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Cellnovo's Mobile Health Approach to Diabetes Care

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Feature Articles / Word Count: 4211 / Article # 2010800201

Executive Summary

Cellnovo is working smack at the intersection of two of the hottest areas in medtech: diabetes and mobile health. Aiming to be the iTunes of diabetes care, the firm hopes to transform today's piecemeal management of the disease. The private company has developed an integrated platform designed to ease the burden for patients with type 1 diabetes, their physicians and their families. Cellnovo's system integrates a blood glucose meter, an insulin pump, and a simple interface that makes it easy to gather and share among all interested parties the many parameters associated with diabetes care: diet, level and frequency of blood glucose readings, insulin delivery profiles, degree of physical activity, and health status, for example. Indeed, because success in type 1 diabetes care heavily depends upon the compliance and adherence of patients to numerous daily tasks as they try to live normal lives, the disease is a good test case for the first end-to-end, patient-centric solution.

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Mary Stuart

Cellnovo is operating at the confluence of two popular areas of investment: diabetes and mobile health.

Established product companies are being challenged to fit their core products and business models into the connected systems of mobile health. But with no such legacy issues, Cellnovo built, from the ground up, an end-to-end solution for diabetes care.

Cellnovo has developed its own medical device, a novel insulin pump, but it thinks very differently than traditional medical products companies about solutions to the problems diabetes poses.

Thus, it has in parallel built service aspects around the product and factored that investment into its cost of goods. In that and other aspects, Cellnovo sees itself more as the *iTunes* of diabetes than a medical device company selling a new widget.

Two of the highest priorities for innovation among both medical device and pharmaceutical companies are diabetes and mobile health. The former presents a great societal need, because of the burdens its co-morbidities place on health care

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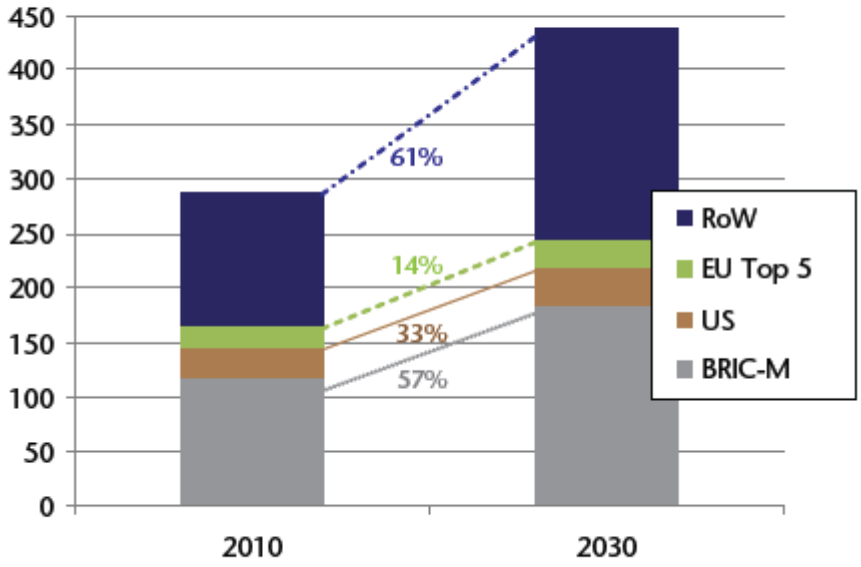
systems, and a large market opportunity because of the sheer size of the patient population. Across the world, 285 million people have diabetes and that number is expected to double within twenty years. (*See Exhibit 1.*) At the same time, product companies and investors are looking to mobile health as an information-age solution to the old problem of disease management, the ongoing and multifaceted care of chronic diseases which, because it largely takes place outside of professional care settings, is left in the hands of patients. Old-style disease management never really took off because its service-based models generally added extra layers and costs to patient care, rather than making it more efficient. But now, companies are looking to the consumer electronics and telecommunications industries – to cell phones, wireless communications networks, and the internet – for new ways to connect disparate aspects of care and patients, providers, and their families to deliver better, and even more efficient, less costly, care.

Exhibit 1

Diabetes Disease Burden To Increase Dramatically By 2030

(Millions of Patients)



Note: BRIC-M refers to Brazil, Russia, India, China and Mexico.
SOURCE: IDF International Diabetes Atlas, 4th edition, 2009

Young company **Cellnovo Ltd.** is at the confluence of those currents. Founded in 2002, it has developed an integrated platform designed to ease the burden for patients with type 1 diabetes, their physicians and their families. The company's system integrates a blood glucose meter, an insulin pump, and a simple interface that makes it easy to gather and share among all interested parties the many parameters associated with diabetes care: diet, level and frequency of blood glucose readings, insulin delivery profiles, degree of physical activity, and health status, for example. Indeed, because success in type 1 diabetes care heavily depends upon the compliance and adherence of patients to numerous daily tasks as they try to live normal lives, the disease is a good test case for the first end-to-end, patient-centric solution.

Cellnovo CEO Bill McKeon holds up a shiny black handheld device with a touch screen that is colorful and appealing. It looks like Apple Computer's *iPhone* or other state -of-the art cell-phones , and so, at a superficial glance it may appear like so many other diabetes-related add-ons designed for off-the-shelf smartphones. **Merck & Co. Inc.** , for example, has launched a mobile application known as *Vree* for type 2 diabetes, which is downloadable to an iPhone or *iPod Touch* mobile digital device. AT&T recently signed an agreement to market a mobile diabetes analytics system designed by **WellDoc Inc.**, also for type 2 diabetes. In fact, numerous companies have designed mobile diabetes applications. Many of these applications address one or some aspects of diabetes care: the need to enter data into a journal, or send blood glucose readings to a remote provider, for example. But none has wrapped themselves

Drug Delivery
Large Molecules
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Therapeutic Categories
Metabolic Disorders
Diabetes

Companies
Cellnovo Ltd.
Merck & Co. Inc.
Insulet Corp.
Medtronic Inc.
Roche
Johnson & Johnson
Tolerx Inc.
Sensors for Medicine & Science Inc.
AgaMatrix Inc.
Sanofi

as completely around the life of a patient with type 1 diabetes as has Cellnovo.

From Widget To Wireless

Cellnovo's handset is not an iPhone, it's a dedicated medical device containing a controller for an insulin pump and a blood glucose meter. It is only one component of a systems approach to the care of patients with type 1 diabetes. Cellnovo's offering consists of a proprietary insulin pump, the handset, which communicates wirelessly to control the pump and to send data to a secure website that can be viewed by patients, their families, and physicians or which can send alerts to the cell phones, of, for example, the parents of a diabetic child that's in school. (*See Exhibit 2.*) But Cellnovo isn't merely dressing the devices used in diabetes care in the garb of consumer electronics. Says McKeon, "If people understand Cellnovo as a device that sends data to a website, they are missing the point."

Exhibit 2

Cellnovo's Systems Approach To Diabetes Care

SOURCE: Cellnovo

McKeon uses Apple Computer as an analogy for what Cellnovo is trying to do. He says, "If you had asked Steve Jobs at Apple about his new MP3 player called the iPod, and how it compares to other MP3 players, he might have said, 'I am not making an MP3 player. I'm bringing entertainment into your life in a number of ways.'"

Apple envisioned a system where the devices were simply delivery mechanisms, but what was truly of value was access to and interaction with the content, says McKeon. "We approached Cellnovo in the same way. We believed that the rest of the world was looking at diabetes and the delivery of insulin with a very device-centric mindset. There is a device that pumps insulin, another device that measures blood glucose, and another device with continuous sensors." The use of separate products for different functions is burdensome for patients.

To lower the burden for patients and their providers, Cellnovo has incorporated the best features of today's consumer electronics into a medical platform: the appealing look and feel of devices, with icon-driven intuitive graphical displays and touch screens, the ability to download new applications over time, the automation of data tracking and sending it wirelessly to users, the use of relational databases offering flexibility in how the data will be interpreted and displayed in the future, and the kind of accessible instruction manuals and training that consumers expect as compared to captive medical device patients.

McKeon challenges the traditional industry mindset that since medical devices offer therapy, they have to be complicated and that a patient has to be geared to deal with the complexity. "Users of medical devices are equally, if not more, deserving of better interfaces because of the implications of errors," he says, and consumer electronics have changed patients' behavior and expectations.

Out Of The Iron Age And Into The Information Age

Cellnovo began its existence with a novel insulin pump but, McKeon says, the company's goal is unlike that of traditional medical device makers which focus on adding features to disparate medical devices. The pump is a means to collect information in a system that unifies all aspects of diabetes care. "For a better

understanding, you have to track many factors, and there should be a constellation of information that makes managing diabetes easier for the patient, easier for the physicians and nurses that manage the patients, and even easier for payors to understand how this whole ecosystem of members comes together."

While it's not calling itself a "widget"company, it's because Cellnovo is offering a new insulin pump with advantages that it is able to bridge, from a clinical and business model standpoint, the two worlds of mobile health and diabetes. As noted, the pump does give the company a way to deliver therapy and collect information, at the same time giving the system a basis for reimbursement.

The company began in 2002 as Starbridge Systems Ltd. to develop a pump designed by Julian Shapley, PhD, now Cellnovo's technology director. At that time, clinical studies were beginning to support continuous subcutaneous insulin infusion as a better alternative for long-term glycemic control than multiple injections. Trends were shifting so that newly diagnosed pediatric patients, once started on multiple daily injections, were put directly upon pumps. **Insulet Corp.** had been recently founded to develop *OmniPod*, its small, disposable insulin pump which operates with a wireless handheld personal diabetes manager and other device developers were looking to downsize pumps and make them easier to use. The notion was that device improvements would bring discretion to patients, improving compliance and perhaps usability. It was thought that those improvements might increase penetration of pumps into the population still relying on multiple daily injections of insulin.

Even today, in a market dominated by leaders **Medtronic Inc.** , **Roche** and **Johnson & Johnson**, penetration rates for insulin pumps are low. In the US there are 1.2 million type 1 diabetes patients requiring intensive insulin therapy, and in Europe, another million patients. (*See Exhibit 3.*) In the US, only one in four of these patients is on insulin pumps and in Europe, only one in six. That's because conventional insulin pumps are bulky, have obtrusive tubing, have small screens that are difficult to read, and are complicated, requiring patients to undergo a half day of training, just on the use of the device, not on therapeutic strategies, which require additional time with health care providers. Physicians have to make prescribing decisions based on whether they think patients can handle the requirements of the devices. *(See "Insulin Device Companies' New Mantra: Real Simple,"* START-UP, *April 2010* "Insulin Device Companies' New Mantra: Real Simple " — *START-UP,* April 2010.)

Exhibit 3

Insulin Pump Markets

- 1.2 million people with type 1 diabetes in the US
- Approximately 400,000 type 1 diabetics using insulin pumps
- Approximately 700,000 patients on multiple daily injections (MDI) in the US
- Approximately 25% of type 2 diabetes population is insulin-dependent (requiring either a pump or MDI)
- According to estimates by Insulet Corp., 70% of users of its patch pump are first-time pump users. (i.e. drawn from the MDI population)

SOURCE: Except where otherwise noted, all statistics from Christopher C. Cooley, Managing Director at Stephens Inc.

Shapley's pump has a novel mechanism of action allowing it to be 30% smaller than OmniPod, with high accuracy and only one moving part, making it inexpensive to manufacture. Cellnovo has kept the expensive parts with the durable electronics (rechargeable batteries for example. The OmniPod contains four batteries which are thrown away with the unit every three days). Only Cellnovo's small plastic insulin reservoir is discarded. The small, low profile pump is removable at any time; it uses a Velcro-like adhesive strip to attach anywhere on a patient's body.

The Cellnovo pump operates on a mechanism called a wax actuator, which is fundamentally different than any other pump in the market. The cellular handset controls the pump and in a fraction of a second wax inside the pump converts from a solid to a liquid, expanding to push a plunger that infuses insulin. According to McKeon Cellnovo's pulsatile pump will be the most accurate product ever to come to market as it delivers insulin within 1-2% of target. The accuracy of some pumps on the market today is plus or minus 25%. McKeon believes that accuracy will become even more important as higher concentration insulins come to market. "As continuous glucose sensors become more accurate and more widely adopted, one has to determine if this accuracy is lost when the sensor communicates with a pump that fluctuates +/-25%," says McKeon, adding, "Cellnovo intends to set the bar higher on accuracy, safety, and ease-of-use."

John Littlechild, managing director at Cellnovo's early investor HealthCare Ventures, has a strong interest in diabetes. His firm has made three investments in the area, including, besides Cellnovo, **Tolerx Inc.**, now in Phase III clinical trials with a drug for the treatment of type 1 diabetes, and **Sensors for Medicine & Science Inc.** , long at work on an implantable glucose sensor capable of measuring glucose for long periods of time without any patient intervention. He credits McKeon, who joined Cellnovo in 2008, with the vision that the company is pursuing today. Littlechild says, "Cellnovo didn't start off as a mobile health company. It started off as a next generation insulin pump, offering a very clever wax actuated pump." HealthCare Ventures was aware of an ongoing shift from large externally worn pumps to smaller micropumps with the ability to communicate wirelessly with a controller. "But Bill made the leap, because he had delved deeply into the incipient wireless medical industry before. [As Medtronic's VP, of strategy and emerging technology, McKeon headed up the company's wireless initiative from 2002-2006.] Bill advised us to expand our thinking, because he said there is a need for the information that is handled here to be shared by the physician, the parent, and the child." Since Cellnovo was already working with a wireless handheld that communicated with the pump, it seemed logical to take the company one step further to connect all aspects of care wirelessly. "As a result of Bill's insight, we found ourselves on the brink of a very interesting evolution in medicine."

Solving The Real Problems In Diabetes

Fiona Leeds, MD, a consultant pediatrician and diabetologist at St. James University Hospital, Leeds, UK, has said that managing diabetes patients is like trying to read a book in which several chapters have been torn out.

In today's facility-based system, patients tend to make 10 to 12 visits to physicians' offices in the first year. They see specialist clinicians three to five times, specialist nurses six to nine times, and diabetes dieticians two to three times. The patients bring into the physician's office their blood glucose meters, their pumps (which record insulin dosages and dietary selections) and their daily journals, in which they are supposed to record notes about their exercise and how they feel. The nurse plugs a cable into the back of each device the patient brings in, downloads the data to a computer, and then begins to look at the ranges of values. He or she might say, "I noticed that on Tuesday you had a high blood glucose reading of 13. What was happening for the five hours before that?" The patient may fumble in his log book, which, in many cases, has been hastily filled out in the parking lot of the physician's office, or will scratch his head, trying to remember what he did or ate on a certain day. "It's a terrible cycle," says McKeon, "filled with guilt and fraught with fragmented information that is not timely and is not accurate."

That's why Cellnovo has built an end-to-end solution that helps a patient manage most of these required tasks simply by wearing the pump, or in some cases, touching an icon on a touch screen. As a patient goes about daily activities, an accelerometer built into the pump measures activity levels, automatically. When he or she tests blood glucose by inputting test strips into a built-in meter (created in partnership with **AgaMatrix Inc.** , which is also partnering on the development of a blood glucose meter for **Sanofi-Aventis** [See Deal]) the handset records the readings. While the patient has the handset device in hand to take a blood glucose reading, he also clicks on icons to log

in how he feels (a smiling face means he feels good), and he can call up a keypad to elaborate, if necessary. A personalized food library, containing only the foods that a patient eats (avoiding the need to scroll through long, irrelevant lists of food items) can be named according to his or her own preference, making the recording of dietary selections easy. McKeon notes that the device automates the recording of all the data that is currently of interest to physicians, except for the dietary choices, and that task is made simple with a touch screen.

To provide a degree of control over a medical-grade environment, Cellnovo has built its applications into a diabetes-dedicated handset, rather than an off-the-shelf smartphone, because, McKeon says, commercial cellular devices might pose a risk to a device that patients' lives depend upon. Phones continually update applications, which makes it impossible to maintain a fully-validated environment, a requirement of the FDA to assure patient safety.

As noted, all of the recorded information is sent automatically to a website that the physician or the patient can view. The physician's dashboard shows a list of all patients under management and their current status; he or she can drill down by clicking on a particular patient, viewing graphical displays that highlight aberrant readings. Physicians can thus manage by exception, spending their time on making therapy decisions for patients that need management, an efficiency that will help physicians manage increasing caseloads of patients with diabetes.

In the future, Cellnovo's platform may reveal hidden benefits. All of the information it records is time stamped, and is thus unified in a relational database. One day it might be easy for physicians to glean insights from the correlation of data points that are now disparate and cannot be overlaid one upon another.

An Economic Model That Makes Sense

The many large companies that have dipped their toes into mobile health haven't yet found the business model that pays them for the effort. Pharmaceutical companies are interested only in investing in technology that increases pharmaceutical sales. Medical device companies have long tried to apply the traditional model of medical device innovation to connected health; adding incremental clinical value to implantable or other medical devices through the gathering of information relevant to the condition being treated, and then looking for payback for their investment in terms of premium pricing. That hasn't worked for Medtronic, with its *Chronicle* heart monitor, which hasn't convinced payors to foot the bill, nor for its *CareLink Personal Therapy Management* website, linking implanted devices in patients to their physicians via a website. There, patients have not shown themselves willing to pay for the extra layer of service. (*See "Wireless Health: Personalized Medicine Comes to the Device Industry,"* START-UP, *October 2009* "Wireless Health: Personalized Medicine Comes to the Device Industry " — *START-UP,* October 2009.)

Cellnovo, however, believes that the way to move the service business forward is to build it into the cost of goods, and it can do this because its insulin pump is inexpensive to manufacture. Cellnovo will thus offer the service aspects of its system to customers for free, perhaps offering, in the future, some additional premium services that patients and their families might be willing to pay for out of pocket. Says HealthCare Venture's Littlechild, "In any area of real innovation, price is not usually a factor, because the innovation has come up with a way to achieve something that can't presently be done or to achieve cost savings. However, in these days of cost containment, we don't want to dissuade the payor organizations by going in at a premium."

Payors are likely to be receptive to Cellnovo's subscription-based model, which is similar to that of Insulet in avoiding a large outlay of cash up front, unlike that of conventional insulin pumps. Current pumps on the market require an investment of $5,000-$6,000 up front (75% which is typically borne by payors, the 25% co-pay by patients) plus another $160 per month for infusion sets and supplies. Payors don't like this model, because they've determined that patients only stay within an insurer's system, on average, for 2.5 years, so they've paid up front for something that they don't

continue to benefit from. The up-front payment also makes attrition very painful, since attrition rates can be high for complicated therapies that have to be used forever. Insulet, by contrast, asks for a low up-front investment – $600 – and $280 per month for supplies. Over the four-year life of the systems, Insulet ends up being 20% more expensive than conventional pumps.

Cellnovo will make that model even more palatable. Through a subscription-fee-based model and owing to its low manufacturing costs, the total offering will be comparable in price to that of conventional pumps over four years.

As noted, other economic benefits may be realized if the Cellnovo system results in better care, and workflow efficiencies that see physicians using their time to manage more patients effectively, or, for example, that help patients adhere to therapy with no gaps because the system automatically reorders supplies.

The Incumbent's Dilemma

Cellnovo isn't the only company that is determined to bundle together all the tools necessary for diabetes care. Leading pump manufacturers like Medtronic have similar goals, as do the leading pharmaceutical companies with diabetes franchises. Sanofi-Aventis, for example, which in January of this year created a dedicated diabetes business unit that will invest not only in pharmaceuticals, but also in devices and services, also aims to create an end-to-end care platform for diabetes patient. Dennis Urbaniak, VP of Innovation and New Customer Channels for Sanofi-Aventis, says that the pharmaceutical company aims to help improve integration in diabetes care in two key steps. First, Sanofi-Aventis is expanding its portfolio of offerings to include innovative treatments, monitoring and diagnostic devices, unique delivery platforms, and patient services. Says Urbaniak, "Diabetes care is heavily influenced by individual preferences and local care delivery, so this step will allow us to offer patients, physicians and payors a range of tools to best meet their individual needs." The company has kicked off that strategy with a partnership to develop a blood glucose monitor with AgaMatrix. (*See Sanofi-AgaMatrix Deal a Harbinger*," IN VIVO, *April 2010* "Sanofi-AgaMatrix Deal a Harbinger " — *IN VIVO,* April 2010.)

In order to achieve this goal, Sanofi will look at the continuum of diabetes, from type 1 diabetes, to pre-diabetes, in which prevention is a focus, to type 2, when managing complications becomes a priority. As a second step, says Urbaniak, the company will collect real-life evidence. "We will need to demonstrate that this platform approach will improve outcomes and costs associated with managing diabetes while making it easier for patients to be successful in living their lives with the condition." That stated goal accords with Cellnovo's vision of diabetes care as well. But in the end, as a pharmaceutical company, Sanofi's goal is to differentiate itself and its drugs in diabetes care. (*See "Personalizing Patient Care: Sanofi Recasts Its Diabetes Efforts,"* IN VIVO, *July 2010* "Personalizing Patient Care:Sanofi Recasts Its Diabetes Efforts" — *IN VIVO,* July 2010.)

The goal of serving core businesses has held back medical device companies as well, and as a start-up, Cellnovo has enjoyed a certain freedom to operate. McKeon knows this because he has worked at Medtronic and other large companies. "Established companies have the burden of supporting the legacy product platform. Start-ups don't have the legacy of having to carry that technology forward. They can start new with new parts, they can start with a mobile orientation, and they don't have to work with engineers that know how to make pumps but are unfamiliar with cell phones." Large medical device companies are burdened by their history, McKeon says. "The market leaders have a legacy of mindset, a legacy of margin, a legacy of business in front of them, and they are trying to focus, quarter to quarter, on making money to grow their top and bottom lines. That's a challenge for market leaders and why new innovations are acquired from new companies."

Cellnovo was able to start out on a very different journey, McKeon says. "We set out to build a network of devices that talk and communicate with each other from the very beginning. We are building toward the journey rather than taking devices that were

never meant to be connected and trying to iterate or modify them to be connected."

Cellnovo was free to hire the kinds of people it needed. "It was freeing to go out and get people that had experience in secure websites, into which all this data moves. I didn't want to just hire health care people; I wanted to hire people with mobile services backgrounds. They may have been serving Vodafone yesterday, and they are serving Cellnovo today." McKeon notes that such R&D people have a very different view of their mobile communities than medical device developers thinking about the patients that buy their devices. "The way you talk to patients, the way you set up your support, the way you train them is very different if you come from Motorola or Vodafone than it is if you come from the medical device industry."

In two years, and on $20 million in venture funding, Cellnovo has gotten to the point where it is ready to launch in the UK (where the company is based) in early 2011. It anticipates US market entry in late 2011. Diabetes blogs are already getting requests from patients asking how they can get the Cellnovo device. Challenges lie ahead of course; the ultimate proof of success will be acceptance of the product in the marketplace.

If the product is successful, a first-mover advantage could stifle multi-billion dollar companies from adopting similar models. McKeon harkens back to what happens in the information world. "Someone could make another Facebook or another iTunes with even better features, but would people move to them? We don't believe so, because they have already extended to a large community of people using them, sharing and growing with the information. We have unleashed a whole new, freer way of looking at this disease." Cellnovo has set off alarm bells, which is good for the industry, McKeon says, and others are trying to emulate what Cellnovo has done. But, he says, "They are tied to infrastructures that they have had for the last ten years. Their expertise and intellectual property are designed around this infrastructure, which can be limiting. We are doing things that don't come naturally to a medical device company as evidenced by the fact that there are very few mobile connected health care devices today from companies that surely have the money to invest in this space.