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Now more than ever, our transformation depends on R&D

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BÄ±Ã§akcÄ±lar is one of Turkeyâ??s largest medical technology companies, selling disposables and focusing on the operating room, any hospitalâ??s most profitable part. Souheil A. ElHakim, the companyâ??s CEO, reflects on the companyâ??s 62-year history, their current portfolio and explains how the new European CE mark rules change the way they operate. Moreover, ElHakim explains how he is leveraging his past R&D experience â?? including work in the development of the first 3D free-hand ultrasound imaging system and the first digital mammography system â?? to help BÄ±Ã§akcÄ±lar innovate.

Can you begin by introducing yourself, your decades-long career in healthcare, R&D experience, and current role as CEO for one of Turkeyâ??s largest medical technology companies?

After graduating from university, I worked at a hospital in Lebanon for one year. I later moved to Canada where I truly started my career while doing a masters and PhD in biomedical and electrical engineering. During that time, in 1993, I participated with a team of seven engineers and physicians in the development of the first 3D free-hand ultrasound imaging system, improving the early detection of fetal anomalies; we sold the rights to Vital Images.

I remained in North America until 1998 when an opportunity sent me to France where I joined Admiral, an IT company. But my affinity to medicine landed me a job at GE medical systems, where we specified and designed numerical algorithms of the first digital mammography system.

My next step was Medtronic, where I spent 15 years in various leadership positions, including a year as interim director for the Turkish affiliate and director for some businesses in Western Europe. When you move up an organization such as Medtronic, you are able to push the senior top management and change the way business is conducted. We implemented new models to go beyond the regular selling of products, switching to solutions.

Reflecting on all these years, I am proud to be part of the healthcare industry, especially during the COVID-19 pandemic.

I joined BÄ±Ã§akcÄ±lar as CEO in June 2017, leading its operations and strategic direction with full responsibility for bottom-line factors including short to long term planning, operational and production efficiencies, new product development and management, new strategic alliances with innovation hubs, international commercial expansion, and government relations.

The company started with simple things: suction systems, heater coolers for cardiac surgery. A few years later, the company began producing disposables. In 2011, the company was acquired by an institutional investor, no longer being run by the family. I joined in 2017 with the mandate of transforming the company.

Speaking about the COVID-19 pandemic, what role did BÄ±Ã§akcÄ±larâ??s products have and how was the company affected by protective measures taken by the Turkish authorities?

Since we produce many of the products we sell, the Ministry of Health forbade us to export some of our products for a short period of time, which was fine because we wanted to prioritize Turkey as well. We were asked to reserve some of our production for only two months.

In my opinion, the entire pandemic was extremely well managed in Turkey. The authorities were able to provide support for people in need, implemented smart lockdowns and supported the healthcare industry as well.

Internally, we also managed to keep our employees safe, implementing mask mandates early on; not one of our 800 employees got infected at work. However, we had employees with COVID who acquired it outside the company.

The diversity of our portfolio helped maintain a healthy and balanced operation; elective surgery products declined but were offset by our solutions and equipment for ICUs. For instance, the demand for surgical aspirators skyrocketed.

We were able to foresee the disruptions in the supply chain, therefore we took precautions by increasing our inventory of raw materials which allowed us to continue producing without any interruption.

In terms of portfolio, what is the current focus of BÄ±Ã§akcÄ±lar and how does the upcoming product pipeline look like?

We sell disposables in different sectors, we also specialize in OR solutions technologies such as OR tables, lights and aspirators. We are enhancing our technology portfolio by developing more accessories and enabling technologies to serve both the cardiac and neurosurgical spaces.

Part of our upcoming pipeline includes a solution to treat incontinence in women, a condition suffered by one in four women over the age of 18. In comparison to the current products available in the market, our solution can be adjusted easily without the need of going back to the operating table; and in this sense, it has innovative features.

Having worked in the R&D of innovative medical technology during your career, obtaining several patents along the way, how do you describe the difference between R&D in pharma and medtech?

They are not so different except for the fact that in medical devices we do not rely much on animals. For medical technology products, it really depends on the type of project you want to develop, they are classified as class I, II, or III. The differences between the classes are mostly risk, amount of contact with a patient and their internal systems, and whether a device is critical to sustaining life.

Regarding the process, you create a prototype that goes through pre-clinical testing, the same as with pharmaceuticals. After receiving approval from the notified bodies, regulatory bodies, then you can proceed with human testing and trials. Medical device development requires substantial investment for clinical trials, biocompatibility, biotoxicity, sensitivity, stability, and so on.

In May of this year, *ConformitÃ© EuropÃ©enne* (CE) mark regulations changed, changing the regulatory environment in Europe. Before, bringing a product to the market required companies to follow guidelines and pay a fee; that is why I had reservations about some products since it was not clear how much testing was done. With the new regulation, any new medical device must follow the EU MDR (Medical Device Regulation); it regulates every aspect of the device, even the companies behind its production, from raw materials to the finished product.

This process is extremely expensive and requires highly specialized skills. In BÄ±Ã§akcÄ±lar, for example, we have a medical doctor on staff and a team working on the technical documentation which is sometimes ambiguous but extremely rigorous. Fortunately, we at BÄ±Ã§akcÄ±lar were ready for this moment, initiating the new CE process two years ago and obtaining the MDR compliant certification a couple of months ago.

The certification provided to companies is given by notified bodies that are licensed by the European Union and, after achieving the CE mark, the process to get US FDA approval is straightforward.

Having to navigate a highly competitive market, which companies do you consider to be your main rivals and how do you interact with them, if at all?

We do not see ourselves competing with others but we consider each company that has an overlap of services with us brings a different set of values to the market. Therefore, we do not see companies as competitors but potential partners because, for example, we produce for several multinational companies.

Our focus is the surgical space. Through the years we acquired knowledge about the workflow and developed the technology that serves it.

With your unique research and development experience for multinationals as a backdrop, can you outline BÄ±Ã§akcÄ±larâ??s approach to R&D?

Now more than ever, our transformation depends on R&D. Historically speaking, BÄ±Ã§akcÄ±lar was a manufacturer for only the Turkish market. The country wanted to be less reliant on imports, so there was more emphasis on localized production and less on innovation. Throughout the years, the company realized that it was too risky to depend on a single market and searched for international opportunities. But, to succeed abroad, you must add value through innovation.

We found a way to boost our innovation, investing in our internal capabilities while working with third party R&D hubs. One of our agreements is with a company based in Ankara where our teams work closely together on an exclusive basis.

We also have an agreement with the largest Turkish defence company, Aselsan, which has a sub-unit focusing on medical devices.

The company has promoted its international reach as a key selling point. Where do you sell and through which models? Do you have your own affiliates in other markets?

Internationally, we sell through distributors exclusively and directly to multinationals for their private labels. We do not see it as reasonable at this stage to have a direct presence in most markets, but having scientific offices is being seriously considered. Western Europe is currently the heart of our business abroad, as most of our international sales come from this market.

Has the company thought about going public as an enabling factor for its international expansion?

That is extremely possible, but I cannot comment more at the moment.

Digitalization has become the biggest buzzword in the medtech industry, with many multinationals investing heavily to increase their digital capabilities. Is that an important element for BÄ±Ã§akcÄ±lar?

I look at digitalization in two different ways. The first one is internal, looking at ways to use our systems and tools to make our operations more efficient. The second is external, looking to transform some of our solutions into automatic data collectors. Connectivity has become affordable today but there are some issues related to standardization.

How is BÄ±Ã§akcÄ±lar addressing the issue of sustainability as a strategic business decision?

It is a United Nationâ??s mandate for a good reason. As a healthcare company, we should not harm the environment, it would be very hypocritical since it has a direct impact on the patients and people we are trying to help. We are looking to implement more recycled materials in our production as a way to contribute. Moreover, as an example, when we use ETO, a toxic gas used for sterilization, we apply an incinerator. Energy is another way to reduce our footprint. All of this will help us contribute to a safer environment and reduce the costs of production.

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