



Global Medical Solutions
MD&D Business Review
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The Global Medical Solutions (GMS) Group is a diverse portfolio of businesses which compete in large markets that address pressing needs in the global healthcare arena. In 2011, GMS generated \$9 billion with market-leading positions. The portfolio includes:

- Lifescan and Animas:** blood glucose meters and insulin pumps for people with diabetes,
- Johnson & Johnson Vision Care:** contact lenses for vision correction,
- Advanced Sterilization Products (ASP):** infection prevention solutions,
- Ortho Clinical Diagnostics (OCD):** in-vitro diagnostics (IVD) and transfusion medicine products, and
- Sedation Systems Business Unit:** computer-assisted personalized sedation technology.

Johnson & Johnson Family of Diabetes Companies

Johnson & Johnson has a long history of patient-centric innovation and market leadership in the diabetes category. For example, LifeScan, Inc. helped pioneer today's blood glucose monitoring market with the introduction of the original OneTouch[®] Systems that made home blood glucose testing simple and accurate for the first time. The OneTouch[®]Ping[®] Glucose Management System was the first to integrate a full- function insulin pump with a blood glucose meter that also operates the pump remotely. And our newest glucose monitoring platform, OneTouch[®]Verio[®], offers the first and only blood glucose monitoring systems to identify patterns of high and low blood glucose and alert patients right on the screen.

With the shared vision of "Creating a world without limits for people with diabetes," there are five members of the Johnson & Johnson Family of Diabetes Companies:

- **LifeScan, Inc.**, a world leader in blood glucose monitoring,
- **Animas Corporation**, maker of innovative insulin delivery systems,
- **Calibra Medical, Inc.** maker of a unique, wearable mealtime only insulin patch,
- **Children with Diabetes, Inc.**, a community offering support and education for children, adults and their families living with diabetes, and the
- **Johnson & Johnson Diabetes Institute, LLC**, that empowers healthcare professionals with education and training programs to improve the quality of life for people with diabetes.

Glucose Monitoring Product Portfolio Highlights:

- OneTouch[®] Verio[®] IQ Glucose Monitoring System is based on our newest technology platform and is designed for accuracy and precision. OneTouch[®] Verio[®] products with PatternAlert[™] Technology are the first meters to find patterns of high and low blood sugar and provide alerts right on the screen. With every test, the meter compares the current result with previous results and alerts the patient when it finds a pattern. This enables the patient and their health care professional to more easily recognize the issue and take action.
- OneTouch[®] Verio[®] Sync Glucose Monitoring System will wirelessly send glucose results to an Apple iPhone, iPad or iPod touch & allow users to view, manage & share their diabetes-related information—including pattern alerts—from their mobile device. The product is pending 510K clearance.
- OneTouch[®] SelectSimple[™] Glucose Monitoring System was specifically designed to meet the unique needs of emerging markets. With no set-up, no coding, and no buttons, it makes testing blood sugar easier and faster. To help patients understand what their results mean, preset audio and visual alerts signal high or low blood sugar requiring action. Priced to make testing more accessible in emerging markets, the product was launched in India and is now available in eight countries in Asia Pacific including, China, Korea and Indonesia as well as Russia and Mexico.
- OneTouch[®] Verio[®] Pro+ Glucose Monitoring System meets the needs of point of care facilities throughout ASPAC & EMEA where patients visit their local hospital or outpatient clinic for periodic glucose testing and counseling. Based on our OneTouch[®] Verio[®] platform, it is specially designed so healthcare professionals can provide care in a high-volume, multi-patient setting with confidence. The product became available in Malaysia in August and will be launched in 22 countries, including China, throughout 2013.

Insulin Delivery Product Portfolio Highlights:

- Wearable Mealtime Only Insulin Patch. In July 2012, the Johnson & Johnson Family of Companies acquired Calibra Medical, Inc. of Redwood City, CA. Calibra Medical is the developer of a unique, wearable three-day insulin patch designed to offer a convenient and discrete mealtime insulin dosing option for people with diabetes who take multiple daily injections (MDI) of insulin. This new wearable insulin patch is intended to make it easier for patients to adhere to their prescribed mealtime insulin therapy and help them achieve and maintain good diabetes control.
- OneTouch[®] Ping[®] Glucose Management System is the first system to integrate a full-function insulin pump with a blood glucose meter that also operates the pump remotely.

OneTouch®Ping® gives pumpers the option to use the meter-remote or the pump unit directly for many glucose management functions like calculating and delivering a bolus.

- Animas®Vibe™ Insulin Pump and CGM System integrates Dexcom continuous glucose monitoring technology with an Animas insulin pump providing adults living with diabetes even more options for improved blood glucose control than when on MDI or with pump therapy and SMBG. The advanced Dexcom® G4™ Platinum sensor is approved for up to seven days of wear. It is the only CGM-enabled pump that is waterproof (up to 12 feet for 24 hours) and has a high-contrast color screen for outstanding readability. The Animas® Vibe™ System is currently available in Europe. Now that the FDA has approved Dexcom's G4 Platinum continuous glucose monitor, we are committed to submitting the PMA for our joint Animas® Vibe™ Glucose Management System as soon as possible.

Future Innovations:

- Closed-loop insulin delivery. In January 2010, Animas began collaborating with industry, academia and advocacy organizations, like the JDRF, to develop a significant advancement in treating type 1 diabetes: closed-loop insulin delivery. Recently, we completed the 2nd phase of human studies and the data have been accepted for presentation at the Advanced Technologies and Treatments for Diabetes (ATTD) meeting in Paris, France (Feb.27 – March 2). We are encouraged by the positive data we have seen in our clinical studies to date. Our path forward will focus on the development of an algorithm that will predictively manage low glucose—a major unmet need in pump therapy today.

The Johnson & Johnson Family of Diabetes Companies are well positioned for continued leadership and success in the category as we continue to drive innovation in our core businesses while entering and creating new market segments to more fully meet the needs of patients throughout their lives with diabetes along the continuum of care.

Johnson & Johnson Vision Care, Inc.

Johnson & Johnson Vision Care, Inc. is the world's leading innovator and manufacturer of disposable contact lenses. Anchored by its mission to bring healthy vision to everyone, everywhere, every day, the Company has set industry standards through groundbreaking technology and revolutionary products. Its best-selling ACUVUE® Brand revolutionized the contact lens industry with the world's first disposable soft contact lens in 1987 and has since introduced numerous first-to-market innovative products.

Recent additions to the ACUVUE® Brand portfolio include:

- Designed to keep eyes looking white and healthy, *1-DAY ACUVUE® TruEye®* Brand Contact Lenses, the world's first daily disposable silicone hydrogel lens, is a breakthrough in

contact lens technology with a distinctive balance of properties that enables it to offer exceptional comfort, comparable to a contact lens-free eye.

- *1-DAY ACUVUE® DEFINE™ NATURAL SHINE™* is designed to enhance the natural beauty of one's eyes in a subtle, yet meaningful way. The lens provides bigger eyes that look naturally sparkling and luminous every day without compromising comfort or health.
- Along with the health and convenience benefits of wearing a fresh contact lens every day, *1-DAY ACUVUE® MOIST®* Brand Contact Lenses for ASTIGMATISM feature a proprietary *BLINK STABILIZED™* Design, which harnesses the natural pressures of a blinking eye to help keep the lens in place and quickly realign the lens if it rotates out of position, providing wearers with consistent, all-day vision.

The Vision Care Institute™, LLC, a Johnson & Johnson Company, (www.tvciedu.com) is an innovative professional resource for eye care providers. Headquartered in Jacksonville, Fla., with 17 centers around the world, these state-of-the-art facilities give participants a rare opportunity to experience the latest in vision diagnostic and treatment technologies through hands-on instruction, including training on contact lens fitting and prescribing. More than 70,000 (8,500 US) attendees have received training worldwide.

ASP

One out of 20 hospitalized patients will contract a healthcare-associated infection (HAI), according to the Centers for Disease Control and Prevention. ASP (Advanced Sterilization Products) is a global developer of innovative infection prevention solutions and educational programs. For over 25 years, the company has been dedicated to protecting patients, healthcare workers, and the environment with technology, products, and services that focus on raising the standard of care.

Infection Prevention Platforms and Key Product Lines

ASP's four global business platforms* are targeted at helping healthcare facilities raise the standard of care for patients and reduce the risks and costs of Healthcare Associated Infections (HAIs):

- Terminal sterilization is a process whereby the medical device is sterilized in its final container and available for immediate or later use. Offering the highest level of sterility assurance, ASP's STERRAD® System technology is the proven leader in advancing sterilization practices. STERRAD® Systems provide fast, terminal sterilization using low-temperature hydrogen peroxide gas plasma technology.
- High-level disinfection ensures delicate endoscopes and semi-critical medical devices are disinfected for patient use. ASP's high-level disinfection solutions—such as the EVOTECH®

ECR— reduce the labor and time involved in manual endoscope processing. This product was the first FDA-cleared high-level disinfection system that eliminates the need for manual cleaning of endoscopes.**

- Automated Area Decontamination (AAD) is an important complement to traditional healthcare facility cleaning. ASP's newest infection prevention technology, GLOSAIR™ Automated Area Decontamination, provides effective and thorough disinfection of patient environments when used as directed as an adjunct to manual cleaning. GLOSAIR is currently not available in the U.S. market but is available in other markets around the world.
- Hand hygiene is one of the most effective ways to prevent the spread of infections and the core of our Healthcare Antisepsis Solutions (HAS) platform. ASP offers a full line of MICROSIELD® Skincare Products in many parts of the world to keep skin clean and protected from the risk of infection.

** Not all products are available in all markets.*

*** Does not eliminate bedside precleaning. Manual cleaning of medical devices (endoscopes) is not required prior to placement in the EVOTECH® ECR when selecting those cycles that contain a wash stage.*

Ortho Clinical Diagnostics

The Ortho Clinical Diagnostics (OCD) franchise is a global business specializing in the development of instruments and tests for transfusion medicine and clinical laboratories. Ortho Clinical Diagnostics is a leading provider of *in vitro* diagnostic products and services, offering accurate, timely, and cost-effective solutions for screening, diagnosing, monitoring and confirming diseases. The company is committed to providing customers with products, services and process solutions to make labs more efficient in delivering the quality test results doctors and patients need. For nearly 70 years, Ortho Clinical Diagnostics has pioneered some of the most important technological advances in diagnostics.

Recent product launches for the company include the VITROS® Immunodiagnostic Products Total PSA II and Free PSA Assays, two new diagnostic tests that aid in monitoring and detecting prostate cancer; the VITROS® 4600 Chemistry System, a state-of-the-art analyzer that delivers high-quality, reliable test results for mid- to high-volume laboratories using the same core technologies that drive reliability and efficiency throughout the company's portfolio of products; and the Avioq® HTLV-I/II Microelisa System assay, a new test developed in partnership with Avioq, Inc. to screen blood and organ donations for antibodies to human T-lymphotropic virus (HTLV) type I and II.

On December 27, 2012 Ortho Clinical Diagnostics sold the Therakos business to The Gores Group, an investment firm. This decision enables OCD to refine their focus on the core diagnostics business and better position the company to seize the defined and emerging growth opportunities in this space.

The business is committed to enabling diagnostics to fulfill its important role in the continuum of care. OCD aims to develop new growth platforms that can lead to further understanding of health and disease, enabling doctors to predict conditions and select personalized treatment opportunities for their patients.

Sedation Systems Business Unit

The Ethicon Endo-Surgery, Inc. (EES) Sedation Systems business unit was created in 2001 to establish the foundation for a transformative new medical device category in patient sedation (CAPS). The CAPS system is designed to provide trained healthcare professionals access to propofol for patients undergoing routine colonoscopy, and upper gastrointestinal endoscopy (EGD) procedures with the belief that this would encourage additional screenings, detect issues early and potentially save lives.

The business unit focused its attention on the field of gastroenterology and the diagnostic procedures that detect and help prevent colorectal cancer (CRC), a deadly disease that, when detected early, is among the most preventable cancers. The Centers for Disease Control estimates that only about one-third of Americans who should be screened are following the recommended screening guidelines. As a result, a staggering 42 million Americans remain unscreened.ⁱ

Sedation Systems worked initially with an anesthesiologist who developed the concept of CAPS. Then, gathering experts in anesthesia, anesthetic pharmacology, patient safety, drug administration technology, patient monitoring, human factors engineering, gastroenterology and nursing, Sedation Systems built upon the concept to create the CAPS system, which would respond to the colon cancer screening need.

By integrating state-of-the-art drug delivery and patient monitoring, the SEDASYS[®] System enables physician-led teams to deliver personalized sedation to healthy adult patients undergoing routine colonoscopy and EGD procedures. It automatically detects and responds to signs of over-sedation (oxygen desaturation and low respiratory rate/apnea) by stopping or reducing delivery of propofol, increasing oxygen delivery and automatically instructing patients to take a deep breath. The SEDASYS[®] System monitors and records patient vital signs and additional parameters and patient responsiveness.

In 2008, EES submitted applications for regulatory approval for the SEDASYS[®] System in the United States, Canada, Australia and the European Union. In 2009, Health Canada approved the

SEDASYS[®] System for use during colonoscopy. In 2010, the European Union granted the SEDASYS System CE Mark authorization for colonoscopy and EGD procedures. Also in 2010, the SEDASYS[®] System was approved in Australia for colonoscopy and EGD procedures. In addition, the business unit has initiated a clinical development program for the SEDASYS System in Japan.

The SEDASYS[®] System remains an investigational device in the U.S. An approvable letter was received in early 2012. To date the amendments containing information on labeling and post-approval study design have been submitted, and the business unit is currently in dialogue with the Food and Drug Administration (FDA) regarding final requirements for the independent third-party training program. The business unit is hopeful that the FDA will review the amendments in a timely fashion and issue an approval order for the SEDASYS[®] System PMA application.

The Ethicon brand is used for the products of Ethica, Inc. and Ethicon Endo-Surgery, Inc., two companies with a long history of medical innovation, which provide globally a broad range of surgical technologies and products (including sutures, staplers, clip applicators, trocars and meshes) used to treat colorectal and thoracic conditions, women's health conditions, hernias, cancer and obesity. Ethicon, Inc. and Ethicon Endo-Surgery, Inc. are part of the Johnson & Johnson family of Companies.

SEDASYS[®] is a trademark of Ethicon Endo-Surgery, Inc.

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i Seeff L, Manninen DL, Dong FB, Chattopadhyay SK, Nadel MR, Tangka FK, Molinari NM, Is there endoscopic capacity to provide colorectal cancer screening to the unscreened population in the United States, *Gastroenterology* 127, 6, 1661-1669
