AFTER three decades during which the treatment of end-stage renal disease (ESRD) has altered very little, things are at last starting to change. And one of the companies driving that change is Alcester, UK-based Quanta Fluid Solutions Ltd., a venture-backed concern that is hoping to make its market debut later this year.

Also known as chronic renal failure, ESRD occurs when kidney function is below that needed to sustain life. Its leading causes are diabetes and hypertension, which between them account for around 70% of cases. African Americans are about three and a half times more likely to develop the condition than Caucasians, and Hispanics about one and a half times more likely. Overall, ESRD is more common in individuals aged 70 years or more.

According to the Centers for Disease Control and Prevention, there were some 300,000 hemodialysis patients in the US in 2011. Worldwide, there were 2.75 million patients with ESRD in that year. Fewer than a quarter of ESRD patients are currently living with a functioning transplanted kidney.

For a long time, the mainstay of ESRD treatment, for those patients not fortunate enough to receive a transplant, has been dialysis, of which there are two types: hemodialysis and peritoneal dialysis. Although the technologies differ in the way they are performed, the principle is the same: waste matter and excess fluid are removed from the circulation by passing the blood over a semi-permeable membrane. In the case of hemodialysis, the blood flows through an external filter that incorporates an artificial membrane, whereas in the case of peritoneal dialysis, the patient’s own peritoneal membrane is pressed into service as the filter. In either case, waste matter is removed from the blood across the membrane by a process of osmosis. Currently, approximately 90% of dialysis patients receive hemodialysis.

Traditionally, the dialysis market has been dominated by a handful of international companies: Fresenius SE & Co. KGAA of Germany, Baxter International Inc., and Gambro AB (which since last September has been part of Baxter). Fresenius offers a complete line of instrumentation and consumables for chronic dialysis and products specifically targeted at acute and home therapy. Baxter also offers a full line of dialysis products, with an emphasis on peritoneal dialysis, while Gambro’s offering...
Medical Devices

includes products for hemodialysis and related therapies. Toray Medical Co. Ltd., part of the Japanese chemicals, plastics, and textiles conglomerate Toray Industries Inc., is also a major manufacturer of hemodialyzers and hemodialysis machines – in fact, the widely used closed circuit system was invented by Toray. Other, smaller players in the dialysis market include Nipro and Nikkiso of Japan, and NxStages Medical Inc. of the US.

The complicated nature of conventional hemodialysis, with the need for skilled personnel to operate the equipment, together with factors such as patient passivity and reimbursement patterns, have meant that the procedure has traditionally been carried out by health care professionals in dedicated dialysis centers. The advent of peritoneal dialysis some years ago was a turning point in the sense that the patient could remain ambulatory during treatment and, for the first time, treatment in the patient’s own home became a realistic option. However, not all patients are suitable for peritoneal dialysis, and there has therefore been a trend in recent years to look at ways of performing hemodialysis in the patient’s home, rather than in the dialysis center or hospital.

There are some attractive benefits associated with home hemodialysis. According to the National Kidney and Urologic Diseases Information Clearinghouse in the US, the big advantage is that it lets the patient set the schedule, so that he or she can choose treatment times to fit in with other activities. In addition, it can be carried out more frequently than dialysis at a clinic – this means that waste materials do not build up in the body to the same degree, which in turn means that patients feel better and have more energy. Furthermore, there is abundant evidence that patients on home hemodialysis have better blood pressure control, requiring fewer drugs, better control of phosphatemia, fewer restrictions on diet and fluid intake and, not least, display better survival rates

A good example of the growing interest in home hemodialysis is the UK, where the National Health Service (NHS) has set a target for 15% of hemodialysis patients to be treated in the home.

A good example of the growing interest in home hemodialysis is the UK, where the National Health Service (NHS) has set a target for 15% of hemodialysis patients to be treated in the home.

Heading for Home Markets

More recently, systems better suited to the home environment have started to appear. One of the pioneers of this type of treatment is Lawrence, MA-based NxStages, whose System One hemodialysis system was approved for use in hospitals and clinics in 2003. NxStage describes the system as offering the benefits of traditional dialysis machines “in a smaller, portable, easy-to-use form that can be used by health care professionals and trained lay users alike in a variety of settings, including patient homes.”

By contrast, System OneOne to the clinic, rather than directly to patients. Most customers buy rather than rent the systems. System One is still NxStage’s primary product (it also sells blood tubing sets and arteriovenous fistula and apheresis needles), accounting for approximately two-thirds of the company’s sales. In 2013 sales stood at $263.4 million, the majority of which were achieved in the US.

It is fair to say that the System One device has played a pivotal role in developing the home hemodialysis market in the US and elsewhere. Nevertheless, critics of the system say it has a number of limitations. For example, it works on a batch system: a batch of dialysate must be prepared before the system can be operated; once the batch has been exhausted dialysis must cease. This limits both the flow rates and session duration System One can support, limiting the dose and requiring more frequent dialysis sessions to achieve adequate clearance. This bears an important cost implication, as a complete set of consumables is required for each session.

Now, however, NxStage’s dominance of the home hemodialysis sector looks set to be challenged by the new kid on the block, Quanta Fluid Solutions. Quanta has developed a hemodialysis system that the company’s CEO, John E. Milad, says offers a number of advantages over existing systems. Quanta’s hemodialysis system is called SelfCare+. Although its name might suggest that it is targeted primarily at the home market, it is in fact equally appropriate for the domestic and clinic settings, and Quanta plans to market it for use in both locations. The fact that patients would be able to use the Quanta system in the dialysis center, and then begin home hemodialysis using an identical system, gives SelfCare+ an obvious commercial advantage.

Quanta describes SelfCare+ as compact, portable, intuitive to use, and uncomplicated in operation. This flexibility is achieved by using a disposable cartridge to generate dialysate for each treatment session, and to act as a fluid control system. The user interface has been designed following input from clinicians, nurses, and patients, together with close collaboration with the NHS Devices for Dignity program in the UK, meaning, Quanta claims, that training times for patients are significantly shorter than for traditional dialyzers.

SelfCare+ uses the same dialyzer technology as traditional hemodialysis systems – its
novelty lies in the disposable fluidic management cartridge. Milad refers to this as "design conservatism"—another expression might be "not reinventing the wheel." Whatever you call it, it makes sense: Quanta has no special expertise in membrane technology, so using traditional materials and techniques is a sensible approach. But the company does have considerable strengths in the management of fluid flow, and playing to these strengths means lower risk and lower capital requirements in the product development process.

The SelfCare+ cartridge itself is quite small: made of injection-molded polycarbonate, it is approximately 25 cm square by 1 cm thick. Depressions on its surface represent the fluid channels and other fluidic circuits. A PVC film made of injection-molded polycarbonate, it serves in the product development process. Considerable strengths in the management of fluid flow, and playing to these strengths means lower risk and lower capital requirements in the product development process.

The SelfCare+ cartridge itself is quite small: made of injection-molded polycarbonate, it is approximately 25 cm square by 1 cm thick. Depressions on its surface represent the fluid channels and other fluidic circuits. A PVC film made of injection-molded polycarbonate, it serves in the product development process. Considerable strengths in the management of fluid flow, and playing to these strengths means lower risk and lower capital requirements in the product development process.

IMI developed the hemodialysis cartridge system as far as proof of principle. This of course led to a major decision point in the development process—whether and how to proceed. One of the major issues that IMI faced was how to approach the medical device regulatory process, a daunting challenge for a non-medical company and something of which IMI had no experience. For this and other reasons, IMI took the decision to spin out the new technology, thus leading to the birth of Quanta in 2008.

MOVING TOWARD COMMERCIALIZATION

IMI funded Quanta for its first year, but the other significant point was reached when it was realized that venture backing of the fledgling company would be needed. A £9 million (€14.3 million) Series A round followed in September 2009, with support from three investment groups: NBI Ventures, a venture capital fund with a focus on medical technology companies; Seroba Kernel, a European life science venture capital fund; and Wellington Partners, a pan-European venture capital group based in Germany.

At the time, Milad was investment manager at NBI, and he joined the board of Quanta in 2009 to guide the company’s development.

The board went on to appoint him CEO in January 2014, based not only on the five years that Milad had already spent with the company, but also on his boardroom experience with other life science companies that had made a similar commercial journey—such as the Swiss specialty pharma company Nitec Pharma (now part of Horizon Therapeutics).

For his part, Milad, who also has experience in the banking sector, was convinced (and still is) that Quanta will be an exceptional success story. Although Quanta’s investors may have an eventual exit strategy in mind, Milad is adamant that the company’s primary focus is on developing and proving the value of its platform and growing into a scalable, sustainable business.

To bring the SelfCare+ system to international markets, Quanta is adopting the now frequently used strategy of first obtaining CE marking, and gaining initial experience in EU markets, before tackling the bigger US market. Milad says that the company hopes to be awarded CE certification and to get the first patients using the system by the end of this year. It is currently raising a pre-IPO round of funding to finance the commercial launch.

Unsurprisingly, the UK is likely to be the first market to be addressed: all dialysis services in the UK are funded by the NHS through just over 70 renal trusts—which means in effect that there are a manageable number of customers to be persuaded of the benefits of the SelfCare+ system. The company anticipates a “soft launch” targeting a limited number of carefully selected centers from which to generate initial clinical feedback, establishing confidence in the system's performance and cultivating national centers of excellence. This phase will be followed by a broader rollout in the UK and other European markets. Milad says that Quanta will sell direct in the UK, and in other geographies will consider the various options on a case-by-case basis. Pricing strategy has yet to be announced, but the company’s intention is to price the system to fit within existing reimbursement levels.

In the US, Quanta will be working toward 510(k) clearance in 2016, with US introduction soon thereafter; the US Centers for Medicare and Medicaid Services funds 85% of all dialysis therapies.

Quanta says it believes the mushrooming demand for increased dialysis capacity across the world will drive the demand for innovative solutions like the SelfCare+ system. With the system being designed specifically to address the needs of the self-care hemodialysis sector, in both the in-center and in-home settings, the signs are that it will go a long way to meeting this demand.

© 2014 by Informa Business Information, Inc., an Informa company. All rights reserved.