDI Policy.

◆ Did you know? ◆

The equipment and instruments, consumables and implants segments have attracted the most FDI. During the period between April 2000 and March 2017, USD 1.57 billion worth FDI came into the country.

With a scope for the big India opportunity, an increasing number of MNCs are setting up their manufacturing bases like the Becton Dickinson's manufacturing plant in Haryana, and the Medtronics acquisition by Philips Medical Systems.

Government Support:

In the last two decades, the Medical Devices Industry has undergone a transformation, with the government taking various steps to ensure that the medical devices sector is significant to the country by enabling the ease of doing business, ensuring availability of quality medical devices, etc. The year 2017, in fact, saw the most significant 'medical device' highlights that showed Medical Devices was key in Government's agenda.

The government's move to separate manufacturing of medical devices from drugs in the regulatory perspective held much weight, which could now usher in better transparency and a level playing field for medical device makers. This will go a long way in building robust standards ecosystem, boost domestic production as well as exports, bring in greater foreign investment, and better both infrastructure and processes.

Other notable points:

- Periodic renewal of licenses will not be required.
- Manufacturing and import licenses will be valid until it is suspended or cancelled.
- A culture of self-compliance by manufacturers of medical devices: The manufacturing license for certain medical devices are granted without prior audit of the manufacturing site. In such cases, the manufacturer has to do self- certification of compliance with the essential requirements and on the basis of such certification, the licence will be issued.
- GOI's BMMP takes care of 7,56,750 number of equipment in 29,115 health facilities across the country, costing approximately Rs. 4564 Crores.

GOI

MEDICAL DEVICE HIGHLIGHTS

MEDICAL DEVICE RULES 2017 PUBLISHED

Separate rules for medical device & drugs
Conformity with Global Harmonisation Task Force (GHTF) framework
Enhanced clinical trial norms as per International best practices.

NATIONAL REGULATORY AUTHORITY, CDSCO

Classification in place for MDs in terms of risks, also designated regulation authority.
Single window clearance: To not just focus on self-reliance, but also work towards making India the global hub of production in medical devices.
Online service - for grant of import, manufacture, clinical investigation, sale and distribution licences of medical devices and diagnostics through 'Sugam portal'.

NMD POLICY

Envisages interest subsidy for MSMEs, concession on power tariffs, seed capital and minimum or zero duty on raw materials, among others.

NATIONAL PHARMACEUTICAL PRICING AUTHORITY

Slashed coronary stent prices by as much as 85%
Imposed price ceilings for all drug-eluting stents and bioabsorbable stents.
Capped prices for orthopaedic knee implants as well, in a move to make medical devices more affordable.

MAX RETAIL PRICE

Amendments to the Legal Metrology Rules resolves the issue of Maximum Retail Price to benefit consumers, who were asked to pay as per their capacity.

NATIONAL HEALTH MISSION (NHM)

Many tech intensive programs have flourished, which have been implemented under Public Private Partnership (PPP) mode to increase healthcare access to public.

BIOMEDICAL EQUIPMENT MAINTENANCE PROGRAM

A sustainable model to support states for BMMP and for provisions for radiation safety

STANDARDS AND QUALITY

NABCB has been identified as an accreditation body for the certification bodies + Launch of 'specific criteria for Medical devices calibration discipline' by National Accreditation Board for Testing and Calibration Laboratories (NABL)

MEDICAL DEVICE PARKS

AMTZ in Andhra Pradesh, MD Park in Telangana, with additional ones planned for Gujarat, TN and Maharashtra, shows emphasis on excellence in Research and Development (R & D).

Conclusion:

The medical devices market in India is moving at a rapid pace, newer regulations on medical devices, GST impact, Make in India initiative, rise of startups - triggering innovation & inspiration, increasing govt. support, etc., is bringing about more collaborations and foreign entry.

As the government, the players and the consumers are at the influx of a tech revolution, the market is gearing up for an ascend, and both local/foreign producers will be able to benefit immensely, as they satiate the ever-rising demand for healthcare.

While doing business in India may be a combination of challenge and opportunity for the new players, TAT's team of sub-continental experts and its wide network will make the entry simpler, collaborations swifter, as making inroads in a vast and hungry market becomes easier.

Write to us for more info and see how we can explore the India potential together / to participate in the above mentioned MedTech events this year and next!

Tat CAPITAL

Corporate Finance & FX Advisory

Phone: +612 8387 5901 | Email: info@tat.capital | Website: www.tat.capital
Address: Level 14, Suite 1403, Spring Street, Sydney, NSW 2000, Australia