Acotec shares plunge in Hong Kong debut amid regulatory changes in Chinese health care sector

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China's ongoing efforts to tighten regulations across the board is hitting medical device companies. Two companies that issued shares in Hong Kong for the first time over the past week saw their shares tumble right out of the gate.

Acotec Scientific Holdings Ltd. (HK: 6669) shares fell more than 25% on their first trading day on the Hong Kong Stock Exchange on Aug. 24 amid regulatory changes in China's health care industry. Still, the company raised HK$1.63 billion (US$210 million) at an offer price of HK$23.8 per share through the IPO. Shares were down to HK$17.82 after opening at HK$18.32.

Another newly public company, Shanghai Heartcare Medical Technology Co. Ltd.'s shares also plunged by about a quarter in their Aug. 20 debut.

"The pace of regulatory change in China health care has been fast for at least a decade. The last three years have brought some major external triggers for new policies, to which policymakers everywhere around the world are responding," Stephen Sunderland, a partner at L.E.K. Consulting LLC told *BioWorld*. "We are now at the start of a new five-year planning cycle in China – the 14th, so we shouldn't be too surprised at a slew of new policies in 2021."

Sunderland believes the two biggest triggers for change in China are trade disputes with the U.S. and the COVID-19 pandemic.

"Both China and the U.S. are now taking measures to enhance their national security via industrial policy. That change of posture clearly extends to essentials such as health care and more specifically med-tech," Sunderland said.

"As with any change to the 'rules of the game', there will be winners and losers, both amongst the players on the pitch and those on the bench awaiting their chance," Sunderland said.

Sunderland points that the wider regulatory changes now ongoing occurring in China's med-tech industry are "broadly positive" for innovators.

Sunderland said that the Chinese government has recently launched policies to support med-tech innovation with accelerated and lower cost product registration, potentially faster and wider market access with a national reimbursement list, and increasing clarity in regulation that allows for more certainty.

Meanwhile, "we're seeing the expansion of volume-based procurement which is squeezing prices on more mature med-tech products with the intention to pay for more innovation and set up a more affordable platform to serve long term health care demand growth," Sunderland added.

"One area of regulatory tightening is NMPA's increasing supervision of the medical device lifecycle," Anna King, a business consultant at Cisema (Hong Kong) Ltd., told *BioWorld*.

There has been a general shift in approach by the NMPA over the last few years from point-in-time registration to total life cycle review. The management of whole-of-product lifecycle is increasingly emphasized by the regulator as an ongoing requirement to track safety for users.

"This means medical device manufacturers must develop a strong postmarket surveillance system. This may increase the frequency of factory inspections going forward, potentially also overseas factory inspections. Manufacturers should keep a close watch on the changes to ensure they remain in compliance and optimize their China registrations," King said.

Acotec proceeds

Still, going public may be the fastest and easiest way for companies to raise funds, as Acotec did.

A large portion of the proceeds from the listing will be used for the R&D, clinical trials, and product registration of its two core products in China, the U.S., and the European Union. The company will use the remaining funds to develop other products in its pipeline and expand its manufacturing capabilities.

The IPO was backed by Morgan Stanley, China International Capital Corp. Ltd., China Merchants Securities Co. Ltd, and Valuable Capital Ltd. Acotec attracted 13 cornerstone investors, including China Universal Asset Management Ltd. Liability Co., CPE Investment Wu Ltd., and China International Capital Corporation Ltd.

Beijing-based Acotec develops medical devices for interventional treatment of vascular diseases, especially in the field of drug-coated balloons (DCB) and thrombus aspiration catheters.

It launched the first peripheral DCB product Acoart Orchid & Dhalia in China in 2016 and took over a share by revenue of around 86.9% in the peripheral DCB market in the country in 2020. It is indicated for treating superficial femoral artery and popliteal artery lesions.

In 2019, the FDA granted Breakthrough Device Designation to the company's second DCB product Acoart Tulip & Litos for the treatment of below the knee (BTK) lesions. The product has received marketing approval from the NMPA, becoming the world's first BTK DCB product receiving regulatory approval and the only BTK DCB product approved by the NMPA.

The company is also in the process of developing 24 products in its pipeline and looking to expand indications of its DCB products for the treatment of arteriovenous fistula stenosis, vertebral artery origin stenosis, and vasculogenic erectile dysfunction.

With the growing prevalence of vascular diseases caused by atherosclerosis such as peripheral artery disease, coronary artery disease, and stroke, minimally invasive interventional procedures have been adopted to treat them.

Treatment solutions evolved from percutaneous transluminal angioplasty (PTA) balloons to stents and further to DCBs.

PTA balloons have a high incidence of short-term vessel restenosis while Stents may cause complications such as thrombosis, stent fracture and in-stent restenosis (ISR) although it is effective in preventing vessel restenosis.

DCB therapy is a relatively new therapy that uses angioplasty balloons coated with anti-proliferative drugs. It can effectively inhibit neointimal hyperplasia, reduce the risks of vessel restenosis, thrombosis, avoid stent fracture and ISR, compared to PTA balloons and stenting.

Acotec primarily focuses on the peripheral artery disease DCB market, which accounted for about 13.4% of the overall DCB market in China in 2019, and is expected to account for up to half of the overall DCB market by 2030, according to Frost & Sullivan.

Meanwhile, Acotec is developing other therapeutic, procedural, and ancillary medical devices such as thrombus aspiration devices and radiofrequency systems.

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