



# DIABETIC INVESTOR

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## “Make the Connection” David Kliff, Publisher

Just when you thought there were more than enough blood glucose meters on the market, along comes another entry into this already crowded field. Like other new meters that have come on the market recently, this latest entry is different than what's currently on the market. Only this time the difference isn't the size of the blood sample or a fast test time. The people at Hypoguard have come up with a disposable blood glucose meter that contains 100 test strips. Called the Hypoguard Advance, the meter recently received 510K approval from the FDA and plans are underway to have the meter in stores sometime later this year.

Unlike BD who is new to the meter world, Hypoguard has been around for quite some time. (Long time readers may recall that Hypoguard bought the meter business from Chronimed.) Although Hypoguard has played in the retail world, their target market up to this point has been managed care facilities where price is premium. According to the company, they do not plan to market the Advance system on their own;

The Hypoguard Advance-  
The first disposable glucose  
meter. The Advance contains  
100 test strips and comes  
ready to use- no calibration.



Photo courtesy of Hypoguard

rather they have decided to co-brand the product.

With an expected retail cost of around \$70 or \$75, about the same price as a box of 100 premium test strips, it will be interesting to see what type of reception the Advance receives. At first glance it appears Hypoguard is targeting the older patient who is less concerned with

speed or sample size. The Advance is also larger in size than most of the newer meters, and similar in size to the Medisense SoftTac.

It also appears that the Advance is not targeted to compete directly with Roche's Compact, another meter that offers self-contained test strips. With the Compact, there are 17 test strips contained in each drum. Besides offering a smaller blood sample size, the Compact device is small enough that it can easily be transported.

It should not be underestimated just how important the size of the device is. One of the main problems facing the SoftTac has been its lack of transportability. This basically limits the meter to at-home usage, which ultimately limits sales. While it may seem obvious that a meter should be easy to carry, this fact sometimes gets lost during the design phase.

Of bigger concern with the Advance is reliability. For example, if there is a problem with a Compact test strip

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cartridge, it can be easily thrown away and replaced. Should there be a problem with the Advance, the whole device must be replaced. This could lead to higher than average costs for Hypoguard. According to people who have seen the Advance, it jammed on more than one occasion; this is not a problem with the majority of meters on the market today.

The Advance also faces another obstacle, in that the meter cannot be given away for free. The glucose meter market has long followed the razor/razor blade business model. Meters are typically given away for free in order to get the continuing

glucose meter, especially a co-branded version. All of the major retailers currently have a co-branded glucose meter, and with the exception of Wal Mart, these meters have received a lukewarm reception from customers. Wal Mart's success has more to do with their cost conscious customer base, with nearly 70% paying cash, unlike Walgreens, where nearly 80% of their customers receive some sort of insurance reimbursement.

It is possible that in the right environment, like a Wal Mart, a co-branded effort could be successful. Wal Mart is committed to its ReliOn brand of diabetes products and has the necessary experience in meters.

Other than the unique situation at Wal Mart, the bottom line here is really not much different than the problems facing other new meters entering the market. Namely, what compelling reason is there for a consumer to change from their current meter to the Advance?

revenue stream from the sales of test strips. With an expected retail price of nearly \$75, Hypoguard must find another way to get customers to try their meter. Giving away the Advance for free, even for a limited try time when the product first comes out, would be an expensive proposition. Hypoguard also must convince insurance companies to add the Advance to their formularies; not an easy task - just ask the people at Therasense.

Finally, there's the whole issue of being disposable. Everyone knows that Americans have a love affair with disposable razors, pregnancy tests, and thermometers; however, it's an open question as to how patients would perceive a disposable blood

Wal Mart also has the clout to command lower pricing and could possibly offer this new meter closer to the \$50 level.

Other than Wal Mart, few other retailers are committed to co-branded meters due to their customers' insurance reimbursement situation. A Wal Mart customer looks for low prices and trusts the ReliOn brand.

Other than the unique situation at Wal Mart, the bottom line here is really not much different than the problems facing other new meters entering the market. Namely, what compelling reason is there for a consumer to change from their current meter to the Advance? Consumers may feel comfortable with disposable

razors or diapers; Diabetic Investor isn't so sure they will feel comfortable with a disposable blood glucose meter. Given its size, cost, and lack of brand name recognition, the Advance faces an uphill fight.

The Roche Compact currently the only all in one glucose meter on the market.



Image Courtesy of Roche

**Alternate Delivery of insulin - has the quest to develop a non-injectable form of insulin stalled?**

A few years ago, the diabetes industry was buzzing over the prospects of alternate delivery options for insulin. Inhaled Insulin, an insulin patch, even an insulin pill were all the rage. It only seemed like a matter of time before insulin injections were a thing

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The Exubera Delivery Device-Once the leading candidate for alternate delivery of insulin, now stuck in trails. Will this product even make it to the FDA?



Photo Courtesy of Nektar Therapeutics of the past. Inhaled insulin, in particular, was attracting the majority of attention. Backed by large pharmaceutical companies, many assumed it was a mere formality that there

would be an FDA approved product on the market in no time.

Leading the way was Exubera, an inhaled form of insulin developed by Nektar Therapeutics (then called Inhaled Therapeutics), Pfizer and Aventis. Initially, everything looked great and expectations soared. A fund manager at the time boldly predicted that Exubera would quickly reach sales of \$3 billion.

How times have changed.

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While officials at Pfizer and Aventis insist that Exubera isn't stalled, merely delayed, the majority of diabetes researchers have turned their attention elsewhere. The question has to be asked, just where is the development of alternate delivery systems

headed?

Like so many ideas in the diabetes area, alternate delivery systems, or should we say non-injectable forms of insulin, seem like a great idea. There are patients who are needle-phobic and even with the newer, thinner lubricated needles there is a pain factor when injecting. The real factor driving this research is that the majority of primary care physicians are reluctant to recommend insulin due to the fact that it must be injected or pumped into the patient.

Worried that patients may not comply with this treatment regimen, physicians often prescribe oral medications as their primary treatment option. Typically, insulin is not prescribed until it's determined that orals aren't doing the job.

As good as oral medications can be, study after study indicates that insulin ultimately provides one of the most effective forms of glycemic

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## The Diabetic Investor Model Portfolio

Stock	Current Value	% Change LFT	% Change YTD	% Change Month
<b>JNJ</b>	\$ 56.21	55.06%	4.65%	-0.95%
<b>LLY</b>	\$ 63.28	-9.03%	-0.35%	8.73%
<b>NVO</b>	\$ 35.55	-19.20%	23.01%	6.60%
<b>ABT</b>	\$ 39.49	-19.85%	-1.28%	0.51%
<b>PLMD</b>	\$ 30.94	-17.54%	0.31%	0.10%

The AERx System - Aradigm's entry into the race to develop inhaled insulin. It remains to be seen if patients will find this device simple to operate.



Photo courtesy of Aradigm

control. Theoretically a non-injectable insulin would benefit both the patient and the physician: a win-win situation.

That is until you look at how most companies have pursued this area. For reasons never understood by Diabetic Investor, most of the research in this area has forgotten a key element - ease of use. Insulin isn't something that's taken once in a while. Many patients inject themselves four to eight times each day. Syringes and insulin pens, the two most popular methods of injecting insulin, are relatively easy to use. Although an insulin pump requires a fair amount of time to calibrate, once done, insulin pumps are also fairly easy to use.

Compare this to delivery devices used by the two leading forms of inhaled insulin. Exubera's delivery device does look like a drug delivery device only for a far different type of drug. It's difficult to imagine a patient carrying this device to each

meal and using it publicly without attracting attention. (Even with the epidemic growth rate of diabetes, many patients are extremely sensitive and do not wish to call attention to their diabetes.) Of course, patients could excuse themselves to the restroom to inhale, but this adds another step to the process.

Aradigm's device requires the patient to wait for a green light that indicates they are breathing properly. Compare this to a pen user who simply dials out the necessary dose and shoots. The pen can easily be carried in a pants pocket or purse and, speaking from firsthand experience, shots can

Generex Biotechnology- The simplest device to use and the insulin is adsorbed in the mouth NOT inhaled into the lungs. Will it become the leading alternate delivery system should inhaled insulin fail to achieve FDA approval?



Illustration courtesy of Generex

be done without anyone noticing. Syringe users often pre-fill their syringe, making injects nearly as easy and private as a pen user. In

terms of privacy, pumpers have the ultimate, because to a layman, an insulin pump looks like a pager.

Winning the device design contest is Generex Biotechnology's delivery device for Oralin, insulin that's absorbed in the mouth, not inhaled into the lungs. The device is nearly identical to an asthma inhaler. Not only is the device easy to use and transport, most observers will think the patient has asthma, not diabetes. While neither ailment is desirable, the public's perception of asthma is more understanding than diabetes.

From this point of view, it would seem that an insulin pill would be the ultimate. Nobex Corporation and Emisphere Technologies are two companies working in this area. As enticing as this may sound, Diabetic Investor has yet to find a researcher that believes insulin in a pill form will ever become a reality. This won't, of course, stop the efforts in this area. The same can be said for an insulin patch or drinkable insulin.

No doubt, at the upcoming American Diabetes Association annual conference in June, there will be numerous presentations on these and other alternate delivery, non-injectable forms of insulin. As in the past, there will be a great deal of interest and much potential. In the end, however, Diabetic Investor sees little chance that insulin injections will become a thing of the past in the near future. We'll never say never, but even the most optimistic estimates puts a safe and effective non-injectable insulin at least five to seven years away.