Closer Look

MEMORANDUM

Edwards 1Q12 - Second-gen GlucoClear remains on track for 2H12 CE mark - May 10, 2012

Executive Highlights

- Edwards/Dexcom's second-generation GlucoClear critical-care CGM recently completed the first phase of clinical evaluation in Europe and is still on track for CE mark filing in 2H12.
- The final system will include unspecified enhancements, presumably based on the evaluation.

Edwards CEO Michael Mussallem recently led the company's 1Q12 results call. Mussallem said that Edwards/Dexcom's second-generation GlucoClear critical-care continuous glucose monitoring device has passed through the first phase of clinical evaluation in Europe and remains on schedule to receive CE mark in 2H12. Mussallem mentioned accuracy performance and positive clinician feedback as highlights of the evaluation. He noted that the final system will be "enhanced," which we assume means that Edwards and Dexcom are choosing to enact some of the "additional enhancements" that Mussallem said were being considered as of Edwards' 4Q11 call. During Dexcom's 1Q12 call, management corroborated as much, saying that Dexcom's team would be wrapping up its side of development in 2H12 (see the May 3, 2012 Closer Look at bit.ly/Ky8K5R).

As a reminder, in late 2011 Edwards and Dexcom adopted the 2H12 CE mark target after they had redesigned the GlucoClear so that anticoagulant directly coated the device (rather than being stored in a separate bag). Designed to improve usability, the change moved the GlucoClear onto a longer regulatory path (previous forecasts had called for CE mark by the end of 2011). The companies also voluntarily decided to gather more data than originally planned.

Edwards management did not discuss the GlucoClear's regulatory timeline in the US. As of Dexcom's 3Q11 call in November, the planned start of the US pivotal trial was pushed back from 1H12 to 2H12. To our knowledge, neither company has provided an update since then.

As a reminder, the second-generation GlucoClear uses the same intravenous glucose monitoring technology as the prototype first-generation system, which received CE mark in 4Q09 and was temporarily available in Europe as part of a small test launch. However, the new product features several improvements in user interface; Mussallem has described the first system as accurate but "kludgy" in his remarks at the 2011 JP Morgan Healthcare Conference (see pg 27 of our report at bit.ly/nA8ym4).

Close Concerns Questions

Q: What enhancements are being made to the second-gen GlucoClear between now and European regulatory filing?

Q: How many more rounds of clinical testing will the system undergo during that time?

Q: What is the current timeline in the US?

--by Joseph Shivers and Kelly Close