

## Stryker signs agreement to acquire Wright Medical for \$5.4bn

US-based medical technology company Stryker has entered a definitive agreement to acquire 100% of the issued and outstanding shares of Wright Medical Group for \$30.75 per share.

The deal takes the total equity value to approximately \$4bn in cash and total enterprise value to around \$5.4bn.

Founded in 1950 and with global sales reaching \$1bn, Wright Medical Group has a presence in upper extremities (shoulder, elbow, wrist and hand), lower extremities (foot and ankle) and biologics markets.

The acquisition of Wright Medical will complement Stryker's trauma and extremities business while also strengthening the latter's position in this high-growth segment.

Wright Medical CEO and president Robert Palmisano said: "We believe this transaction will provide truly unique opportunities and will create significant value for our shareholders, customers and employees.

"By merging our complementary strengths and collective resources, we will be able to advance our broad platform of extremities and biologics technologies with one of the world's leading medical technology companies that share our vision of delivering breakthrough and innovative solutions to improve patient outcomes."

The boards of directors of both the firms have approved the transaction.

Subject to customary closing conditions and approvals, the acquisition is expected to complete in the second half of 2020.

The transaction is not expected to have an impact on Stryker's net earnings and adjusted net earnings per diluted share this year.

In August, Stryker entered a definitive agreement to acquire 100% of the issued and outstanding stake in spine solutions maker K2M Group in an all-cash deal valued at around \$1.4bn.



## US researchers use biomarker blood test to reveal heart disease risk

Preventive cardiology researchers at UT Southwestern Medical Center in the US have found that a blood test for protein biomarkers could help to identify high-risk heart disease in patients currently not receiving treatment.

Researchers collected data of approximately 13,000 individuals from three notable patient populations, including multiple ethnicities.

They found that around one-third of adults suffering from mild hypertension, not recommended for treatment, had higher levels in one of the two biomarkers, indicating that those patients were more likely to suffer from heart attacks, strokes, or congestive heart failure over the next decade.

UT Southwestern Medical Center internal medicine assistant professor for preventive cardiologist Parag Joshi said: “We think this type of test can help in the shared decision-making process for patients who need more information about their risk. These blood tests are easily accessible and are less expensive than some other tests for risk assessment.”

The research team, led by Dr Parag Joshi and Dr Ambarish Pandey, studied data from notable patient populations with a mean age of 55 years who have suffered 825 cardiovascular events over a median follow-up time of ten years.

According to the team, additional studies are required to determine whether informing blood pressure treatment with these biomarkers impacts patient outcomes.

UT Southwestern Medical Center internal medicine assistant professor for preventive cardiologist Ambarish Pandey said: “One of the proteins, high sensitivity troponin, measures injury to the heart muscle and the other, called NT-proBNP, measures stress on the heart muscle.

“The presence of these proteins is indicative of subtle long-term cardiac injury, like wear and tear over time.”

High blood pressure is one of the main factors to increase the risk of several cardiovascular events. Reducing blood pressure cuts down this risk.

Additional factors that increase the risk of cardiovascular disease include high cholesterol, age, gender, smoking and poor diet, as well as lack of exercise and diabetes.



## World Health Summit 2019: what's happening in digital health?

The World Health Summit pulls together stakeholders from across the healthcare sector each year to discuss the latest innovations in the industry, from the deployment of health data to expanding access to care in remote areas. Chloe Kent profiles the highlights on digital health from 2019's Berlin conference. Speaking at the World Health Summit (WHS) in Berlin, Ada Global Health Initiative managing director Hila Azadzoy said: "We've built a very sophisticated medical reasoning engine that is combining and linking thousands of symptoms with thousands of conditions, from communicable to non-communicable to rare disease, bringing that all together to have a system in place that can compute common and complex symptom constellations within minutes."

Ada aims to free up clinicians and empower patients, and is having a strong impact in low- and lower-middle income countries. One third of the app's user-base is concentrated in these resource-limited settings, where quality healthcare can be out-of-reach for many patients.

Azadzoy said: "Over four billion people lack access to even basic primary healthcare services, and that's due to a massive shortage of healthcare workers all around the world as well as geographical and huge financial barriers. The ones that have access may not necessarily experience efficiency or any quality guaranteed, with countless hours spent in the waiting room to then, such as in Bangladesh, have an average consultation time of 45 seconds.

"In circumstances like there, where access is constrained and misdiagnosis can happen very easily, we fundamentally believe that AI and mobile technology can make a huge difference. Traditional models of healthcare delivery will not solve this huge global challenge."

Ada's medical reasoning engine can process a patient's symptoms and provide a potential cause for their condition within minutes, which they can present to their physician for formal diagnosis, saving a significant amount of time.

A median of 45% of people in developing nations own smartphones, according to the Pew Research Center, peaking at highs of 60% in South Africa and Brazil to as low as 24% in India. To increase the reach of Ada's technology, the company is looking into upskilling semi-skilled community health workers by equipping them with the technology, to help them diagnose and treat patients whose conditions would be otherwise beyond their reach.

### **The gamification of prevention**

Researchers at the Berlin Institute of Health have developed two mobile apps, Smokerface and Sunface, designed to shock users into cutting down on smoking and minimise UV exposure. Berlin Institute of Health chair for clinical translational sciences Christof von Kalle said: "These apps are gamification of prevention. They teach people what they are going to look like if they smoke X packs of cigarettes or expose themselves to X decades of sunlight."

Simply snap a selfie and upload it to one of the apps, and they'll use AI to show you a picture of what your face could look like after years neglecting your health. These aren't perfect renderings – the 'five-year' predictions are arguably somewhat exaggerated – but as the algorithm animates the face to cough and grimace, it's undeniably effective.

von Kalle said: "One of the most effective things you can do in healthcare today is spread this app with five people you know, the younger the better."

### **The life-saving power of mobile technology**

Poor families in Sub-Saharan Africa and other resource-limited regions often have no assured regular financial income, meaning traditional health insurance companies are rarely willing to cover the costs of their care when they all ill. This means out-of-pocket payments are the primary way of covering healthcare costs in these areas, even when these expenditures often exceed the budgets of most low-income households. However, over the last ten years mobile phone ownership has more than doubled in low- and middle-income countries, with mobile payment services now acting as a common alternative to cash. Mobile money enables consumers to send, receive and store virtual money via their mobile devices.

This initially allowed digital insurance products to spring up as loyalty schemes between mobile money operators and their customers, which are still available at scale and easily verifiable.

## Roundtable: choosing a contract device manufacturer

Medical device contract manufacturing is a rapidly growing sector, with the market expected to reach a value of more than \$91bn by 2024 from just \$55bn in 2019. But for medical device firms considering outsourcing the manufacturing of their devices to a contract operator, what are the biggest risks and rewards? In this roundtable feature, we find out the industry's perspective. What are the biggest risks when outsourcing device manufacturing?

**Martin Cowie:** Large medical device companies often lack a senior understanding of 'digital' and outsource in fear of missing out on cutting-edge techniques and approaches. But they are usually sold a 'pig in a poke', as they cannot really do due diligence on this due to lack of familiarity and even understanding of the lexicon. This often leads to overspending and under-delivering.

**Andrew Thompson:** Regulation presents the biggest risk. Manufacture of medical devices is highly regulated, but it differs depending on jurisdiction. US uses licenced facilities, Europe looks to ISO-13485 accreditation, and others. This is the biggest risk; if the original equipment manufacturer (OEM) is inexperienced in medical devices, issues can arise that can drastically affect whether devices are marketed. If the OEM operates in multiple industries like electronics or metal fabrication, then generally a separate workforce is needed for that specific product.

It requires manufacturers to establish good communications with their outsourcing partners, usually through dedicated personnel. Sometimes involving them during development helps; many of the bigger ones have development and prototyping facilities of their own. This helps integration of the production line.

**Kurt Wanless:** For any medical device developer, protecting their brand and reputation is paramount. An outsourcing partner is, in many respects, a direct extension of the developer's brand. As a result, it is important to select a partner that matches the developer's values.

The selection should extend beyond simple financial criteria. The partner must be capable of delivering products to the highest standard of quality and regulatory compliance within the required timeframe. Another part of the decision-making process should be the outsourcing partner's ability to provide services needed for success. In selecting an outsourcing partner, it's a good idea to visit the partner's locations to get a more detailed perspective on how they will support your business and the depth of their capabilities.

### How can companies spot a good business fit when they're looking into outsourcing?

**David Guez:** I think it depends on the deeper conversations we have. The most important thing is to have someone we want to speak with who understands that we are going to take a decision together, whether that's someone inside a bigger organisation or a start-up. AT: Good OEMs will only do medical devices, and will have a highly developed understanding of medical devices from a regulatory viewpoint. It's making sure these companies have personnel already in place with the appropriate competencies and the managerial level.

**KW:** Finding the right fit in both company culture and business profile is vital as manufacturers vary in levels of experience, capacity and ability to understand product complexity. The partner should be able to demonstrate strength and in-depth knowledge in the OEM's field of expertise. If a company is designing a renal denervation system or a surgical robotic device it would be sensible to partner with an outsourcing provider with similar experience. Is the partner experienced in manufacturing to FDA Class II or III standards? Does the partner have experience managing related regulatory standards such as cyber security and business continuity planning? A good partner has the foresight to predict and eliminate potential obstacles before they arise. At the same time, when unexpected issues arise a good partner will also have the resources and expertise to turn around projects in a short space of time and rethink or revise processes during the manufacturing cycle to solve problems and avoid time-to-market delays.



## Roundtable: choosing a contract device manufacturer...Contd.

### What are the benefits of outsourcing?

MC: Without outsourcing, small digital tech start-ups cannot afford to have staff for many functions as they move from one stage of development to another. DG: Faster innovation. It means that you're going to accelerate the product, building an outsourced portfolio. It's in parallel in fact. We can compare solutions and choose the best one, that's the essence of what we're doing.

AT: Medical device manufacture is often done on a batch basis. This might mean assembly lines that are only used for part of a year, and then switched or repurposed to something else. For small medical device companies, this might mean equipment lying fallow or staff furloughed. OEMs can offer flexibility in deploying staff and flexible assembly lines.

Counterfeiting can be a problem in some countries. A solution one manufacturer came up with was to have small assemblies made at different locations by different manufacturers, but to the same high precision engineering standard (in this case, plastic mouldings used in a molecular diagnostic test consumable), and assembling these at another location. Counterfeiting components could not have resulted in the product being copied.

KW: The medical device market is evolving at a rapid pace and becoming more complex and challenging. Medical device developers have to ensure that their products can be manufactured efficiently to avoid additional costs and, more critically, they have to achieve faster time-to-market. Put simply, working with the right partner can add value, reduce overheads, and speed up time-to-market to ensure that a company remains competitive.

In a perfect world, the manufacturer gets involved at the concept stage to ensure the best possible manufacturability and help support meeting target price criteria. Without this early collaboration, the developer raises the risk of delayed time to market, missed target price criteria, and operational challenges in volume production.

**Parameters for success need to be established early on. Don't underestimate a partner's ability to communicate and interact with its customers as anything less than fundamental to a project's success. Design and manufacturing partners work extremely closely with customers to ensure the end product exactly matches what is required and should, therefore, have a sound structure in place for collaboration.**

