The quest to develop a functioning artificial pancreas system is moving into the later stages, and if the current pace continues, it is possible a product could be ready for regulatory submission in the next few years.

What originally started as a scientific hypothesis supported by a small group of believers has grown into a competitive project now involving some of the biggest names in the diabetes device space. The quest to develop a functioning artificial pancreas system (APS) is moving into the later stages, and if the current pace continues, it is possible a product could be ready for regulatory submission in the next few years. A great deal of enthusiasm and support for this milestone is coming from the business and medical communities, which have seen this technology take tremendous leaps forward in the last 10 years, moving from concept to reality. The development and refinement of insulin delivery pumps, continuous glucose monitors (CGMs), and sophisticated computer algorithms all are credited as major factors in this progress, but improvements in those elements also have been spurred along by a business environment that has supported the right balance of competition and cooperation in one of the most interesting races to see who will be first-to-market.

The demand for innovative products for patients with diabetes is one of the most attractive opportunities in the medical device field, addressing a patient population estimated at 25.8 million in the US and 347 million worldwide. The most serious form of the disease is type 1 diabetes (T1D), and people with T1D make up about 5% to 10% of the total US diabetes population; it is estimated that anywhere from 300,000 to 400,000 of these patients rely on pumps to regularly deliver insulin.

Medtronic Inc. is the clear leader in the insulin pump market, holding an estimated 74% market share in the US, and the company also is one of the two leading CGM manufacturers with its Guardian REAL-Time Continuous Glucose Monitoring System. The US CGM market, valued at $250 million according to Raymond James Financial Inc., is virtually evenly split between Medtronic and DexCom Inc., which produces the G4 Platinum CGM.

Medtronic Achieves Important Milestones

One of the essential elements of creating an artificial pancreas is combining a pump with a CGM, and as the only major company that produces both types of products, Medtronic has been in an enviable position for a while when it comes to developing an APS. Additionally, the company has vast resources to aid its product development efforts, and this has enabled the firm to both invest in in-house research and make acquisitions of smaller companies with innovative diabetes technologies. In the first quarter of Medtronic’s 2014 fiscal year, ending July 26, 2013, the company reported worldwide revenues of $4.083 billion, with $369 million coming from the diabetes group, and in fiscal 2013, sales of diabetes products made up 9% of Medtronic’s overall business operations. (See Exhibit 1.)

It is therefore not surprising – though no less of an accomplishment – that Medtronic was first to market in Europe, and recently, the US, with an approved device that, for the first time, successfully utilizes CGM technology to actively affect the performance of an insulin pump. In Europe, Medtronic’s MiniMed Veo System has been on the market since 2009, and the company received premarket approval from the US Food and Drug Administration (FDA) in late September for the MiniMed 530G with the CGM Enlite sensor. These products represent major milestones in diabetes treatment. In the US, the new system is being touted as a “first-generation artificial pancreas system.” However, like its European counterpart, the MiniMed 530G is not capable of continuously monitoring glucose levels and administering insulin based on those readings, but rather, it is designed to suspend the delivery of insulin.

Specifically, the device has Medtronic’s proprietary Threshold Suspend feature, which automatically stops insulin delivery if a user’s glucose levels reach a threshold that can be set by a health care provider at between 60 mg/dL and 90 mg/dL. (See Exhibit 2.) If that level is met, the system sends an alert in the form of an alarm to notify the user, who can then make necessary changes. However, if the
user does not respond to the alarm, the system will automatically shut off the delivery of insulin to help the patient avoid slipping into hypoglycemia, a problem that can commonly occur when diabetics sleep.

Although the MiniMed 530G is not the full APS the industry has been seeking for a number of years, it is a very important step in a developmental process that the diabetes community is aware will be achieved in stages. Advances and utilization of technology as well as the regulatory process had a lot to do with this step-by-step approach. To its credit, the FDA has been willing to work with industry on this major endeavor by creating an approval pathway specifically for these types of devices. However, that process has been slow at times, hindered by what has been described as a somewhat cautious approach by the agency, which is working in uncharted territory.

The MiniMed 530G is the first system approved under the FDA’s newly created product classification, OZO: Artificial Pancreas Device System, Threshold Suspend. It is currently indicated for use only in patients 16 years of age and older. Medtronic plans to conduct a post-approval study that will include children aged two years and older, a decision viewed as important and necessary given the number of children that could utilize the product. The US Centers for Disease Control and Prevention (CDC) estimates 151,000 people under age 20 have diabetes, and each year more than 13,000 young people are diagnosed with the T1D form of the disease, which has a prevalence of 1.7 per 1,000 US residents aged 0 to 19 years. Most insulin pumps currently on the market have pediatric indications.

The MiniMed 530G features an upgraded CGM sensor, the Enlite, which can be worn for up to six days and is smaller and more reliable than previous versions, the firm says. According to Medtronic, the new system can detect up to 93% of hypoglycemia episodes when the predictive and threshold alerts are engaged. Additionally, the sensor is 69% smaller than previous CGM sensors, which the company says makes it more comfortable for patients to wear. Medtronic has ramped up production of the MiniMed 530G and initiated its US launch earlier this month.

At the American Diabetes Association (ADA) 73rd Scientific Sessions in Chicago in June, researchers presented the results of the pivotal trial that tested the use of Threshold Suspend and was used to support FDA approval of the MiniMed 530G. The ASPIRE (Automation to Simulate Pancreatic Insulin Response) In-Home Study enrolled 247 patients with T1D and documented nighttime hypoglycemia and compared the performance of a MiniMed sensor-augmented pump equipped with

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**Exhibit 1**

**Medtronic’s Business Revenue Mix**

<table>
<thead>
<tr>
<th>Category</th>
<th>Revenue Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restorative Therapies Group</td>
<td>30%</td>
</tr>
<tr>
<td>Neuromodulation</td>
<td>19%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>11%</td>
</tr>
<tr>
<td>Surgical Technologies</td>
<td>9%</td>
</tr>
<tr>
<td>Cardiac and Vascular Group</td>
<td>7%</td>
</tr>
<tr>
<td>Cardiac Rhythm</td>
<td>9%</td>
</tr>
<tr>
<td>Disease Management</td>
<td>11%</td>
</tr>
<tr>
<td>Coronary</td>
<td>30%</td>
</tr>
<tr>
<td>Structural Heart</td>
<td>11%</td>
</tr>
<tr>
<td>Endovascular</td>
<td>5%</td>
</tr>
</tbody>
</table>

Note: The data in this schedule have been intentionally rounded to the nearest whole percent, and therefore do not sum to 100%.

**SOURCE:** Medtronic

**Exhibit 2**

**Medtronic’s Threshold Suspend Feature**

---

**SOURCE:** Medtronic
Threshold Suspend versus a MiniMed pump without the Threshold Suspend feature.

The study, which was published simultaneously in the *New England Journal of Medicine*, found that patients using the pump with the Threshold Suspend feature were able to safely reduce nighttime hypoglycemia events without adversely affecting their glycated hemoglobin levels (HbA1C), the standard measurement used to show an individual’s average blood glucose control over a three-month period. The trial’s primary efficacy endpoint was the area under the curve (AUC) for nocturnal hypoglycemic events, an expression of the event’s combined magnitude and duration. After three months of follow-up, the mean AUC for nocturnal hypoglycemic events was 37.5% lower in the Threshold Suspend group compared with the control group, and nocturnal events occurred about 32% less frequently in the treatment group. The mean AUC for both daytime and nighttime events was 31.4% lower in the treatment group.

The FDA clearance of the MiniMed 530G was given on condition that the company resolves several issues at its Southern California manufacturing facility, which FDA detailed in a September 19 warning letter. In a written statement, Medtronic said the letter concerned procedures that cover “corrective and preventative action, complaint handling processes, process validation, process monitoring, design control, and general good manufacturing processes.” The statement also noted that the warning letter acknowledged the extensive work the company has already done to address many of FDA’s concerns.

**Medtronic’s Next Steps**

In June, Medtronic also announced the first patient enrollments in its US Investigational Device Exemption (IDE)-approved Overnight Closed-Loop Study, a feasibility trial investigating the firm’s third-generation, fully automated artificial pancreas system. That system, which consists of a MiniMed insulin pump, CGM, and an Android phone, has a closed-loop algorithm designed to automatically achieve a specified target glucose level throughout the night, and thus represents a major step forward compared with the glucose suspend technology that was recently FDA approved.

The third-generation system is classified by the FDA as a “Control-To-Target” system, according to Medtronic, which means it requires no interaction from the user except for calibration of the CGM. The system automatically adjusts insulin delivery to achieve a pre-specified glucose value. The feasibility trial will enroll up to 85 patients at six US centers and is expected to be completed in September 2014. The study also will test the system’s new “fault detection technology” by simulating system failures and “examining the algorithm’s ability to prevent over or under delivery of insulin,” the firm said in a statement. According to Medtronic, the fault detection technology is a key component enabling the development of a safe and effective closed-loop device.

Meanwhile, Medtronic is preparing to file for European approval by late 2013 or early 2014 for its next-generation *MiniMed 640G* pump with “predictive low-glucose management.” This pump not only has the ability to suspend insulin delivery when a certain threshold is crossed, but it also can suspend delivery when hypoglycemia is predicted. It is possible a submission for FDA approval of this device could come as early as 2015.

The competition has certainly been watching Medtronic’s recent milestone achievements, particularly as the MiniMed 530G provides a boost that will help the company maintain its huge market share in the pump market.
company’s technology into J&J’s *Animas Vibe* pump, and the combo product was CE marked in Europe in June 2011.

J&J submitted an application for FDA approval of that system in April of this year, and if the review process runs smoothly, it is possible US approval could come by the end of 2013 or early 2014. The system features DexCom’s new G4 sensor, which is also used in DexCom’s G4 Platinum Continuous Glucose Monitoring System and is capable of continuously measuring and displaying glucose values for up to seven days.

The *Animas Vibe* features some of the same technology being used in J&J’s first-generation closed-loop insulin delivery system, currently in the later stages of development. In June, at the ADA conference, researchers presented data from the second phase of human clinical trials on a still unnamed product that the company is calling a predictive Hypoglycemia-Hyperglycemia Minimizer (HHM) System, which includes a continuous subcutaneous insulin infusion pump, a CGM, and a control algorithm used to predict changes in blood glucose.

The trial was a feasibility study designed to evaluate the system’s automatic control algorithm with specific emphasis on overnight use from 9 pm to 7 am, and was conducted on 20 adults with T1D. Researchers say the system demonstrated encouraging performance, with the participants, on average, spending more than 90% of the overnight period with blood glucose values in the range between 70 mg/dL and 180 mg/dL. Additionally, fewer than half of the study participants had blood glucose values less than 70 mg/dL during the overnight period.

The results build on data presented earlier in the year in Paris at the 6th International Conference on Advanced Technologies & Treatments for Diabetes, where the company showed the system has the promising ability to minimize the number, duration, and severity of hypoglycemic events with no safety concerns. J&J is believed to be planning a third study as it moves toward preparing a regulatory submission for the system, perhaps as early as 2014.

**Collaborations Foster Innovation**

As the diabetes device market has evolved through the years, collaborations between companies, along with the support of charitable institutions, have become the engine driving innovation in the field. And one of the leaders of this effort is the JDRF (formerly the Juvenile Diabetes Research Foundation), which has emerged as an important source of funding and clinical support in the drive to develop an APS.

Several competitors are currently working with the JDRF, including Medtronic, which is partnering with JDRF to develop a novel redundant sensor system, designed to improve the accuracy and reliability of an APS. The work is being performed in collaboration with the Helmsley Charitable Trust, which has committed more than $100 million to T1D research and programs since 2009. In the Medtronic/JDRF project, the research focuses on an orthogonally redundant sensor system, which combines an electrochemical sensor with an optical sensor to provide accurate glucose values. The two sensors work as a check and balance to increase the safety of an APS, something that is a paramount goal for both medical as well as potentially legal reasons. Automated devices carry a high risk of liability, and Medtronic, familiar with the precautions needed in this area, believes redundancy offers one of the best fail-safe methods.

As competition grows between companies, JDRF’s Aaron Kowalski, PhD, VP of treatment therapies, says the current collaborative environment is one of the best ways to foster innovation. The organization does not have a preference as to which company achieves the greatest individual success, he says, because the foundation’s stake is decidedly sided with patients. And, in addition to Medtronic, JDRF currently has industry partnerships with J&J as well as *Tandem Diabetes Care Inc.* and *Becton Dickinson & Co. (BD).*
Tandem produces the t:slim Insulin Pump, which received FDA approval in April of this year. The company announced its relationship with JDRF in January to develop a novel, dual-chamber infusion pump that could simultaneously deliver insulin along with other drug therapies used for diabetes management. During the next two years, JDRF will support Tandem with funding based on performance milestones, with the goal of creating a pump capable of delivering two injectable hormonal drugs at the same time. JDRF says developing such a device is an important step in creating an effective APS, because infusion pumps currently on the market only deliver one hormone; however, a healthy pancreas produces several hormones in addition to insulin that assist in metabolism, digestion, and blood sugar control.

Tandem also is working with DexCom to incorporate the CGM company’s sensors into Tandem pumps, and although the original agreement specified DexCom’s fifth-generation (G5) sensor, still in development, the companies recently amended the agreement to include the currently available G4 PLATINUM device. The G5 sensor, which could be ready for the US market by 2015, is being developed with an open communication feature that will allow glucose readings to be sent directly to smartphones, tablets, and computers. Meanwhile, a similar market timetable exists for a DexCom partnership with Roche, which calls for the two companies to develop a handheld insulin-pump controller that would likely be paired with a next-generation Roche Accu-Chek pump as well as the company’s patch pump technology. (See “Novel Insulin Delivery Systems Pump New Life Into Diabetes Device Market” — Medtech Insight, September 2013.)

The JDRF partnership with BD, like the one with Medtronic, is funded in collaboration with the Helmsley Charitable Trust and is focused on accelerating the development of BD’s proprietary glucose-sensing technology, which the company says has shown promise in providing very accurate and reliable continuous glucose information.

**JDRF’s Sizeable Impact**

BD has not released any kind of timetable for when its product might reach the market, but the deal with JDRF is another example of the variety of players investing resources toward developing an APS. It also highlights the importance and breadth of JDRF’s heavy involvement in helping to develop such a system. In fact, many industry observers credit the foundation with helping push new technologies through regulatory red tape as well as fostering a large number of active clinical trials. Among its accomplishments, JDRF has successfully helped lobby the FDA to issue an all-important guidance for outpatient APS trials, released in November 2012. The guidance is considered a crucial step because it provides definitive information on what the agency expects to see in terms of human clinical trials and marketing. (See “Artificial Pancreas Guidance Allows For More Flexibility In Trial Design” — “The Gray Sheet,” November 19, 2012.)

An interesting note in the APS guidance that could have an effect on products in the future is the agency’s statement on the most accurate way to estimate blood glucose levels from a CGM. The guidance says that currently the best method is for the patient to periodically calibrate the CGM using a blood glucose measurement from a blood glucose device (BGD), which would include meters. Therefore, the agency says BGDs still play a critical role in the proper management of patients with an APS. “However, over time, we anticipate that improved CGM performance may obviate the need for periodic blood glucose checks with a BGD.” How much of an effect the development of an APS will have on the BGD market remains to be seen, but currently four players divide up the bulk of the worldwide BGD market: Roche, with 29.1%; J&J/LifeScan Inc., with 26.5%; Bayer Corp./Bayer AG, with 14.6%; and Abbott Laboratories Inc., with 14.6%, and they are no doubt watching recent developments in this area very closely. (See Exhibit 4.) According to Roche, blood glucose monitoring is an $8 billion market worldwide; however, with changes to the Medicare program enacted on July 1, a significant reduction in sales could be seen in the US market. (See “Medicare Durable Equipment Cuts Will Deepen In Next Round Of Competitive Bidding” — “The Gray Sheet,” February 4, 2013.)

JDRF also helped establish the first-ever artificial pancreas workshop with the FDA and...
the National Institutes of Health (NIH) in 2005, followed by one in 2008, and the most recent one in April 2013, which brought together leading experts from industry, academia, and government to discuss innovation in the APS field. Among other things, that meeting highlighted the progress made with multiple outpatient studies, portable mobile phone-based systems, increases in CGM accuracy, and robust artificial pancreas algorithms. Many of these studies have been conducted by members of the JDRF Artificial Pancreas Project academic consortium and NIH-funded investigators. (See Exhibit 5.) One important study in particular is being led by Boston University (BU), and also supported by the Helmsley Charitable Trust, and it has been dubbed the “Bionic Pancreas” project. The work is led by Edward R. Damiano, PhD, associate professor of biomedical engineering at BU, who developed the concept and helped design this APS.

Like many of the other projects underway, the Bionic Pancreas project will feature a CGM sensor that reports patient glucose readings every five minutes. In the current investigational version of the Bionic Pancreas, the CGM readings from a Dexcom G4 CGM are streamed automatically by an iPhone, which houses the control algorithm that determines insulin and glucagon dosing. The iPhone then automatically communicates the dose by way of Bluetooth low-energy protocol down to two Tandem pumps, one that delivers insulin to lower glucose levels and one that delivers glucagon to raise glucose levels. Earlier generations of the BU’s Bionic Pancreas used Abbott’s Freestyle Navigator CGM and Insulet’s OmniPod patch pumps in inpatient clinical studies.

The aim is to develop a dual-chamber pump that is integrated with the CGM receiver and control algorithm all as one stand-alone Bionic Pancreas device that would automatically maintain glucose levels within or near normal range. The patient would be able to passively monitor its performance via a smartphone. The system is currently in its third generation of development and is being tested in clinical studies based at Massachusetts General Hospital. BU’s Edward Damiano plans to have the Bionic Pancreas ready to submit for US market approval by 2016 and on the market by 2017. However, that ambitious goal will require several additional technology advancements, including the successful development of the dual-chamber pump (something, as mentioned, Tandem is already working to develop) and the development of a liquid formulation of glucagon that is stable at room temperature (a project several drug companies are currently tackling). In June, JDRF announced a partnership with Xeris Pharmaceuticals Inc. and Latitude Pharmaceuticals Inc. to support development of soluble glucagon formulations.

Inhaled Insulin Studied In APS Research

Another research project being watched closely comes from the Sansum Diabetes Research Institute and the University of California, Santa Barbara (UCSB), where the still experimental inhaled insulin from MannKind Corp. is being used in an APS research trial. (See “MannKind Gears Up To Make Commercial Case For Inhaled Insulin Afrezza” — Pharmaceutical Approvals Monthly, September 2013.) JDRF’s Kowalski told Medtech Insight the study is the only one where Afrezza (insulin human [rDNA origin]) Inhalation Powder, a fast-acting insulin, is being used in an APS. The study is investigating the use of Afrezza in conjunction with a regular basal and bolus system, and the equipment in the study includes an OmniPod patch pump from Insulet and a DexCom sensor. In a joint announcement with JDRF, the project’s lead researcher, Howard Zisser, MD, explained that the trial addresses one of the big questions in diabetes research: “How do we manage meals with the artificial pancreas?”

The issue is a concern, because following a meal many diabetics have a difficult time managing their glucose levels, and the standard subcutaneous method of delivering insulin is slow compared with how fast glucose
Artificial Pancreas

appears in the bloodstream after a meal. Co-principal investigator Francis J. Doyle, III, PhD, associate dean of research engineering at UCSB, explained that using “inhaled, ultra-rapid-acting insulin, we have a chance now to manage blood glucose even better by emulating a more natural pancreatic function. We can get the insulin quickly into circulation and it will be cleared quickly and safely from the bloodstream.” Research has shown a person with diabetes might see a blood glucose spike as high as 60 mg/dL after a meal, but with the fast-acting insulin that spike might be considerably smaller – somewhere around 20 mg/dL. In August, MannKind released data from its Study 171, a Phase III clinical study of Afrezza’s effectiveness using the company’s next-generation inhaler (Gen2), the whistle-sized Dreamboat inhaler, on 518 people with T1D in the US, Russia, Ukraine, and Brazil. During the study, patients were randomized in one of three ways:

- Continuing on subcutaneous insulin as part in combination with a basal insulin (170 patients);
- Switching to Afrezza administered using the Gen2 inhaler in combination with their basal insulin (174 patients); or
- Switching to Afrezza administered using the MedTone inhaler in combination with their basal insulin (174 patients).

Exhibit 5

Selected Active Clinical Studies Involving Artificial Pancreas Technology

<table>
<thead>
<tr>
<th>Investigator – Institution</th>
<th>Main Focus of Efforts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stuart Weinzimer, Eda Cengiz, Jennifer Sherr – Yale University</td>
<td>Working on inpatient studies investigating ways to speed up insulin action by heating the infusion site with a small heating device called InsuPatch. Faster insulin action will be needed for automated artificial pancreas systems that will not require the bolusing for meals.</td>
</tr>
<tr>
<td>Bruce Buckingham – Stanford University H. Peter Chase – University of Colorado, Denver</td>
<td>Conducting outpatient clinical studies on systems that can predict impending hypoglycemia and switch off a pump at night. This would be more advanced than the recently approved Medtronic system that suspends the pump after a set threshold is reached.</td>
</tr>
<tr>
<td>Boris Kovatchev &amp; Marc Breton – University of Virginia Claudio Cobelli – University of Padova Eric Renard – Montpellier University</td>
<td>Developing and clinically testing a control-to-range system that would keep people with T1D in a safe range and protect them from extreme high and low glucose values. Outpatient studies have been conducted on a research platform designed from a combination of a Dexcom CGM and an Insulet or Roche pump with the algorithm running on an Android-based smartphone.</td>
</tr>
<tr>
<td>Gary Francis – Virginia Commonwealth University</td>
<td>Studying the use of heart rate information as an input into the artificial pancreas so exercise would be automatically detected. Currently, the individual would need to inform the system that he/she is going to start exercise.</td>
</tr>
<tr>
<td>Ali Cinar – Illinois Institute of Technology</td>
<td>Studying ways to further increase safety by detecting and mitigating system failure events.</td>
</tr>
<tr>
<td>Howard Zisser – Sansum Diabetes Research Institute Frank Doyle &amp; Eyal Dassau – University of California, Santa Barbara</td>
<td>Collaborating on the development and testing of advanced algorithms for fully automated artificial pancreas systems. The researchers are also studying ways to accelerate insulin action, and recently reported clinical pilot studies showing that inhaled insulin (Afrezza – MannKind) and intraperitoneal delivery through a port (DiaPort – Roche) accelerated the action of insulin.</td>
</tr>
<tr>
<td>Edward Damiano – Boston University</td>
<td>Conducting outpatient studies on bimodal (glucagon/insulin) approaches to closed-loop control. JDRF funded much of the earlier inpatient work, but the outpatient studies are being funded by the National Institutes of Health.</td>
</tr>
<tr>
<td>Ken Ward &amp; Jessica Castle – Oregon Health &amp; Science University</td>
<td>Also working on bimodal (glucagon/insulin) approaches to closed-loop control, and now completing an outpatient pilot study.</td>
</tr>
<tr>
<td>Roman Hovorka – University of Cambridge</td>
<td>Working on artificial pancreas system that would control blood glucose to a target level overnight. Recently completed a three-week study of overnight closed-loop control in young people at home and now set to launch a larger study of overnight control for three months at multiple sites.</td>
</tr>
<tr>
<td>Tim Jones – University of Western Australia, Perth</td>
<td>This group is working on predictive low glucose suspend approaches.</td>
</tr>
<tr>
<td>David O’Neal – University of Melbourne</td>
<td>Clinically testing an overnight control system in the inpatient setting with plans to do outpatient pilot studies in early 2014.</td>
</tr>
<tr>
<td>Remi Rabasa-Lhoret – University of Montreal Ahmad Haidar – McGill University</td>
<td>Studying bimodal (insulin/glucagon) approaches to closed-loop control.</td>
</tr>
</tbody>
</table>

SOURCE: JDRF
Over the 24-week treatment period, A1c levels decreased comparably in the Afrezza-Gen2 group (–0.21%) and the insulin aspart group (–0.40%) and the Afrezza device met its non-inferiority endpoint. (See Exhibit 6.)

MannKind is expected to submit data from Study 171, as well as Study 175, which showed positive results of Afrezza’s use by T2 diabetics, to the FDA by the end of this year. The agency rejected MannKind’s submission in 2011, and requested additional studies. (See “Cautions, FDA Is Obstacle For Burgeoning Diabetes Device Market” — Medtech Insight, August 2011.) However, many analysts now expect Afrezza to receive regulatory approval. The product has a large market potential, estimated by some in the multibillions; however, MannKind is likely to need a partner to help with the expensive task of commercializing the product if approved. So far, a partner has not emerged publicly, but potential matches could come from one of several major diabetes companies such as Novo Nordisk AS, Sanofi, Eli Lilly & Co., or J&J.

Numerous other APS endeavors are taking place around the globe, including one involving the product development firm Cambridge Consultants, which announced in June a partnership with the Institute of Metabolic Science (IMS) at Addenbrooke’s Hospital in Cambridge, UK. The project is designed to develop an application that would allow a CGM to communicate with a smartphone or tablet via Bluetooth and then link to an insulin pump. Company officials say a nurse-assisted system has previously been trialed in a hospital setting, and home use of the system has already been established.

As the race to bring an APS to market moves closer to the finish line, more deals and partnerships are likely to be announced, and new companies are expected to join the race — either with a goal of reaching the market, or developing a technology that could be acquired by the larger players in the field. The diabetes market has been seen as a fairly attractive space, with the right mix of innovation and a very large and engaged patient population that not only offers vigorous feedback on products, but also is willing to advocate for new treatments that make managing their disease easier and safer.

SOURCE: MannKind Corp.

RELATED READING

“Novel Insulin Delivery Systems Pump New Life Into Diabetes Device Market” — Medtech Insight, September 2013 [A#20130700106]


“MannKind Gears Up To Make Commercial Case For Inhaled Insulin Afrezza” — Pharmaceutical Approvals Monthly, September 2013 [A#06130901020]

“Cautious FDA Is Obstacle For Burgeoning Diabetes Device Market” — Medtech Insight, August 2011 [A#011400055]

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