BTG

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Driving innovation in interventional medicine

BTG combines medicines, device technology and new techniques to deliver more targeted treatments, and is leading the way in bringing these innovative interventional medicine therapies to market.

mage-guided, minimally invasive therapies are fast replacing traditional surgical procedures and, where appropriate, systemic drug treatments, bringing many benefits to patients and physicians. The trend is driven by improvements in imaging technologies, coupled with interventional medicine techniques that use relatively small access points into the body, such as a minor leg incision to gain arterial access or entry via the airways to treat a lung.

BTG is an international specialist healthcare company with a growing portfolio of innovative interventional medicine therapies inspired by the needs of specialist physicians and their patients. **CO** "We have products in our portfolio that really benefit patients, are important to the physicians who use them and have a great impact on clinical outcomes," said Peter Stratford, chief technical officer at BTG. "It's that real focus on what is important to patients and the physicians who use our products that I think sets us apart from other companies."

Growing portfolio

Alongside BTG's specialty pharmaceuticals and licensing operations, interventional medicine is now BTG's fastest-growing business area. Established through a series of strategic acquisitions, the portfolio includes interventional oncology, vascular and pulmonology products (Fig 1).

BTG entered interventional oncology in 2011 when it acquired Biocompatibles International and its portfolio of embolizing and drug-eluting bead products for the treatment of liver tumors. TheraSphere, which comprises millions of glass microspheres containing radioactive yttrium-90, was added to the product line after acquisition from Nordion in 2013.

BTG's interventional vascular business also grew in 2013 when the company acquired EKOS Corporation and its EkoSonic Endovascular System, which uses innovative ultrasonic accelerated thrombolysis technology to treat severe blood clots and pulmonary embolisms. The device complements BTG's Varithena (polidocanol injectable foam) product, launched in the United States in 2014 to treat varicose veins.

More recently, BTG entered the emerging area of interventional pulmonology after completing the acquisition of PneumRx and its PneumRx Coil in early 2015. This innovative treatment for patients with advanced emphysema consists of small shape-memory Nitinol implants designed to tighten the airway network when placed in a diseased lung.



Figure 1: BTG has a growing interventional medicine portfolio comprising interventional oncology, vascular and pulmonology products.

Underserved patient populations

Together with physicians, BTG identifies the unmet patient and physician needs that can be met by novel, minimally invasive solutions. It then supports these efforts with significant investments to generate high-quality data that enhance the potential of the new therapy. In 2014, the company invested more than US\$100 million in R&D, over half of which funded indication expansion and product innovation.

For example, since acquiring TheraSphere, BTG has accelerated three phase 3 trials of the product in the United States to support pre-market approval (PMA) applications for advanced hepatocellular carcinoma and second-line treatment for patients with metastatic tumors in the liver from colorectal cancer. There is also a fully recruited phase 3 study in the United States to support a PMA application for the PneumRx Coil, as well as a pivotal study to support label expansion of EkoSonic into the treatment of chronic deep vein thrombosis and post-thrombotic syndrome.

Once new therapies are approved, BTG measures endpoints such as patient quality of life and cost-effectiveness, which are important to payers and for physicians making a case for their use within a hospital system. "We bring real focus and an understanding of the interventional medicine area, including how to work with novel technology, how to generate the clinical data and how to work with the payers and reimbursers, to make sure that those products are successful," said Stratford.

Importantly, BTG's capabilities include bringing drug-device combinations to market, a process that can be complex from a regulatory perspective. "As the world of medicine becomes more complicated, some things cease to be easily characterized as either a medicine or a device, and from that point of view I think we are very well placed," said Stratford. Varithena, for example, combines a proprietary microfoam-generating device with a low (1%) concentration of the sclerosing agent polidocanol and is regulated as a drug by the US Food and Drug Administration (FDA). It was FDA approved in November 2013 for patients with incompetent veins and visible varicosities of the great saphenous vein system.

Geographic expansion is another growth driver for BTG; it recently opened a regulatory and medical hub in Hong Kong supporting expansion in Asia, and established new direct-sales

forces in Europe and Taiwan. The company's bead product was recently approved in China.

Future opportunities

BTG is set to become a world leader in interventional medicine therapies by 2021, and expects to earn over US\$1.25 billion of revenue through organic growth of the current portfolio. The company remains open to relevant partnering or acquisition opportunities, focusing on products and expertise that complement its core areas in interventional oncology, vascular medicine and pulmonology. "In particular, we would seek to acquire high-content technologies that offer opportunities to maximize potential through our unique capabilities," said Charles Brigden, head of business development at BTG. "We also continue to seek opportunities to build our established specialty pharma business."

In return, potential partners can benefit from BTG's growing interventional medicine sales force, regulatory capabilities and careful approach to integrating the businesses it acquires. "The benefit for the partner or acquired company is that they retain the entrepreneurial nature of their business and are able to realize their ambitions, but with the support, resources and infrastructure of BTG," said Brigden.

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