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FDA nods open door for medical device maker

HealthSTATS wins approvals for its biomonitor products. By **JASLENE PANG**

HOMEGROWN medical device company HealthSTATS International is expanding its presence in the arteries of the bio-monitoring body with its Food and Drug Administration (FDA) approvals for two of its products, CASPal and CASPro.

"Prior to the FDA approval, we launched them in Singapore, Malaysia and Hong Kong in October. Now, with the FDA approval, it makes it easier for CASPal and CASPro to penetrate new markets such as the United States and Europe," says Ting Chom Meng, chairman and chief executive officer of HealthSTATS.

The recent FDA approvals – just about two weeks old – brings the total number of FDA approvals for the company to four, the most for any Singapore company in the bio-monitoring arena. The two other FDA approvals were for parent products A-PULSE CASP and BPro.

HealthSTATS had realised that it was hard to install the A-PULSE software in Europe due to the difference in computer language. There is also translation of languages to be done and the difference in speed processing in computers used.

So HealthSTATS came up with CASPro and CASPal, which could do away with all these troubles and come up with the central aortic systolic pressure (CASP) of the user in 10 seconds.

One-in-all device

CASP is the pressure at the root of the aorta, the biggest artery in the human body leading away from the heart. CASPal is designed for usage at home while CASPro is designed for a clinical setting.

"A-PULSE needs a computer to install, a calibrator outside, and you need a watch to plug into the USB port. But we have removed everything and it becomes a one-in-all. The BPro watch is replaced with a sensor. So you see a progression of simplifying in terms of the equipment and operation," says Dr Ting, explaining how CASPal and CASPro evolved from their parent products.

Moreover, the products have in them a set of normal ranges so that users will know if they fall out of the normal range.

"We are the first in the world to

come up with a normal range based on 3,000 normal subjects in Malaysia, Singapore and China, aged between 20 and 90 years old," says Dr Ting.

The CASPro comes with a printer. With a USB port, doctors and researchers can also export data to study trends, either inter-patient or intra-patient.

Previously, there were two ways of measuring central pressure – either an invasive method involving the insertion of a pressure-sensor tip tube into a blood vessel through the patient's groin, or paying \$60,000 to get a machine and have a trained operator use a chopstick-like device to take a patient's pulse. The latter takes at least half an hour just to get the pulse and is found in labs.

Need for detection

Now with cardiovascular diseases – heart diseases and stroke – as leading causes of death globally, there is an urgent need to detect signs of disaster before it strikes.

In Singapore, 15 people die from heart disease and stroke every day. By 2030, it is projected that almost 23.6 million people worldwide will die from cardiovascular diseases mainly from heart disease and stroke.

"There is an urgent need for technology to measure CASP," says Dr Ting. "CASPal will go into the home monitor market. In America last year, just the home market is about US\$800 million, growing at a rate of 10 per cent per year for the next five years."

But in Singapore, it was much harder to get doctors to listen about his products. So HealthSTATS had to overcome that obstacle.

"In Singapore, we turn the tables around. We empower the patients to know about CASP. The patients will then ask the doctors what their CASPs are. Doctors might think the patient is talking rubbish, but if the second, third and fourth patients all come, they think, 'I need to find out' and then they start coming to us."

"Whether our products go into the market replacing others or the public pushes the doctors to learn, CASP will be the main story soon." The same professor who told me I was mad is now giving a lecture on central pressure," says Dr Ting.

Many countries are now amending medical guidelines to include central



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pressure, creating a flurry in the medical arena. For example, the UK NICE guidelines – a guideline for hypertension treatment – is also going to be changed to include central pressure as a necessary step as part of patient management.

With these developments, the future of the new products looks rosy, reveals HealthSTATS.

At the launch of CASPal alone, about 300 were sold. And orders have continued to come in since its FDA approval. Already, there are orders for 5,000 units of CASPro coming from China.

And HealthSTATS is not planning to stop at just commercialising these products. It already has plans to commercialise and roll out more value-added products.

"We have products lined up for the next three years. We have products for stroke, we are also going to have the wireless module coming in... and all these are in different phases. Some have already finished validation, some are going through clinical trial and some are still in the early stage of development," says Dr Ting.

He says that HealthSTATS is planning to roll out the wireless model of BPro in Shanghai at the end of this year. Some 50,000 units will also be made available subsequently in four other cities in the second year, and finally 100,000 in eight cities in the third year. And in Shanghai alone, HealthSTATS already has 20,000 committed users.

Going overseas

In the wireless model, information on the user's CASP will be transmitted to the user's mobile phone which will dial up the telco, which will dump the data to their service provider platform.

Dr Ting hopes that his first-of-its-kind devices can spread to more countries. To achieve this, he has planned to expand HealthSTATS' distributorship network to about 50 countries by 2012.

Dr Ting also explains how HealthSTATS crafts different business models to suit different countries.

"It is not just about sales of the devices. We also have the rental model, the voucher model and also the top-up model, where people can buy the number of times they want to use the service. Many doctors use this model, because there is no capital outlay needed for them and whatever the difference between what they pay us and what they charge the patients, they earn it," says Dr Ting.

Having grown from revenue of a few hundred thousand to some \$4 million for its latest financial year, the small company of 20-odd staff now has several options on its plate – be it an initial public offering (IPO) or merger and acquisition plans.

"Our first choice is still IPO. We are giving serious thought to Hong Kong and Nasdaq," says Dr Ting.

"Nasdaq has analysts who are very attuned to technology and the market there can translate to technology better. That means they can raise a higher amount due to the sheer size of the market there. Hong Kong is near to us and China – which eventually will be our largest market – and has the same time zone."

"We have so many options to consider now. But having to decide all these, it is a happy problem to have... As for CASP, it is going to be a tsunami."

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