



DIABETIC INVESTOR

“Make the Connection” David Kliff, Publisher

ADA 2008

It would be an understatement to say this year’s American Diabetes Association (ADA) conference was a newsworthy event. With three major studies releasing results and the ruckus over GLP-1 therapy, there were several equally newsworthy items that got lost in the shuffle. When it’s all said and done, people might just look back at this year’s conference as a major turning point in the diabetes market.

Heading into the show, everyone was anxiously awaiting the results of the three major studies - Advance, Accord and the Veterans Administration Diabetes Trial. The major question to be answered: Does tight control benefit or harm the patient with type 2 diabetes? Prior to the show, Diabetic Investor speculated that we may not get a clear answer to what appears to be a simple question; a speculation formed during the AACE meeting when researchers were already questioning how the studies were designed and questioning the results even though nothing had been released publicly.

Unfortunately, our speculation proved accurate and once again patients and the physicians who treat them didn’t

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get a clear answer. According to Anushka Patel, MBBS, SM, PhD, Study Director of the Advance Trial, “The results clearly demonstrate that intensive control of blood glucose, as recommended by the most current clinical guidelines, has an important role in the prevention of renal complications of type 2 diabetes. The other major finding of the trial was that major macrovascular events- heart attack, stroke and death from cardiovascular disease – were not significantly reduced with intensive glucose control, although there was a trend towards improvement in these outcomes. However, the results suggest that a multifactorial approach addressing all the major risk factors including blood pressure and blood lipids is required to prevent macrovascular disease.”

This statement is offset by Robert Byington, PhD, head of Accord, who stated, “The major clinical implication

is that there is some risk associated with this level of intensification of glycemic control in high risk cardiovascular patients with type 2 diabetes similar to Accord patients and that has to be considered by clinicians in the management of the disease.”

Finally, adding to the debate was William C. Duckworth, MD, Director of Diabetes Research, Carl T. Hayden VA Medical Center in Phoenix, Professor of Clinical Medicine, University of Arizona and Co-Chair of the VA trial, “While we found that intensive treatment of patients with type 2 diabetes suggested some benefits from glucose control, it did not reach significance for a reduction in the primary endpoint- a composite of specified cardiovascular disease events – in this population.”

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So, what did we learn from these three major trials which enrolled over 23,000 patients across the globe? Not a damn thing. There will be many who suggest that these trials were doomed from the beginning, as each covered different types of patients using different treatment regimens. Researchers and clinicians will surely debate the nuances found in the data to justify their particular philosophy. Yet, when it's all said and done, these three major studies have done little to advance the treatment of type 2 diabetes.

Although the results were disappointing on several fronts, there were some nuggets of information that shed light on what the future will look like for treating type 2 diabetes. Like too many things with diabetes, these nuggets revealed both good and bad news. First, the good news: achieving an HbA1c of 7% or below is doable. In all three trials, the groups assigned to intensive treatment were able to lower A1C levels to below 7%. In VADT the average was reduced to 6.9%, Advance 6.5% and Accord 6.7%. It was also shown that using standard therapy, A1C was reduced, just not to below 7% - 7.5% in Accord, 7.3% in Advance and 8.4% in VADT. (It should be noted that in the VADT trial, the baseline was 9.5% compared to 8.1% in Accord and 7.5% in Advance.)

In the no good news goes unpunished department, consider the following:

“As compared with standard-therapy group, the intensive-therapy group had significantly higher rates of hypoglycemia, weight gain and fluid retention.” – Accord

“Intensive glucose control was associated with an increased risk of severe hypoglycemia and an increased rate of hospitalization, as compared with standard control.” – Advance

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The increased risk of hypoglycemia, weight-gain and fluid retention are the main reasons physicians do not treat type-2 diabetes more aggressively. This is also the reason insulin is not more widely prescribed to treat type 2 diabetes. Physicians are caught between a rock and a hard place. Do they assign their patients an intensive treatment regimen, which as all the studies prove, helps them achieve an A1C of 7% or below? However, by assigning an intensive treatment regimen, the patient is at greater risk of hypoglycemia, a possibly life threatening event. Weight-gain and fluid retention are also contributors to the increased incidence of cardiovascular events.

The silver lining in what looks like nothing but dark clouds is the other big story coming out of the conference, namely how GLP-1 therapy could become the dominant treatment option for type 2 diabetes. What makes GLP-1 therapy so promising is its proven ability to lower A1C, low incidence of hypoglycemia and ability to help patients lose weight. This is nearly the exact opposite of what occurs when physicians use a combination of oral medications or insulin plus orals to reach good control.

It's no wonder, given these set of circumstances, that physicians, when faced with treatment choices, more often than not opt for standard treatment even though this regimen is unlikely to bring

the patient under what is defined as good control. This is the ultimate nightmare scenario which forces the physician to ask, “Will this treatment option do more harm than good?”

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GLP-1 therapy also has several additional advantages over existing therapy options. Unlike insulin which requires a high level of patient education, GLP-1 therapy is very patient friendly. Patients using Byetta, from Amylin (NASDAQ:AMLN), currently the only approved GLP-1 available, do not need to check their glucose levels prior to injecting or worry about what and when they eat. The patient simply dials out a predetermined dose and shoots.

On track to cross the billion dollar mark in sales, Byetta has proven that patients will use an injectable therapy. This is not to say that Byetta or any of the other GLP-1s currently under development have no drawbacks. The most common adverse event associated with GLP-1 therapy is nausea, which typically goes

away after a short period of time. It is also known that patients using Byetta fall into three groups. The first group does not see the A1C improvement or weight loss. The second sees just the A1C improvement and no weight loss, and the third gets both A1C improvement and weight loss. As with other therapy options, there is no one option that works with every patient. Looking at both the pros and cons of Byetta and other GLP-1s under development, taken as a whole, the pros outweigh the cons.

When the long-acting once-a-week version of Byetta, Byetta LAR, comes to market sometime in 2010, the advantage will swing solidly in favor of GLP-1 therapy. Byetta LAR has proven to be even more powerful than Byetta in controlling A1C and equally effective at producing weight loss. It also appears that LAR has a lower incidence of nausea than Byetta. The biggest obstacle appears to be LAR's delivery system. Although Amylin has not made public the final delivery system for LAR, what we know so far is the drug will need to be mixed prior to injecting and the needle size will be slightly larger than a conventional needle. Diabetic Investor suspects that the product will use either a 25 or 27 gauge needle, with the future delivery system being a pen like device that automatically mixes the drug.

Soon to join the market is Liraglutide, which Novo Nordisk (NYSE:NVO) recently submitted to the FDA, and Roche who has moved R1583 Taspoglutide into phase III trials. Novo and Roche are not the only companies set to enter the GLP-1 market as there are several early and mid-stage programs underway. Before we comment on these two drugs, it's important to recognize that all the GLP-1s, either on the market or under development, have similar profiles. They all are effective at lowering A1C, have a low incidence of hypoglycemia, varying degrees of weight loss

Will the GLP-1 market come down to data or delivery system? Is needle size more important than weight loss? Twice a day, once a day or once a week- is dosing frequency the ultimate driver?



Photo Courtesy of BD Diabetes



Photo Courtesy of Amylin

and the primary adverse event being nausea.

The differences center on frequency of delivery and type of delivery system. Byetta is delivered twice daily, Liraglutide once a day and R1583 and Byetta LAR once weekly. According to Novo and Roche, their compounds will be delivered using a pen like device with a 29 or 31 gauge needle.

Diabetic Investor sees Liraglutide having a place in the market, although we would disagree with Novo's characterization that Liraglutide is superior to

Byetta. The data just does not support this claim. Both of the drugs are effective lowering A1C, nausea is the primary adverse event and there is low incidence of hypoglycemia. Liraglutide has the advantage of once a day dosing; Byetta has superior weight loss results.

Based on the available data, R1583 appears comparable to Byetta LAR, but more data is needed to evaluate whether or not the drug is superior to LAR or just a me-too product. Given that LAR will have the advantage of coming to market

well before R1583, the drug has the additional hurdle of being better than LAR. At least with Liraglutide, Novo can offer the patient less injections than they would have with Byetta. It's an open question if this one slight advantage will overcome Byetta's superior weight loss capabilities.

In many respects, Diabetic Investor sees this market developing along the same lines as the long-acting insulin market currently dominated by Lantus from Sanofi-Aventis (NYSE:SNY). Launched well before Levemir® from Novo, Lantus has become the world's number one selling insulin. Realizing they were well behind Lantus when Levemir came to market, Novo looked to overwhelm physicians with data in an attempt to find any advantage to get physicians to switch insulins. While Novo would argue that Levemir is superior to Lantus, physicians have no compelling reason to switch from what has proven to be a very effective insulin. The reality is Novo once again was late getting Levemir to market, placing them in the difficult, if not impossible position, of playing catch up.

It appears Novo is trying the same tactics with Liraglutide. Already established in the market, Byetta has first mover advantage and is the standard by which all other GLP-1s will be judged. Other than having the advantage of less frequent injections, once daily as opposed to twice daily, Diabetic Investor does not believe Liraglutide offers physicians a compelling reason to switch patients from Byetta.

The real battle will come when a new patient starts therapy; that's a market where Liraglutide has a chance. To blunt Liraglutide from gaining acceptance in the market, Amylin and their partner Lilly (NYSE:LLY) could easily cut the cost of Byetta in half, forcing Novo not

only to prove superiority but match them price wise too.

Superior or not, price does matter, and given the option, physicians will go for the cheaper therapy option. Amylin and Lilly see LARs huge potential and may be willing to sacrifice some short term Byetta profits until LAR arrives. This move would give them the added enjoyment of getting payback against Novo who's been kicking Lilly's keyster in the insulin market.

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After seeing all the data from all the drugs, Diabetic Investor stands firm in our belief that LAR will be a paradigm shifting technology and a mega-blockbuster. We further believe that GLP-1 therapy will gain widespread adoption that will touch every aspect of the diabetes market. While insulin usage has been gaining ground, GLP-1s will slow growth in this market, particularly with type 2 patients. It's true that insulin plus orals, as demonstrated in all three studies, has proven to be an effective treatment option for patients with type 2 diabetes. However, the studies also demonstrated the drawbacks of this option. Given the choice, physicians are more likely to choose treatments which are effective yet avoid the drawbacks of other forms of intensive therapy.

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Sales of oral medications will also be affected, although not as dramatically as insulin sales. The fact remains that orals are and always will be the first therapy option chosen for type 2 diabetics. Drugs like metformin have a long history, a well known side effect profile and are generic. Used in combination with a TZDs or DPP-4, many patients can achieve solid control.

Overlooked is how the increasing usage of GLP-1 impacts the medical device market. It's well known that type 2 patients fail to monitor their glucose regularly and are the least frequent users of test strips. As Diabetic Investor has reported, several studies are now questioning the value of testing for type 2 patients. GLP-1s will only make matters worse, as there is no need for patients to monitor their levels when using a GLP-1.

Insulin pump sales will also see a slow-down. With the increased usage of insulin for type 2 patients, it appeared pump makers would finally have the opportunity to penetrate this market. However, the effectiveness and simplicity of GLP-1 therapy provides physicians with a solid alternative. Of all the therapy options available, insulin pump therapy is the most labor intensive. Effective as it is, insulin pump therapy cannot compete with GLP-1s when it comes to the Diabetic Investor SSE (Safe, Simple and Effective) scale.

The bottom line here is that the results of the three major trials proved that using intensive therapy, patients can

A combined Bayer and Abbott would give the company the size and resources they need to compete in the market that matters most - formulary placement. It would help Bayer better control their costs as they would control production of the popular FreeStyle line of monitors and they would not be totally dependent on Panasonic who currently makes their popular Contour monitor. This move would also give Bayer access to the insulin pump patient, who monitors their levels on average seven times each day. Abbott has two pump relationships: one with Smiths Medical and the other with Insulet (NASDAQ:PODD). Abbott also has the Aviator insulin pump which has been approved by the FDA but has yet to be brought to market. The fact is, to fully compete in the BGM market, Bayer knows they must have relationships with one or more insulin pump companies.

achieve good control. The studies also showed the limitations of intensive management. While no one therapy option is perfect and there is no silver bullet for all patients, GLP-1 therapy offers the most compelling option to achieve solid control and avoid hypoglycemia while helping patients lose weight. Based on the Diabetic Investor SSE scale, GLP-1 therapy scores well and of all the GLP-1s on the market or underdevelopment, Byetta LAR is the best of a good bunch.

The biggest news to come out of the medical device area wasn't actually made at the show. It was made by Diabetic Investor when we reported that Bayer is in serious discussions to buy Abbott's (NYSE:ABT) diabetes care unit. While both companies deny that discussions are taking place, it is known that Abbott has been shopping their unit for some time and, in reality, this deal makes perfect sense.



Photo's Courtesy of Bayer and Abbott

Bayer has done an outstanding job of reinvigorating their once failing glucose monitoring business, while Abbott has done an equally poor job of running their glucose monitoring unit. The two companies have switched places, with Bayer now in third place and Abbott falling to number four. LifeScan, a unit of Johnson and Johnson (NYSE:JNJ) continues to hold the top spot with Roche a close second.

What both Bayer and Abbott know is that alone, they can only get to a certain size as LifeScan and Roche have a major advantage when it comes to formulary placement. As Diabetic Investor has been saying, when it comes to blood glucose monitoring (BGM), size does matter. This is no longer a market where you can come out with an innovative product and steal market share from the Big Four; just ask the people at privately held AgaMatrix. AgaMatrix has an outstanding product line and low prices, yet they lack the resources to compete with the Big Boys making it difficult to gain share. As one company official stated, "We have to play in the markets where we can compete."

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(Besides owning LifeScan, JNJ also owns Animas, currently number two in insulin pumps and has a deal with Medtronic (NYSE:MDT), the market leader in insulin pumps. Roche spent over a billion dollars to buy Disetronic, at the time the number two player in pumps, only to run into a series of problems with the unit which is now an also ran in the pump market.)

The reality is the BGM market is changing rapidly and not for the better. BGM companies are facing an increasingly

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competitive market and margins are being squeezed. Even before competitive bidding came in, companies were facing pressure to lower prices. Competitive bidding will only accelerate this pressure and lead to even lower reimbursement rates. At the same time, there is a growing threat that insurers will no longer provide reimbursement for non-insulin using patients. As we pointed out earlier, there are just too many studies that show that there is no correlation between testing and better outcomes for non-insulin using patients. With healthcare costs increasing, insurers will use these studies as justification for only reimbursing patients that take insulin. And, as we just indicated in our discussion about the increasing adoption of GLP-1 therapy where there is no need to test glucose levels, the industry's future looks cloudy at best.

Add in the fact that the BGM market has fully transformed from a medical device market to a consumer product/commodity type market, and you have the recipe for trouble. For years, BGM companies spent millions on introducing new technologies such as smaller sample sizes, alternate site testing and monitors that could download results. Solid advances all, however, what the majority of patients wanted was simplicity. This is one reason why Bayer has done so well with their Contour monitor. Bayer understood they had an advantage with Contour's no-coding feature which made the monitor more patient friendly. They also knew that this no-coding feature would be quickly copied, just as alternate site testing was copied after it came out.

Partially due to Bayer's success, their competitors were quick to jump on the ease of use bandwagon. In their ads for the OneTouch UltraMini, LifeScan talks about ease of use and how the patient can get the monitor in various colors.

What's truly refreshing about Intuity and their OnQ system is it actually works and the company understands this is not a revolutionary product, merely the natural next step in glucose monitoring. About the size of a traditional glucose monitor, the patient simply inserts a cartridge which contains 10 test strips and lancets. The patient then places their finger on the device and OnQ does the rest. No need for the patient to carry around a monitor, test strips and a lancing device, everything is in one nice neat little package.



Photo Courtesy of Intuity Medical

Roche now sells skins that can be placed on their monitors, Abbott launched a FreeStyle that does not require coding and Bayer now offers the Contour in colors.

Finally, in an ironic twist, all the companies have found religion and realize that patient education is more important than fancy features or what color the monitor is. For years, Diabetic Investor has maintained that the reason the majority of patients fail to monitor their glucose levels on a regular basis has nothing to do with pain. The reason is lack of education. Patients not only do not understand what the test result means, but there is no action step for the patient to take after the test. This is why insulin pump patients are the most frequent testers; they understand what the numbers mean and there is usually an action step involved after the test. The same is true for patients on multiple daily injection (MDI) therapy, the second most frequent group of testers. When a patient is

on oral medications alone or orals plus Lantus, rarely is there any action taken after the test is performed. The patient quickly realizes there is little value to this data, so why get it in the first place?

Contributing to this problem is that patients see little difference between monitors; to the patient, all monitors do the same thing and they're free to boot. While Diabetic Investor understands the razor/razor blade business model, the decision to give monitors away for free to get the continuing test strip revenue has done irreparable harm to the BGM market. The patient reasons that since the monitor is given away for free, the information isn't all that important. To the patient, the "brains" of the system is the monitor, when in reality all the technology is in the test strip. The fact is if patients actually had to pay for the monitor, they would test more frequently.

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This feeling that monitors aren't all that important is reinforced by insurers who constantly switch patients from brand to brand based on which company is willing to offer better pricing to get favorable formulary placement.

A few years ago, Diabetic Investor speculated that co-branded monitors would gain share. We reasoned that since all monitors do the same thing and there is



Photo Courtesy of Insulet

very little difference between monitors, patients would ask the next logical question: which monitor is cheapest? Why pay more for LifeScan OneTouch Ultra when a CVS monitor does exactly the same thing at a cheaper price? While co-branded monitors have gained some share, the major brands decided to fight back coming out with cheaper monitors of their own, a move that pushed the market even further towards a commodity market. Now, patients can use name brand monitors at value prices.

Seeing this, BGM companies began acting like traditional consumer product companies by advertising on television, couponing and flooding the market with free samples. Sales reps spread out across the country calling on physicians and diabetes educators, leaving free monitors in their wake. Understanding that insurers played a critical role in determining market share, companies fought tooth and nail to get preferred

formulary placement. This is where the battle is being played today and the reason why Bayer will buy Abbott's diabetes unit.

BGM companies may have found religion when it comes to educating the patient; however, this is like the smoker who vows to quit smoking after they discover they have lung cancer - a good move, but too little and way too late. The dye has been cast here and there is no turning back.

Watching all this with some amusement has to be the people at Insulet. The OmniPod system is gaining traction in the market and the company already has a second generation system waiting in the wings. While the new system is not as revolutionary as the original, it does have several notable new features, including a smaller, less costly to manufacture pod and a thinner PDM with a color screen. Having just signed a deal with Ferring Pharmaceuticals of Saint Prex, Switzerland, to develop the OmniPod System for the delivery of a Ferring drug, the company is expanding beyond the diabetes market. This deal comes on top of their agreement with Abbott to keep the FreeStyle monitor as part of the OmniPod system.

One company that should benefit from the changing dynamics of the BGM market is privately held Intuity Medical. Of the many small BGM companies at the conference all offering the same old thing, a standard monitor that does the same thing as what's already on the market only at a cheaper manufacturing cost, Intuity has a new twist on an old idea. For years, BGM companies have struggled to develop a working all in one device, the most recent example being the ill-fated Soft-Tac from Abbott. This monstrosity of a device was supposed to let patients simply place the device on their finger and test. Roche is

trying to get to an all in one device based on their Accu-Chek Compact platform as is Bayer with their Breeze2 monitor. With these two monitors, the test strips are contained in the monitor, so all the patients have to do is lance their fingers to get a blood sample. There is also Pelikan Technologies who has the Pelikan Sun automatic lancing device. Pelikan says they are working on an all in one device just as Abbot has been saying they are working on an improved version of the Soft-Tac. What's truly refreshing about Intuity and their OnQ system is it actually works and the company understands this is not a revolutionary product, merely the natural next step in glucose monitoring. About the size of a traditional glucose monitor, the patient simply inserts a cartridge which contains 10 test strips and lancets. The patient then places their finger on the device and OnQ does the rest. No need for the patient to carry around a monitor, test strips and a lancing device, everything is in one nice neat little package.

The company expects to file a 510K with the FDA sometime next year and admits that there may be changes to the device. One feature the device does not have, which could be added, is the ability for the users to select lancing depth. This may not seem like much of an issue; however, skin thickness varies among users and a one depth for all approach will not be deep enough to get an adequate blood sample. Even without this feature, Diabetic Investor was impressed with the product; of all the products that have traveled down this path, the OnQ stands the best chance of getting to market and gaining acceptance.

The path for Intuity is also a well traveled one, as more than likely the company will be acquired by one of the Big Four, soon to be Big Three. It also

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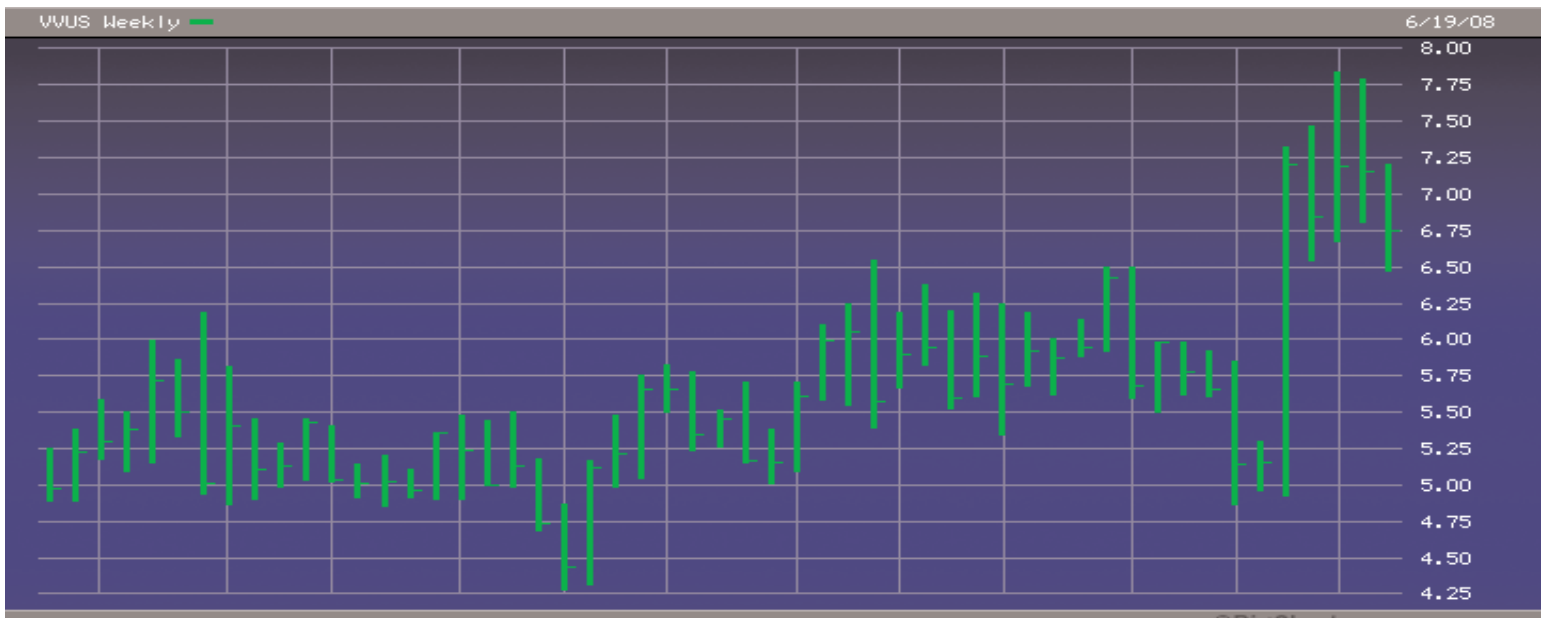
wouldn't surprise Diabetic Investor at all if Intuity experiences another all too familiar experience, the intellectual property lawsuit. As we have seen with past actions by all the major players, the BGM market is not one for the faint hearted. Besides needing vast resources

has had to redesign some aspects of the system. (Can we say IP concerns anyone?) There are also rumors that the company may not even make it to the FDA.

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Medtronic holds a commanding, almost insurmountable lead. Johnson and Johnson is using Animas as a conduit to sell more test strips for the LifeScan brand of glucose monitors and will soon introduce a LifeScan monitor that communicates with the Animas pump. These companies have also struck a deal that helps LifeScan sell even more test

Given the high level of interest in the diabetes/obesity drug market as highlighted by GlaxoSmithKline's (NYSE:GSK) decision to buy Sirtis for \$720 million, it's almost a sure thing that with this new data Vivus will attract the attention of a major pharmaceutical company. Delivered orally, Qnexa scores well on the Diabetic Investor SSE scale, and fits nicely into the diabetic market. With a market cap of just under \$405 million, the company is well positioned for an offer.



to compete, strong IP is almost as valuable as formulary placement.

Speaking of IP and the prospect of facing a lawsuit, word on the street is Medtronic is preparing to go after Insulet. Medtronic has already announced plans to introduce their own version of a wireless pump and sees that Insulet is not only gaining share, but expanding the market for insulin pumps. They also see that there are many Insulet wannabes waiting in the wings with their own version of a wireless pump. The company gaining the most attention is Medingo, who was supposed to file a 510K for their device sometime this year. Diabetic Investor has learned the filing has been delayed as the company

the market and the company already has a second generation system waiting in the wings. While the new system is not as revolutionary as the original, it does have several notable new features, including a smaller, less costly to manufacture pod and a thinner PDM with a color screen. Having just signed a deal with Ferring Pharmaceuticals of Saint Prex, Switzerland, to develop the OmniPod System for the delivery of a Ferring drug, the company is expanding beyond the diabetes market. This deal comes on top of their agreement with Abbott to keep the FreeStyle monitor as part of the OmniPod system.

When it comes to the insulin pump market, the facts speak for themselves.

strips with the new UltraLink system. (It should also be noted, in a continuation of their strategy of fully penetrating the insulin using market, LifeScan plans on introducing a glucose monitor that contains a bolus calculator. Look for this product to be introduced at the upcoming American Association of Diabetes Educators conference in August.) Roche, Smiths Medical and the many others who play here cannot effectively compete as they have nothing new to offer. Insulet is taking full advantage of being first to market with a wireless system, making it difficult when the many Insulet wannabes come to market, if they ever get here.

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Sitting firmly in the catbirds seat, Insulet knows they have two issues to take care of before they are eventually acquired. First, and most importantly, the company must lower their manufacturing costs and become margin positive. Second, they must maintain their aggressive marketing approach and build their installed user base. Based on what Diabetic Investor has seen, the company is moving forward on both fronts. There is no doubt in our mind that, like so many others, Insulet will complete the cycle and be acquired in the next 12 to 24 months.

Another company following this path is Vivus (NASDAQ:VVUS). At the conference, the company released detailed data on the obesity/diabetes drug Qnexa. In a 28-week, phase 2 clinical trial in type 2 diabetics, subjects treated with Qnexa had a reduction in HbA1c of 1.2 percent, from 8.7 percent to 7.5 percent, as compared with a reduction of 0.6 percent, from 8.6 percent to 8.0 percent, in subjects in the placebo group ($p < 0.001$). Subjects treated with Qnexa also lost 8.0 percent of their baseline body weight, or 7.7 kg, as compared to 1.2 percent weight loss, or 1.3 kg, observed in the placebo group ($p < 0.001$). The company also stated Qnexa patients had significant improvement in cardiovascular risk factors including blood pressure, triglycerides levels and waist circumference.

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In a way it's sad that diabetes had to reach epidemic proportions before the agency took action. Hopefully, everyone is getting the message loud and clear that patients and the physicians who treat them need better drugs and devices; a message that must be delivered in a clear and understandable format. We can no longer afford to have researchers delivering mixed signals, complaining about study design and discounting results which are not yet in the public domain. The entire diabetes industry must come together along with the FDA if we are to ever stem the growth of diabetes and contain the damage being done to patients who are struggling to keep their disease under control. As John Stuart Mill wrote back in 1836, "Cooperation, like other difficult things, can be learned only by practice: and to be capable of it in great things, a people must be gradually trained to it in small. Now, the whole course of advancing civilization is a series of such training."

the attention of a major pharmaceutical company. Delivered orally, Qnexa scores well on the Diabetic Investor SSE scale, and fits nicely into the diabetic market. With a market cap of just under \$405 million, the company is well positioned for an offer.

Once again, going back to where we started when this issue began, the results of the Accord, Advance and VADT trials highlight how the market for diabetes drugs is changing. While the FDA has traditionally used glycemic control as the primary marker for approving new drugs, they can no longer ignore secondary markers such as weight gain, blood pressure, lipids and other cardiovascular endpoints. Nor can the agency ignore the fact that obesity is directly correlated to growth in diabetes and that there are over 50 million people who have pre-diabetes who will likely develop full blown diabetes. Diabetes is no longer just a healthcare issue; it is also an economic issue. By doing nothing, the FDA risks seeing this epidemic morph into a national healthcare issue, which will not only overwhelm the healthcare system, but cause major economic consequences as well.

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