



MEMORANDUM

FDA approves Animas Vibe insulin pump with Dexcom G4 Platinum integration - December 1, 2014

Executive Highlights

- Today, J&J Animas [announced](#) FDA approval of its Vibe insulin pump integrated with Dexcom's G4 Platinum CGM. Animas is now accepting orders for the Vibe and anticipates shipments beginning in January 2015.
- The approval represents Dexcom's first CGM-integrated pump in the US, and helps Animas stay competitive with Medtronic, Tandem, Insulet, and Asante.

Today, J&J Animas [announced](#) FDA approval of its Vibe insulin pump integrated with Dexcom's G4 Platinum CGM. The official approval came on November 25, marking a lengthy ~20-month review from the [1Q13 PMA submission](#). Happily, however, Animas is now accepting order requests for the Vibe [on its website](#) and anticipates shipments beginning in January 2015. The approval was expected following [Dexcom's 3Q14 call](#), though the hope for a commercial launch before year-end will be narrowly (and understandably) missed - still, to have the approval before year end (we weren't sure given general unpredictability associated with past expected approvals) was great to see. There are no upgrade details at this time - in the past, Animas has promoted a \$99 ezAccess Upgrade Program to offer existing users the company's latest pump technology. We assume something similar will come online once the Vibe is launched and we hope to have an answer to this very important question soon.

The Animas Vibe insulin pump has a retail price of \$7,150, and the Dexcom G4 Platinum components are on top of that: \$799 for the transmitter and \$499 for a four-pack of sensors. Of course, the Vibe eliminates the need for (and cost of) the G4 Platinum receiver.

The approval is a convenience win for patients, as it displays Dexcom CGM data directly on the pump screen and eliminates the need for a standalone G4 Platinum receiver. It also signals excellent news for J&J's LifeScan/Animas business, which has experienced year-over-year sales declines in the US in eight of the past nine quarters - granted, most of this has been driven by the LifeScan BGM business following competitive bidding, though we believe the pump business has not been growing substantially. J&J's insulin delivery business has not seen a new US product since the launch of the OneTouch Ping in 2008 - the Vibe will certainly give reps something to talk about.

The approval also helps Animas stay competitive with Medtronic's MiniMed 530G, the only CGM-integrated pump on the US market. According to a Dexcom customer survey from April 2012, "one in four Dexcom users on pumps" use a Medtronic pump - we assume this has only expanded in the past two years, and we would estimate that represents roughly 10,000 patients now. The Animas Vibe also brings a competitive offering vs. Dexcom's three other pump partners: [Tandem](#) (launch of a G4 Platinum-integrated t:slim expected in mid-2015/early 2016) and [Insulet](#) and Asante (both to be integrated with Dexcom's Gen 5, likely meaning a 2016+ launch). It will be interesting to see if Animas offers a trade-in program to encourage non-Animas pump+Dexcom CGM users to switch to the Animas Vibe. The company is exploring its options on this front, but there is nothing to report right now.

As a reminder, the Animas Vibe received a CE Mark in 2011 and is currently available in Europe, Australia, New Zealand, and Canada. Dexcom's financial results calls over the past year have repeatedly highlighted the strong sales of the Animas Vibe in Europe against the Medtronic Veo, which could bode well for the US launch.

Below, we enclose more details on the Vibe, the upside for Dexcom, a SWOT analysis of J&J LifeScan/Animas, and our key questions.

Table of Contents

Executive Highlights

Animas Vibe Background
J&J LifeScan/Animas SWOT Analysis
Close Concerns Questions

ANIMAS VIBE BACKGROUND

- **The Vibe approval is only approved for patients 18 years and older.** The original Animas Vibe PMA submission did not include the pediatric indication, as the Dexcom G4 Platinum was not approved for this use at the time of the Vibe filing in 1Q13. Dexcom has since [received approval of a pediatric indication](#) (February 3, 2014), and now that the Animas Vibe is also through the FDA, Animas can submit a PMA supplement to add the pediatric indication - we assume this review would be fairly quick. For context, the [MiniMed 530G was similarly approved](#) for patients ≥ 16 years old, as Medtronic did not have pediatric data prior to approval.
- **Aside from the change to mg/dl and language, the user interface and design of the US version of the Vibe are the same as the international version we've seen in exhibit halls over the past few years.** The G4 Platinum CGM graph is displayed on the pump home screen in color. Otherwise, it looks like the OneTouch Ping that has been available since 2008. We had hoped Animas would have opted for menu navigation and design improvements, but that will have to wait for a future version of the pump. Of the pumps currently on the market, the Animas user interface requires more button pushing than offerings from some other companies (e.g., no back or home button). That said, keeping the core human factors the same was presumably the fastest way to secure approval, and we assume further modifications would have only lengthened the timeline.
- **When a new user orders the Animas Vibe, patients will receive separate boxes from Animas and Dexcom.** The pump will be shipped from Animas and the CGM sensor will be shipped from Dexcom. If a patient only wants the Animas Vibe pump, they will not have to contact Dexcom. If a patient decides to use the CGM system after receiving the pump, he or she will need to call Dexcom directly. We assume patients will contact the companies separately to reorder supplies. All training will be conducted by Animas. Like the Dexcom G4 Platinum and Animas OneTouch Ping, the Animas Vibe will be downloadable to Diasend.
- **[Animas' marketing](#) emphasizes the Vibe's color screen display of CGM, integration with Dexcom's "world class" sensor, waterproof durability, and precise delivery.** [A marketing page](#) has two short videos from Animas Chief Medical Officer Dr. Brian Levy and Dexcom CEO Mr. Terry Gregg. Both are fairly general in scope, but emphasize fewer devices for patients to carry around, the value of integrated CGM and pump data, and a new valuable option for patients to choose - we like seeing these and believe this is great for patients and families who see too much paper sometimes!
 - **Notably, [a new FDA page posted today](#) - "More Choices Available for Diabetes Management" - highlights the approval of the Animas Vibe.** The page is broken down into three sections: (i) "Why managing blood sugar levels is important"; (ii) "Devices that can help you now"; and (iii) "The coming innovation: artificial pancreas." The page notes the two currently FDA-approved, CGM-enabled insulin pumps: the Medtronic MiniMed ("approved in April 2006") and the Animas Vibe System ("approved on Nov. 25, 2014"). Regarding the latter, the FDA notes, "This approval gives consumers more choices in the types of CGMs that can be integrated wirelessly with an insulin pump. Lower down in the artificial pancreas section, the page further notes, "The availability of an insulin

pump that is already compatible with the G4 Platinum system will make the development and approval of APDS [artificial pancreas device systems] that use this technology easier. The FDA will continue to prioritize the development of an APDS and will continue to keep you and health care professionals informed of developments."

- **We thought the new FDA page was notable for a few reasons:** (i) it continues to signal FDA prioritization of diabetes technology, including the artificial pancreas; (ii) it was published today in tandem with the Animas Vibe announcement (quite timely for the FDA); and (iii) it recognized the value of providing more options for patients.
- **For Dexcom, the Animas Vibe approval brings financial upside and very little risk.** Dexcom will benefit from J&J sales reps bringing news of the Vibe to doctors, nurses, and patients, which will add to Dexcom's field sales force of ~90 reps (per the last update we heard). In addition, Animas pays Dexcom a royalty for each pump sold, milestone payments, and reimbursement of R&D expenses - we cannot recall seeing details on this agreement, though for context, the 2012 Tandem agreement is a \$100 royalty per pump sold + three \$1 million milestone payments. We assume the Animas agreement is along similar lines, though it was signed four years earlier in 2008. Overall, we see integration as a major win-win for both Animas and Dexcom - Dexcom can sell more sensors, while Animas can compete more directly with Medtronic and perhaps pave the way for future automated insulin delivery devices.
 - **Dexcom is riding very impressive momentum, with six-quarters in a row of 60%+ year-over-year growth, along with four FDA approvals this year:** Animas Vibe, [new G4AP algorithm](#) (November 6), [Dexcom Share](#) (October 20), [G4 Platinum pediatric approval](#) (February 4). The [company's pipeline](#) looks very strong and profitability has never been higher.
 - **The Animas Vibe will unfortunately not be able to upgrade to the [recently released G4AP algorithm](#).** Those patients will need to wait for a next-gen version of the pump (e.g., compatible with Dexcom's Gen 5, Bluetooth-enabled transmitter) or need to purchase a standalone Dexcom G4 Platinum receiver. We assume that Dexcom will produce two transmitters in the foreseeable future - one for the G4 Platinum-integrated Animas Vibe and Tandem t:slim (under FDA review), and another for the Gen 5 mobile platform (smartphone app + small receiver, to be submitted to the FDA in 1Q14). This will be viewed as a disappointment to some patients; we understand quite a few have upgraded already.
- **While CGM integration may not be the top reason that patients choose a pump, we believe it is becoming increasingly important as CGM adoption expands.** To date, market leader Medtronic has offered the only CGM-integrated pump in the US, an important advantage over other pump players. It's hard to know if the Animas Vibe will have a major impact on Animas' US market share, though it can only help. Most estimates peg US CGM penetration at roughly ~10% in type 1 diabetes, while pump penetration is often pegged at ~30%. Some key opinion leaders, such as Dr. Irl Hirsch, have asserted that CGM penetration will one day outstrip pump penetration - it's hard to call at this point, since it depends on so many factors, including an insulin dosing claim for CGM, factory calibrated CGM, automated insulin delivery, reduced cost, reduced hassle factor, etc.
- **It remains to be seen how/if J&J Animas will become involved in automated insulin delivery in a major way.** J&J's [3Q14 call](#) offered no timing updates on the status of the company's automated insulin delivery efforts, a partnership that was [originally signed with JDRF in 2010](#); a small feasibility study was presented at [ADA 2014](#), though this whole part of the pipeline has moved very slowly indeed. We hope to see J&J jump in full force, since it will be a requirement to stay competitive with Medtronic (who has very openly stated its goal to close the loop, and is on the way with the MiniMed 640G and 670G), and presumably other pump companies like Asante, Roche, Tandem, Insulet.

J&J LIFESCAN/ANIMAS SWOT ANALYSIS

Strengths Pump and diabetes industry experience First Dexcom-integrated pump on US market Brand recognition Sales force Strength of Invokana	Weaknesses BGM market challenges No noteworthy pipeline products aside from Finesse Less "cool" factor vs. other pumps Less nimble vs. smaller pump companies
Opportunities Vibe launch Automated insulin delivery Calibra Finesse and type 2 diabetes	Threats Medtronic's MiniMed 640G and 670G Stronger competition from Tandem, Insulet, and Asante Continued BGM challenges, which reduce funds for R&D

CLOSE CONCERNS QUESTIONS

Q: Will Animas decide to offer a trade-in program to encourage patients on other companies' pumps to switch to the Vibe?

Q: Why did FDA approval of the Vibe take so long?

Q: Will Animas more aggressively pursue automated insulin delivery now that the Vibe is approved?

-- by Adam Brown and Kelly Close