**Insulet Corporation**

Company Description: Insulet Corporation develops and manufactures insulin pumps for insulin-dependent diabetics. The company sells its OmniPod system directly and through distributors. The company recently acquired Neighborhood Diabetes, a diabetes supply distributor. Insulet was founded in 2000 and is based in Bedford, Massachusetts.

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**Pump up the portfolio with expanding margins; initiating with BUY and $19.80 PT (PODD - $15.75) BUY**

**Key Points**

- Next generation OmniPod set to drive expanding margins.
- OmniPod’s ease-of-use important for both patients and prescribing physicians.
- Entrance into foreign markets provides opportunity.
- Neighborhood Diabetes acquisition gives Insulet the ability to accelerate growth.
- Initiating with BUY rating and $19.80 price target (5.3x FY2012 OmniPod EV/sales plus 1.0x EV/sales for Neighborhood Diabetes FY2012 sales).

Insulet's next generation OmniPod insulin pump system is set to drive expanding margins. The company has submitted its second generation OmniPod system to the FDA and is currently responding to comments; we believe they are on track for a late 2011 or early 2012 approval. Importantly, the second gen version saves ~$3-$4 per OmniPod (current manufacturing cost ~$14 per, ASP of ~$28) which should help drive gross margin on direct sales to 65%+ versus ~50% currently.

Ease-of-use represents an important factor in adoption of insulin pumps for both patients and prescribing physicians. Most endocrinologists would prefer to place their patients on insulin pumps instead of multiple daily injections (MDI) of insulin. However, the time spent training new pump patients impacts the number of patients a physician is able to see and the profitability of the practice. The OmniPod is the easiest-to-use pump on the market and consequently the likely first choice for a physician transitioning a patient from MDI to pump therapy. This is evidenced by ~75% of new Insulet customers coming from MDI and an estimated 20%-25% win rate of new installs (compared to Insulet’s ~7%-8% market share).

The company recently signed distribution agreements with Ypsomed and GlaxoSmithKline to bring the OmniPod to Europe, Canada, and China. While this will lower the company’s gross margin overall, operating margin will be over 20% on the distributed OmniPods. The Ypsomed agreement carries with it $100 million in minimum purchase commitments over five years, but is heavily back-end loaded, similar to Insulet’s revenue ramp in the US.

Insulet's Neighborhood Diabetes acquisition (a profitable, fast-growing medical supply distributor focusing on diabetics) provides the company the ability to accelerate growth and capture additional revenue. Neighborhood counted ~18,000 customers (of ~60,000 total) using MDI and competitor’s pumps to manage their diabetes. We believe Insulet will be successful converting a number of them into OmniPod customers over time. Perhaps more importantly, Neighborhood excels at back-office order processing and fulfillment, something that “bottlenecked” Insulet’s past growth. We anticipate these capabilities will allow Insulet to gain efficiencies from their existing sales force and ultimately accelerate growth once the second gen OmniPod hits the market.
INVESTMENT THESIS

We believe that Insulet’s unique place within the insulin pump industry will allow it to compete successfully. Their key intellectual property, particularly with regard to automated cannula insertion, will make it difficult for new “patch” pump entrants to compete in terms of ease-of-use and profitability in our view. Insulet has continually taken market share from larger entrenched players and we estimate they are winning 20%-25% of new insulin pump users, far ahead of their 7%-8% market share. We anticipate that the Neighborhood Diabetes acquisition will provide Insulet with the back-office capabilities to accelerate growth once the next generation OmniPod hits the market. Historically, diabetes-related acquisitions have carried higher multiples and we believe that Insulet’s growth rate and positioning deserves a multiple at least inline with other high-growth medical technology companies. Therefore, we have assigned the company a $19.80 price target based upon sum-of-the-parts methodology incorporating a forward EV/sales multiple of 5.3x on their OmniPod sales plus a 1.0x EV/sales multiple on the recently acquired Neighborhood Diabetes (roughly the same level as Insulet paid in the transaction). Thus, we believe that Insulet is undervalued at present levels and rate the company a BUY.

Opportunities

Ease-of-use. An easy-to-use insulin pump is not only preferable to the patient, it is also very important to the prescribing physician. If training a patient to use an insulin pump requires too much time, a physician is less likely to prescribe pump therapy. Over 70% of Insulet’s customers come from the multiple daily injection (MDI) population, making the company a market expander as opposed to a direct competitor to traditional pump players. The ease-of-use of the OmniPod system makes it more attractive for both patients and caregivers, giving Insulet a competitive advantage over traditional pumps.

Next-generation OmniPod set to expand margins. The next-generation OmniPod will cost $3-$4 less to manufacture, expanding gross margin from ~50% on the current version to approximately 65% on the new version. Eventually, the company believes it will be able to attain gross margin of nearly 70% on pumps sold directly.

Large, growing markets currently untapped by Insulet. The insulin pump market has been growing at high single-digits worldwide and should continue to do so. Insulet’s access to the Canadian and European markets through the GlaxoSmithKline and Ypsomed agreements, respectively, should further increase Insulet’s reach in markets that are currently less penetrated than the US.

Neighborhood Diabetes acquisition. While the Street appeared to view the Neighborhood Diabetes acquisition as a modest negative, sending the stock down 9% in the week following the announcement, we are inclined to take the opposite view. Back office processing of customer orders has “bottlenecked” Insulet’s sales in the past, restraining growth. The acquisition of Neighborhood Diabetes offers Insulet a solid back-office platform from which to roll out its next gen OmniPod without restraining sales volumes. Additionally, this provides Insulet with access to nearly 18,000 insulin-dependent diabetics not currently using their pump. Please see the “Neighborhood Diabetes Acquisition” section for further discussion of the reasons we view this transaction as a smart move.

Technology and intellectual property advantage. The OmniPod pioneered the “patch” pump market and its intellectual property, particularly with regard to automated cannula insertion, makes it difficult for competitors to offer an easy-to-use product at a similar cost. Manufacturing disposable pumps such as the OmniPod is a difficult task and Insulet has had difficulty in the past improving their gross margin. We believe competitors are likely to go through the same growing pains which may make investment in a higher-complexity competing product less likely.

Large potential opportunity in Type 2 diabetes. Roughly 28% of all US diabetics use insulin in some fashion. Being that 5%-7% of diabetics are Type 1 diabetics, expansion into the remainder of the insulin-using diabetics represents a huge potential opportunity for the insulin pump industry. The reimbursement environment is not there presently for it to make sense for Insulet to go after this population, the opportunity to do so in the future would result in a potential market five times the size of today’s value.

Risks

Direct Competition. Insulet faces competition from several large insulin pump players, including Medtronic (MDT – not rated), Johnson and Johnson (JNJ – not rated), and Roche (RHHBY – not rated). Combined, these firms make up over 85% of the market compared to Insulet’s 7-8% market share. Further, a number of firms are developing “next generation” insulin pumps (please see the “Competition” section for a detailed analysis) as well as “patch pens”. While some of these
pending competitors target market segments that Insulet is not currently in, such as Type 2 diabetics, they may hamper
Insulet’s competitive position in these markets going forward.

**Indirect competition from other insulin delivery options.** In addition to facing competitive threats from other insulin
pump manufacturers, Insulet must compete with multiple daily injections (MDI) of insulin. MDI is less expensive than
continuous subcutaneous insulin infusion (CSII) and has also become more effective with the introduction of long-acting
insulin analogs. The company has made note of the fact that 20-40 year old men have been the most likely to switch back
to MDI during the current economic downturn in order to save money, negatively impacting Insulet’s attrition rate.
Additionally, several smaller studies have suggested that bariatric (gastric bypass) surgery has improved or eliminated
diabetes in a high proportion of Type 2 patients. However, many challenge this claim. We believe it may be overstated and
think it is currently unlikely that carriers would begin reimbursement for such a procedure solely on account of diabetes.

**FDA timeline slippage.** Numerous medical device firms have had difficulty lately in receiving FDA approval of products,
including Insulet. For instance, the Insulet-DexCom combination pump/continuous glucose monitor (CGM) was initially
intended to launch in mid-2009. While the FDA has provided guidance on the criteria by which it will evaluate “low glucose
suspend” systems (a precursor to the artificial pancreas), numerous projected timelines have slipped over the past several
years and it appears the trend will continue. For sake of illustration, Insulet’s FDA submission for their next-generation
OmniPod contained around 7,800 pages which they had to deliver in triplicate.

**Hacking concerns.** Recently, a security researcher gave a presentation at the Black Hat Digital Security Conference in Las
Vegas showing that it was technically feasible to “hack” an insulin pump (a Medtronic Paradigm) using the wireless protocol
(connection) between the pump and control unit. Potentially, this could allow one to induce hypoglycemia in a pump
wearer, which may cause death. However, technically feasible and practically feasible are two far different things in our
view. It is likely that this hack depends on being in close proximity to the pump wearer as signals (or packets) are being
sent for a relatively long period of time, similar to hacking a secure wireless Internet connection (WEP or WPA encryption),
and/or having access to the pumps serial number. The news media seized upon this story and proceeded to exaggerate
the true risk. Since then, a number of politicians have begun making noise on the issue, which has the potential for a
number of negative developments to occur, such as recalls of “insecure” pumps, lawsuits, increased scrutiny of wireless
communication protocols and security in medical devices, and a lengthened FDA approval process.

**Becton Dickinson patent lawsuit.** Becton Dickinson (BDX – not rated) has filed a patent infringement suit against Insulet
centered on patents which Becton acquired. Insulet and their external counsel do not believe that the suit has merit, but the
company could face additional legal expenses defending against the suit. Similarly, there is no telling what a jury may
decide should the suit go to trial.

**Thoughts on Valuation**

**Thoughts on Mergers and Acquisitions in Diabetes-Related Industry**

Disappointing results from certain past acquisitions have seemingly left large medical-device firms adopting a wait-and-see
approach to acquisitions in the diabetes segment – they would rather pay up for a proven opportunity than take chances too
early. Although potentially limiting venture capital investment in the segment, this could drive higher valuations for
acquisitions of successfully proven technologies given the difficulty of gaining necessary approvals. Further, it implies a
larger financial barrier to entry and a limited willingness (or interest) to fund new entrants. This is evidenced by the fact that
it has been half a decade since a major diabetes-related acquisition has been announced. We believe this is a sufficiently
attractive industry thanks to its sheer size and relatively low penetration rates, and that acquisition multiples are likely to be
at least as high as they have been in the past.

The table below lists what we believe to be a representative sample of high-growth medical technology acquisitions over the
past decade. We note that valuations for diabetes-related acquisitions in terms of trailing-twelve-month EV/sales multiples
are approximately a full point higher than those of other high-growth med tech acquisitions. This, in our opinion, is due to
the attractiveness of the diabetes market for the reasons mentioned above, as well as the unfortunate state of affairs when
it comes to new diabetes cases, which are growing rapidly, largely due to obesity and the aging population (a 65-year-old is
more than twice as likely to have diabetes than a 50-year-old). As such, we believe higher multiples are warranted for
diabetes-related firms versus an average high-growth med tech company.
Thoughts on Current Public Company Valuations

In the recent market weakness, multiples for high-growth med tech companies have corrected a great deal. The table below presents the current valuations of high-growth med tech companies with the growth rates given representing the year-over-year growth for the current fiscal year versus next fiscal year. As one would expect, higher-growth firms trade at higher multiples than their slower-growth counterparts. However, Insulet’s year-over-year growth figure in the table below is skewed due to their acquisition of Neighborhood Diabetes in Q2 2011. On a product revenue basis (excluding projected growth). As such, we believe that 5.3x next year’s revenues is a reasonable starting point upon which to value Insulet’s product revenues.

Publicly-traded High-Growth Medical Technology Companies

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Mean  5.9   4.4  25%  28.2  566.5  41.5  102.6

Median 4.6  3.9  16%  18.1  165  28.0  26.9

Insulet Corporation (PODD)
The chart below shows Insulet’s range of adjusted enterprise value to next-twelve-months product sales multiples since its initial public offering. We are removing the purchase price Insulet paid for Neighborhood Diabetes (roughly 1.0x sales) to arrive at adjusted enterprise value and taking into account only product sales. Over the past two years, Insulet’s average low and high multiples on a quarterly basis are 6.4x and 4.6x. The company is currently trading at 4.9x, and the lowest high multiple the company has traded at was in Q4 2009 when it traded at 5.3x, corresponding nicely to Endologix’s current multiple. Therefore, we have chosen 5.3x as the multiple on which to value Insulet’s product revenues. Based on 2012 estimates, this provides an enterprise value of $870.8 million to which we add estimated Neighborhood Diabetes revenues of $61 million and current net cash of $2.6 to arrive at $934.4 million, or ~19.80 per share based upon 47.3 million shares outstanding at the end of Q2 2011.

**Key Model Assumptions**

We have attempted to take a conservative approach in estimating Insulet’s future growth. We have split Insulet’s revenue streams for OmniPod and Neighborhood Diabetes into different buckets due to the differing margin profiles each carries. Our assumptions on various aspects of the company’s financials are as follows:

- International revenues grow roughly inline with the initial growth curve Insulet and a number of other high-growth medical device companies have experienced on launching their product.
- International revenues carry a lower gross margin, closer to ~30%-35% on the next-generation OmniPod, but operating margins in the 20%+ range.
- We have estimated 2011 revenues of $153.5 million versus management guidance of $152 million-$158 million on the Q2 2011 conference call. Estimated Q3 2011 revenues of $44.9 million versus management guidance of $44 million-$46 million.
- Estimated an operating loss of $14.1 million versus management guidance of $13 million-$18 million for the remainder of 2011.
- Our estimates for operating expenses are substantially higher than the current Street consensus for 2012; we think it prudent to take a wait-and-see approach when it comes to the operating expenses of the combined Insulet/Neighborhood Diabetes organization.
- Assumed 9.5% year-over-year attrition rate, the midpoint of management’s 9-10% attrition range.
- Our model suggests that Insulet exited Q2 2011 with ~29,500 current users and based upon past growth, we believe that the company will be able to add approximately 1,000 new users per month on a net basis.
• Despite the acquisition of Neighborhood Diabetes and its fulfillment capabilities and additional salespeople, we have assumed that Insulet continues to grow at roughly the same rate as if its back-office and sales force capacity had not been expanded through 2012.
• We have estimated no tax liability for the foreseeable future due to the significant operating losses Insulet has incurred to date.

Company Overview

Insulet Corporation is a medical device company that develops, manufactures, and markets insulin infusion systems used by insulin-dependent diabetics. Their current product is an insulin management system known as the OmniPod which was the first tubing free insulin pump or “patch” pump. Recently, the company formed two partnerships, one with Ypsomed allowing them (Ypsomed) to distribute the OmniPod in 11 countries and China, and another with GlaxoSmithKline for distribution of their system in Canada. Additionally, Insulet has an agreement with DexCom to integrate Insulet's OmniPod system with DexCom's continuous glucose monitor (CGM).

Insulet sells the OmniPod System directly to patients through referrals from healthcare professionals and through patient leads (~75% of sales are direct), as well as through third-party distributors. The company was founded in 2000 and is based in Bedford, Massachusetts.

OmniPod Overview

The OmniPod system consists of two parts, the “pod” and the “personal diabetes manager” (PDM), as shown in the graphic below. The pod and PDM communicate wirelessly with the PDM controlling insulin delivery by the pod. Additionally, the PDM controls cannula insertion, which is one of Insulet's key intellectual properties and a competitive advantage. This allows the OmniPod to have the fastest insertion and smallest-gauge introducer needle currently available, making insertion virtually pain-free for the user. The OmniPod has no tubing, in contrast to traditional insulin pumps, which eliminates interruptions from kinking, leaking, or disconnecting leading to a more consistent delivery of insulin.

OmniPod's ease-of-use is a key differentiator. Competitors' systems use manual insertions which can increase patient anxiety and lead to inconsistent insertion. The PDM is similarly easy to use, with the fewest steps required to begin delivery of insulin. While ease-of-use is important for patients, it may be even more important when it comes to endocrinologists prescribing the OmniPod. In general, the more patients a given physician can see in a day, the more lucrative his practice. Time spent training a patient on how to use a more complex insulin pump is time that cannot be used to see other patients. We believe that this training burden has slowed insulin pump adoption. Further, the fact that over 70% of Insulet's new customers switch from MDI as opposed to from another insulin pump lends credence, in our view, to the ease of use of the OmniPod system. Thus, we believe that the OmniPod expands the insulin pump market far more than competes head-to-head with traditional insulin pump players.

Next Generation OmniPod

Insulet has submitted their next generation (second gen) of the OmniPod to the FDA for review and is currently in the “responding to comments” phase with the FDA. We believe that it remains on track for a late 2011 or early 2012 approval. The second gen OmniPod “pod” is approximately 40% smaller and 25% lighter than the current version of the system. The PDM controller will be upgraded as well. Perhaps most importantly, the next gen OmniPod will enable the company to
reduce its cost to manufacture a pod from ~$14 to ~$10, expanding gross margin from 50% to around 65% with potential to reach 70%. Insulet plans on having its US users switched over to the next gen version by the end of 2012, as does Ypsomed in Europe.

First Generation OmniPod Compared to Second Generation

Source: Company website.

Insulet/DexCom Combination Pump/CGM Device

Insulet and DexCom have an agreement to combine Insulet's second generation OmniPod with DexCom's fourth generation glucose sensor into a combination pump/CGM device. The intent is to have DexCom's glucose sensors send readings directly to the OmniPod's PDM controller for action by the user. This project has suffered a number of delays, apparently due to a changing FDA approval environment; the companies initially thought they would introduce the product in mid-2009. As of today, the companies expect to be able to file with the FDA in Q2 2012, but that may be delayed if either company has an issue gaining approval for their respective next generation product.

Ypsomed and GlaxoSmithKline Agreements

Insulet has signed agreements with Ypsomed to distribute the OmniPod system in Europe and GlaxoSmithKline to distribute its products in Canada. The Ypsomed agreement guarantees $100 million over five years. However, the agreement is extremely back-end loaded and likely based off of Insulet's revenue ramp in the US (2006: $3.7M, 2007: $13.4M, 2008: $36.1M, 2009: $66.0M, 2010: $97.0M). We believe that the company will be able to generate 20%+ operating margins on distributor sales, but gross margins will be negatively impacted as a whole.

Neighborhood Diabetes Acquisition

On June 2, 2011, Insulet announced the acquisition of Neighborhood Diabetes, Inc. for approximately $63 million in cash and stock. Neighborhood Diabetes is a durable medical equipment (DME) distributor that sells diabetes supplies directly to the consumers largely on the East Coast. At the time of acquisition, the company has about 60,000 customers, ~18,000 of which were insulin dependent (roughly the same ratio of insulin-dependent diabetics nationwide to total diabetics nationwide). Few of the acquired customers, less than 1,000, used the OmniPod, but over 5,000 were users of competitors' insulin pumps. The remaining ~13,000 customers utilized multiple daily injections (MDI) to deliver their insulin.

While investors apparently disliked the acquisition, sending the stock down 4% on the day it was announced and 9% over the following week, we believe that it was a necessary and smart transaction for Insulet for several reasons. First, Insulet gained access to ~13,000 diabetics who use MDI and the company has seen over 70% of new OmniPod users come from the MDI population in the past; Insulet will now be able to directly market to these MDI customers its OmniPod system. Second, Neighborhood Diabetes is quite experienced in processing orders in a high-volume fashion, processing three times the number of orders monthly as Insulet did on a similar basis prior to the acquisition. Importantly, order processing ability has "bottlenecked" OmniPod sales growth historically, many times showing up as reduced salesperson efficiency. Having an experienced back office enables the company's salespeople to concentrate on sales rather than having to be involved in reimbursement, billing, and distribution logistics. Third, Neighborhood Diabetes was profitable at the time of acquisition, earning $3.1 million before taxes in calendar 2010, certainly more than Insulet was earning on its cash position, making the transaction immediately accretive. Additionally, Neighborhood Diabetes was growing rapidly at the time of acquisition, growing revenues at 17% in the trailing twelve months ended March 31, 2011. Lastly, it gives the combined companies the
opportunity to supply other diabetes supplies to current OmniPod users, such as test strips, which might cost a typical Type 1 diabetic $1,000 per year, at a 30%+ operating margin. Insulet estimates that, post-acquisition, it will be able to drive 20% more incremental revenue for each OmniPod user that chooses to use Neighborhood as his DME.

**Competition**

Insulet’s competition emanates mainly from traditional insulin pump such as Medtronic MiniMed, Animas (a division of Johnson & Johnson), and Roche. Insulet currently has no notable competition in patch pumps, but a number of companies have developed or are developing “patch” pumps and “patch” pens. However, the vast majority of these efforts have not seen full market release and some are targeting different market segments than Insulet is currently addressing. The following sections highlight the competition Insulet faces in both tradition and “patch” insulin pumps.

**Traditional Insulin Pump Competitors**

**Animas**

Animas, a division of Johnson & Johnson (JNJ – not rated), currently offers the OneTouch Ping, which gained FDA approval in mid-2008. We believe Animas holds a ~15%-20% market share in the US. The Ping offers a remote control, shown below, with an integrated blood glucose meter. Other features of the Ping include the smallest basal range on the market of 0.025 units/hour, a self-illuminating color screen, and “calorie king” memory, enabling the user to save up to 500 foods and their nutritional values on the pump to make insulin adjustments easier. We have heard complaints about the setup being cumbersome, which may turn off non-technophile pump users.

**Medtronic MiniMed**

Medtronic is currently the market leader in insulin pumps, holding a ~60-70% market share. Their Paradigm Revel pump, shown below, was launched in Q1 2010. The company sees several areas where they have a competitive advantage with their pump, including the largest insulin reservoir capacity (300 units), the lowest insulin-to-carb ratio, and smallest dosing increments. Medtronic also offers a Paradigm combination device with its Guardian CGM system, the only combined system currently on the market, which can warn patients to take action when their blood glucose is approaching hypoglycemic or hyperglycemic levels. Additionally, outside the US, Medtronic offers the Paradigm Veo, a more advanced version of the Paradigm/Guardian combination device, which is a semi-closed loop system (please the see “Artificial Pancreas Projects” section for further discussion) known as a low-glucose suspend (LGS) system. This allows the pump to suspend delivery of insulin when glucose has fallen into the hypoglycemic range as detected by the CGM.
Roche

Roche is currently marketing the ACCU-CHEK Spirit insulin pump. We believe Roche has a mid-single digits market share overall, but is stronger in Europe. It appears that Roche is planning to become more aggressive in the insulin pump space, although we have heard that sales force expansion is unlikely. They acquired Mendingo, an Israel-based patch-pump company last year (see the following section for further discussion) and the company also has an FDA submission pending for a ACCU-CHEK combo system, which includes a “smart blood glucose meter” that can control the insulin pump wirelessly. The ACCU-CHEK was introduced in late 2007, and is viewed by some to be somewhat dated.

Potential Competitors – Patch Pump and Traditional

Asante Solutions

Asante Solutions has received both FDA and CE Mark approval for its Pearl, both coming earlier in Q2 2011. The Pearl represented a first for the industry as the first fully-programmable pump to achieve FDA clearance since the agency implemented more stringent pump guidelines in Q2 2010.

We recently spoke with management of Asante to learn more about the Pearl. In contrast to other pumps on the market, the Pearl uses a 300-unit pre-filled “pen-type” insulin cartridges containing Eli Lilly’s (LLY – not rated) Humalog, which is approved for up to seven days of use. This removes the step of filling the pump reservoir that all other pumps currently on the market require. In addition, the pump unit will be disposable and the need to reverse the motor will be eliminated, enabling the company to lower its cost of goods sold as the moving parts will only need to undergo seven days of wear and tear instead of years. Management believes this makes it a good fit for first-time pump users and removes part of the training headache for the care provider.

It appears that the company intends on offering the Pearl using a payment model similar to Insulet’s. However, Asante believes they will be able to achieve higher margins on the disposable components that they estimate will cost roughly the same as the OmniPod pods to produce but be used over seven days instead of three.
Calibra Medical

Calibra gained FDA approval for the Finesse “patch pen” (shown below) in July 2011. A “patch pen” delivers bolus insulin, but does not deliver basal insulin. The Finesse device sticks to the body like a pump and contains 200 units of insulin. It can be worn for 2-3 days. The Finesse is able to deliver boluses by squeezing the buttons on each side of the device to deliver 1 or 2 units of insulin. It is unclear when the Finesse will reach the market, but it appears their target market is insulin-dependent Type 2 diabetics.

Cellnovo (formerly Starbridge Systems)

Cellnovo (the name of the company and product) considers its pump a “diabetes management system”. The mobile handset controller, shown below, acts as a blood glucose meter and controller for the insulin pump. The controller has a food library and is slightly smaller than the OmniPod PDM. In addition, the controller can send data to a web-based platform on a centralized server so that the patient’s doctor can see how blood sugar, insulin and exercise affect the patient’s diabetes management. Some commentators have referred to it as the “iPhone” of insulin pumps, likely due to the graphical nature of its user interface and connectivity.
The London-based company received CE Mark approval on September 19, 2011 and anticipates pricing the product below that of traditional pumps and the OmniPod. The company had planned to begin trials and file with the FDA in Fall 2011, but that was several months ago and we were unable to confirm the company’s currently projected timeline.

CeQur

The CeQur Device may be on hold. The company’s most recent news release was last year and our attempts to contact the company went unanswered. However, the company is/was developing an “insulin patch infuser” for the management of Type 2 diabetes. The description of the product CeQur had under development, the CeQur Device, seemed to imply it was more of a “patch pen” than a patch pump, having set basal rates with a bolus button. The company appeared to be targeting three days of basal infusion.

Debiotech

Debiotech’s Jewel Pump (shown below) debuted at the 2010 American Diabetes Association (ADA) meeting and drew rave reviews. However, since the debut, the company appears to have gone quiet, and the company did not attend the 2011 ADA meeting. In addition, their website was last updated in February 2011 featuring an “available for license” statement on the product’s web page despite the company filing for 510(k) FDA approval in mid-2010.

The company developed the Jewel with STMicroelectronics (STM – not rated) using a microelectromechanical (MEMS) pumping system. The system is intended to hold 450 units of insulin, good for six days of use, and connects via Bluetooth to a mobile phone to control the unit. The use of a mobile phone and not a dedicated controller may be the reason that the Jewel has yet to be approved by the FDA; the FDA seemingly has an array of concerns regarding connecting a phone wirelessly to a medical device that may be difficult for Debiotech to overcome and may be why it is looking for a partner to commercialize the Jewel.
Medtronic

Medtronic has been attempting to develop a patch pump since at least 2008, consistently projecting launch dates of two years from any given point in time. In their 2008 analyst day presentation, Medtronic stated that their patch pump was, “nearing completion”; yet, it presently appears even a 2013 introduction may be unlikely, with some industry participants of the belief that Medtronic’s patch pump project has been shelved after the company laid off “hundreds” of workers in its diabetes unit in May 2011. However, a July 2011 interview with John Mastrototaro, Medtronic’s VP of R&D, on “A Sweet Life”, a diabetes-focused website, mentioned that Medtronic was, “well on its way to a low-profile patch pump.”

Phluid Corporation

While Phluid Corporation is mentioned in Insulet’s most recent 10-K as working on a patch pump, the company appears to be no longer developing one and may be defunct. It is unclear whether they progressed beyond a press release announcing their planned development of a patch pump with Syprosoft Engineering several years ago. The company’s original website no longer exists.

Roche Diagnostics - Medingo

In April 2010, Roche announced the acquisition of Israel-based Medingo, maker of the Solo patch pump, for $160 million plus up to $40 million in performance milestones. The Solo system, first generation shown below, had a built-in Roche Accu-Check blood glucose meter at the time of acquisition, likely making the acquisition more attractive to Roche as pump users consume approximately 25% of all blood glucose test strips. The first generation Solo is similar in size to the OmniPod and consists of a reusable cradle and reusable pump base with a disposable insulin reservoir. Its controller unit looks similar to the OmniPod, but does not have “situational” menus as the OmniPod does. The Solo was approved by the FDA in 2009. Upon acquisition of Medingo the target global launch was to take place in 2012, after manufacturing was able to scale up. Our discussions with Roche indicate that the company intends on launching a second generation version of the
Solo pump in the US in 2012. Additionally, the company expects to receive CE Mark in Europe late in 2011 and launch in early 2012.

Sensible Medical AG

Sensible Medical has developed a semi-disposable piston pump with a reusable pump drive. The company is based in Switzerland and appears to be seeking out a partnership or collaboration to bring its technology to market.

Spring Health Solutions (formerly NiliMEDIX)

Spring Health Solutions is a D. Medical company (DMED – not rated). The company received FDA approval of its Spring Universal Infusion Set in Q2 2011. The company also filed for CE Mark approval of its Spring Zone insulin pump in Q2 2011. While this product is not a patch pump, the company is developing a pump that can be worn in “patch” or traditional fashion known as the Spring Hybrid Pump.

Valeritas, Inc.

Valeritas, based in Bridgewater, New Jersey, is developing one of the more intriguing products in the patch-pump space – an entirely mechanical insulin pump known as the V-Go. The company and its delivery technology were spun out of BioValve Technologies, Inc. in 2006. In September 2011, Valeritas raised an up round of venture financing totaling $150 million in order to begin commercializing the V-Go, which has received both FDA and CE Mark approvals.

Valeritas intends on targeting the V-Go at the US Type 2 diabetes market, initially ~3 million insulin-dependent Type 2 diabetics who have not been able to meet their A1C goals. The company anticipates launching in the first half of 2012 upon completion of their Shrewsbury, Massachusetts manufacturing facility.

The V-Go, shown in the graphic below, has several different pre-set basal rates ranging from 20 to 40 units per day and the ability to deliver boluses of insulin in two-unit increments. The user holds the V-Go to the skin, presses a button to deploy a stainless steel needle, and may press another button to deliver a bolus of insulin. The device is intended to be worn for 24 hours and disposed of afterwards. It consists of 30-plus parts, nearly all plastic with a few small metal ones. We speculate that retail pricing of the V-Go will fall in the $4-8 range per unit, not including insulin.
Ypsomed AG

Insulet’s European distribution partner, Ypsomed, has had a semi-disposable “continuous injection device” in development since at least 2007. Their goal seems to be similar to that of Valeritas, developing a low-cost continuous delivery device targeted at Type 2 diabetics (expected positioning in the cost-complexity spectrum shown in graphic below). However, Ypsomed differs in that they appear to be targeting the elderly and those in newly industrialized or developing countries. As of the second quarter 2011, Ypsomed had built a number of prototypes and believed it could have its device ready for sale by mid-2013. It is unclear whether Ypsomed’s device will be a true patch-pump.

Management

**Duane DeSisto - President, Chief Executive Officer and Director**

Duane DeSisto has served as President, Chief Executive Officer and Director of Insulet since 2003. Prior to joining Insulet, Mr. DeSisto was with PaperExchange.com, Inc., a business solutions provider for the pulp and paper industry, serving in various positions including President, Chief Executive Office and Chief Financial Officer. Previously, Mr. DeSisto served as Chief Financial Officer of FGX International Holdings Limited (formerly AAI-Foster Grant, Inc.), an accessories wholesaler. From 1986 to 1995, Mr. DeSisto served as Chief Financial Officer of ZOLL Medical Corporation, a medical device company.

**Brian K. Roberts - Chief Financial Officer**

Brian K. Roberts has served as Insulet’s Chief Financial Officer since March 2009. Prior to joining Insulet, Mr. Roberts was CFO of privately held Jingle Networks, the leader in free advertiser-supported directory assistance and voice ad-serving. Previously, he served as CFO of Digitas Inc., a leading digital marketing and media services firm, which was sold to Publicis.
Groupe in 2007. Mr. Roberts has also held senior finance positions at Idiom Technologies, Inc., the Monitor Group and Ernst & Young LLP.

Charles Liamos - Chief Operating Officer

Charles Liamos has served as our Chief Operating Officer since January, 2011 and has served on Insulet's Board of Directors since 2005. Mr. Liamos has over 15 years of experience in the diabetes industry, most recently serving as the Division Vice President of Abbott Diabetes Care. At Abbott, he was responsible for world-wide finance and operations for the Diabetes Care division, including integrating the acquisitions of MediSense and TheraSense. Prior to its acquisition by Abbott, Mr. Liamos was with TheraSense, Inc. as the company's Chief Operating Officer and Chief Financial Officer. Previously, he served as Director of Worldwide Sourcing at LifeScan, Inc., a division of Johnson & Johnson.

Diabetes Overview

Diabetics must manage their blood glucose (BG) concentrations to avoid serious complications. Concentrations below 70 mg/dL are referred to hypoglycemic concentrations and those above 180 mg/dL are referred to as hyperglycemic. Hypoglycemic events can lead to coma or death in extreme circumstances, but symptoms can include fatigue, confusion, nausea, abnormal breathing, and seizures. Spending significant time in the hyperglycemic range causes kidney, neurological and cardiovascular damage. A diabetic will take insulin to bring down their BG level when hyperglycemic events occur and sugar when hypoglycemic events occur.

Diabetes treatment varies depending on the type of diabetes. Type 1 diabetics require insulin and administer it through an insulin pump, injected insulin, or inhaled insulin. Type 2 diabetics and women suffering from gestational diabetes are treated in a number of ways including oral medications such as Metformin, insulin, diet adjustments, increased physical activity, or a combination of the aforementioned. The following chart details the relative proportion of different types of treatments.

In terms of testing blood glucose, only ~5% of those not taking insulin test their blood glucose regularly, while those who do take insulin test BG more often.

Artificial Pancreas Projects

The artificial pancreas is a technology under development to emulate the function of a healthy pancreas to help diabetics. Numerous approaches are under active research, including bioengineering, gene therapy, and medical device approaches.
We believe the medical device approach will be the first to succeed as all the components to build an artificial pancreas are currently available; the remaining hurdles are regulatory in nature. The OmniPod is currently involved in approximately two-thirds of the dozen or so artificial pancreas projects ongoing.

The medical device approach to a "closed-loop" artificial pancreas would minimally require an insulin pump and a CGM working in conjunction. Presently, diabetics who use an insulin pump and CGM do so in an "open loop". First, they test their blood glucose (BG) with a fingerstick and blood glucose meter to calibrate the CGM system (CGMs are currently classified as adjunctive devices). Then, when the CGM indicates that the user needs insulin, the required dose is calculated and the insulin pump is setup to deliver it. A closed-loop system would have the CGM send the estimated insulin dosing level wirelessly to the insulin pump for delivery, likely employing some adaptive filtering techniques that "learn" the unique basal rate of the user.

While the technologies are available to build a medical-device-based artificial pancreas, the FDA is likely several years away from approving such a product. However, on June 20, 2011, the FDA released draft guidance on "low glucose suspend" (LGS) systems. As the name implies, a LGS system suspends insulin delivery when the CGM detects low blood glucose to prevent hypoglycemia. In its draft guidance, the FDA classified LGS systems as "significant risk" devices that will require an IDE prior to filing a PMA submission. In addition, the effectiveness criteria upon which the FDA will be evaluating LGS systems is either a 10% reduction of hypoglycemic events or a 10% reduction in the time spent in the hypoglycemic range as well as being non-inferior on other criteria, such as HbA1c levels. The FDA will likely have several LGS applications before it in the next six-to-nine months, including the Insulet/DexCom combination. We believe that the FDA will need to become comfortable with LGS configurations prior to approving a full-on "closed loop" artificial pancreas system. Further, it appears that the approval timeline for medical devices has stretched considerably under the current FDA. The FDA is concerned with what might happen should a closed-loop system malfunction – problems with a CGM or insulin pump could lead to a potentially lethal dose of insulin being delivered to the user. As such, we believe that diabetics outside the US will be the first to utilize a medical-device-based artificial pancreas.

Diabetes: The Disease, Prevalence, and Growth

Diabetes can take several forms: Type 1, Type 2, and gestational. Type 1 and Type 2 are chronic diseases.

Type 1 diabetes, previously known as juvenile or insulin-dependent diabetes, occurs when the pancreas' beta cells do not produce enough insulin to properly control blood sugar levels and must be treated indefinitely with insulin or the patient must undergo pancreatic transplant or pancreatic islet cell transplantation (neither of which are common). Type 1 diabetes is not fully understood, but is believed to be of immunological origin. Further, most people who develop Type 1 diabetes are otherwise healthy. While Type 1 diabetes cannot currently be prevented, methods of preserving beta cell function are currently being investigated including immunosuppressive drugs and a vaccine containing GAD65, an autoantigen involved in Type 1 diabetes.

Type 2 diabetes commonly results from genetic and lifestyle factors. Of the lifestyle factors, obesity, hypertension, high cholesterol, age, and sedentary lifestyle are linked to the development of diabetes. Approximately 55% of newly diagnosed Type 2 diabetics are obese, although some research shows that diabetes may cause obesity. Of the genetic factors, having first-degree relatives who have Type 2 diabetes raises risks significantly. Type 2 diabetics may not need insulin, at least initially, but as time goes on, the likelihood of a Type 2 diabetic needing insulin increases.

Gestational diabetes occurs during 2-10% of pregnancies. Post-pregnancy, women with gestational diabetes are reported to suffer from diabetes 5-10% of the time and have a 35-60% chance of developing Type 2 diabetes within the following 20 years.

The complications associated with diabetes are serious and include high blood pressure, high cholesterol, kidney disease and failure, stroke, diabetic ulcers (which can result in amputation), peripheral vascular disease, cataracts, nerve damage, cataracts, and blindness. As with nearly any chronic disease, expenditures on treating complications can make up a huge portion of the total cost of treatment.
Diabetes has become a global epidemic. It is currently estimated that 285 million people worldwide are afflicted with diabetes. Spot estimates place the number at 25.8 million in the US with 7 million of those undiagnosed. Estimates do vary, but one thing is clear – this is an extremely large market – afflicting over 8% of the US population and nearly 5% of the worldwide population.

The growth in diabetes is worrisome. Diabetes has become far more common in the US and around the world in the past decade. In the US, diabetes incidence increased from ~3% of the population to a little over 4% during the 1990s. However, since 2000, the trend has accelerated, almost doubling in incidence to nearly 8% of the US population. Worldwide the trend has been similar, in 2000 there were 151 million diabetics, which has nearly doubled to over 285 million. The chart below shows the increasing incidence of diabetes by age group in the US over the past decade.
Prevalence of Diabetes by Age Group
2000, 2005 and 2009

Source: Centers for Disease Control
### Insulet Corporation (PODD)

#### Income Statement

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<th>Q3</th>
<th>Q4</th>
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<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
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#### Operating expenses:

- **Research and development**
  - 2009: 13.2%
  - 2010: 20.0%
- **SG&A**
  - 2009: 64.4%
  - 2010: 73.4%
- **Impairment of assets**
  - 2009: 97.6%
  - 2010: 73.4%
- **Amortization of intangibles**
  - 2009: 0.0%
  - 2010: 0.0%

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<tr>
<th>Year</th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
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<td>47.3</td>
<td>47.8</td>
<td>46.6</td>
<td>48.3</td>
<td>48.8</td>
<td>49.3</td>
<td>49.8</td>
<td>49.0</td>
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</table>

#### Balance Sheet

<table>
<thead>
<tr>
<th>Year</th>
<th>Cash</th>
<th>Current assets</th>
<th>Total assets</th>
<th>Total liabilities</th>
<th>Shareholder's equity</th>
</tr>
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<tbody>
<tr>
<td>2009</td>
<td>128.0</td>
<td>118.3</td>
<td>118.1</td>
<td>103.9</td>
<td>113.3</td>
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<tr>
<td>2010</td>
<td>154.3</td>
<td>142.2</td>
<td>145.6</td>
<td>133.3</td>
<td>144.5</td>
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<td>2011</td>
<td>172.9</td>
<td>159.0</td>
<td>162.0</td>
<td>149.9</td>
<td>156.2</td>
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<tr>
<td>2012</td>
<td>198.0</td>
<td>179.0</td>
<td>23.8</td>
<td>20.4</td>
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<td>2013</td>
<td>89.1</td>
<td>98.2</td>
<td>93.2</td>
<td>69.4</td>
<td>59.8</td>
</tr>
<tr>
<td>2014</td>
<td>110.0</td>
<td>118.1</td>
<td>118.0</td>
<td>116.3</td>
<td>90.0</td>
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<tr>
<td>2015</td>
<td>61.9</td>
<td>40.9</td>
<td>44.0</td>
<td>33.5</td>
<td>66.2</td>
</tr>
</tbody>
</table>
Analyst Certification

I, Ben Haynor, CFA, certify that the views expressed in this research report accurately reflect my personal views about the subject company and its securities. I also certify that I have not been, am not, and will not be receiving direct or indirect compensation related to the specific recommendations expressed in this report.

Important Disclosures:

The analyst or a member of his/her household does not hold a long or short position, options, warrants, rights or futures of this security in their personal account(s).

As of the end of the month preceding the date of publication of this report, Feltl and Company did not beneficially own 1% or more of any class of common equity securities of the subject company.

There is not any actual material conflict of interest that either the analyst or Feltl and Company is aware of.

The analyst has not received any compensation for any investment banking business with this company in the past twelve months and does not expect to receive any in the next three months.

Feltl and Company has not been engaged for investment banking services with the subject company during the past twelve months and does not anticipate receiving compensation for such services in the next three months.

Feltl and Company has not served as a broker, either as agent or principal, buying back stock for the subject company’s account as part of the company's authorized stock buy-back program in the last twelve months.

No director, officer or employee of Feltl and Company serves as a director, officer or advisory board member to the subject company.

Feltl and Company Rating System: Feltl and Company utilizes a four tier rating system for potential total returns over the next 12 months.

**Strong Buy:** The stock is expected to have total return potential of at least 30%. Catalysts exist to generate higher valuations, and positions should be initiated at current levels.

**Buy:** The stock is expected to have total return potential of at least 15%. Near term catalysts may not exist and the common stock needs further time to develop. Investors requiring time to build positions may consider current levels attractive.

**Hold:** The stock is expected to have total return potential of less than 15%. Fundamental events are not present to make it either a Buy or a Sell. The stock is an acceptable longer-term holding.

**Sell:** Expect a negative total return. Current positions may be used as a source of funds.

<table>
<thead>
<tr>
<th>Rating</th>
<th>Number of Stocks</th>
<th>Percent of Total</th>
<th>Number of Stocks</th>
<th>Percent of Rating category</th>
</tr>
</thead>
<tbody>
<tr>
<td>SB/Buy</td>
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<td>72%</td>
<td>3</td>
<td>7%</td>
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<tr>
<td>Hold</td>
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<td>26%</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Sell</td>
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<td>2%</td>
<td>0</td>
<td>0%</td>
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<tr>
<td></td>
<td>61</td>
<td>100%</td>
<td>3</td>
<td>5%</td>
</tr>
</tbody>
</table>

The above represents our ratings distribution on the stocks in the Feltl and Company research universe, together with the number in (and percentage of) each category for which Feltl and Company provided investment-banking services in the previous twelve months.
Date | Nature of Report | Rating | Price Target
---|---|---|---
09/30/11 | Initiation@$15.75 | Buy | $19.80

Feltl and Company makes a market in the subject security at the date of publication of this report. As a market maker, Feltl and Company could act as principal or agent with respect to the purchase or sale of those securities.

**Valuation and Price Target Methodology:**

Our valuation is based upon a sum of the parts methodology. We believe it is appropriate to value the OmniPod revenues differently than those coming from the recently acquired Neighborhood Diabetes. We have chosen 5.3x EV/sales as the multiple on which to value Insulet's OmniPod revenues based upon current high growth medical technology company multiples as well as valuation ranges Insulet has experienced in the past. On the Neighborhood Diabetes revenues, we have chosen a multiple of 1.0x EV/sales, similar to what Insulet paid for the company. Based on our 2012 estimates, this results in an enterprise value of $870.8 to which we add in estimated Neighborhood Diabetes revenues of $61 million and current net cash of $2.6 to arrive at $934.4, or ~$19.80 per share based upon 47.3 million shares outstanding at the end of Q2 2011.

**Risks to Achievement of Estimates and Price Target:**

- Direct Competition. Insulet faces competition from several large insulin pump players, including Medtronic (MDT – not rated), Johnson and Johnson (JNJ – not rated), and Roche (RHHBY – not rated). Combined, these firms make up over 85% of the market compared to Insulet's 7-8% market share. Further, a number of firms are developing “next generation” insulin pumps (please see the “Competition” section for a

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09/30/11  BUY  Target: $19.80
detailed analysis) as well as “patch pens”. While some of these coming competitors target market segments that Insulet is not currently targeting, such as Type 2 diabetics, they may hamper Insulet's competitive position in these markets going forward.

- Indirect competition from other insulin delivery options. In addition to facing competitive threats from other insulin pump manufacturers, Insulet must compete with multiple daily injections (MDI) of insulin. MDI is less expensive than continuous subcutaneous insulin infusion (CSII) and has also become more effective with the introduction of long-acting insulin analogs. The company has made note of the fact that 20-40 year old men have been the most likely to switch back to MDI during the current economic downturn in order to save money; this has negatively impacting Insulet's attrition rate. Additionally, several smaller studies have suggested that bariatric (gastric bypass) surgery has improved or eliminated diabetes in a high proportion of Type 2 patients. However, many challenge this claim. We believe it may be overstated and think it is currently unlikely that carriers would begin reimbursement for such a procedure solely on account of diabetes.

- FDA timeline slippage. Numerous medical device firms have had difficulty of late in receiving FDA approval of their products, including Insulet. For instance, the Insulet-DexCom combination pump/continuous glucose monitor (CGM) was initially intended to launch in mid-2009. While the FDA has provided guidance on the criteria by which it will evaluate “low glucose suspend” systems (a precursor to the artificial pancreas), numerous projected timelines have slipped over the past several years and it appears the trend will continue. For sake of illustration, Insulet's FDA submission for their next-generation OmniPod contained around 7,800 pages which they had to deliver in triplicate.

- Hacking concerns. Recently, a security researcher gave a presentation at the Black Hat Digital Security Conference in Las Vegas showing that it was technically feasible to “hack” an insulin pump (a Medtronic Paradigm) using the wireless protocol (connection) between the pump and control unit. Potentially, this could allow one to induce hypoglycemia in a pump wearer, which may cause death. However, technically feasible and practically feasible are two far different things in our view. It is likely that this hack depends on being in close proximity to the pump wearer as signals (or packets) are being sent for a relatively long period of time, similar to hacking a secure wireless Internet connection (WEP or WPA encryption), and/or having access to the pumps serial number. The news media has seized upon this story and proceeded to exaggerate the true risk. Since then, a number of politicians have begun making noise on the issue, which has the potential for a number of negative developments to occur, such as recalls of “insecure” pumps, lawsuits, increased scrutiny of wireless communication protocols and security in medical devices, and a lengthened FDA approval process.

- Becton Dickinson patent lawsuit. Becton Dickinson (BDX – not rated) has filed a patent infringement suit against Insulet centered on patents which Becton acquired. Insulet and their external counsel do not believe that the suit has merit, but the company could face additional legal expenses defending against the suit. Similarly, there is no telling what a jury may decide should the suit go to trial.

Other Disclosures:
The information contained in this report is based on sources considered to be reliable, but not guaranteed, to be accurate or complete. Any opinions or estimates expressed herein reflect a judgment made as of this date, and are subject to change without notice. This report has been prepared solely for informative purposes and is not a solicitation or an offer to buy or sell any security. The securities described may not be qualified for purchase in all jurisdictions. Because of individual requirements, advice regarding securities mentioned in this report should not be construed as suitable for all accounts. This report does not take into account the investment objectives, financial situation and needs of any particular client of Feltl and Company. Some securities mentioned herein relate to small speculative companies that may not be suitable for some accounts. Feltl and Company suggests that prior to acting on any of the recommendations herein, the recipient should consider whether such a recommendation is appropriate given their investment objectives and current financial circumstances. Past performance does not guarantee future results. Additional information is available upon request.
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