From: Aleksandr Rabodzey
To: Brian Grossman
CC: Vivek Khanna; Sriram Balasuryan
Sent: 1/29/2014 9:43:52 AM
Subject: Theranos diligence calls - Last call with an expert takeaways

Brian,
We had one more diligence call today with a scientist who develops lab based tests, and he confirmed every point that Theranos made with the exception of putting machines at WAG locations.
His view was that CLIA approval is enough for as long as you have machines inside the CLIA lab. No need for FDA approval.
Theranos meets CLIA requirements on most of their tests as we know.
He said, however, that if you want to put a machine in WAG location, it has to be FDA cleared.
He did acknowledge that FDA standards are much higher than CLIA.
Additionally, he did believe that while miniaturizing LH test menu is possible, it will be very hard to do one some tests and accuracy will deteriorate (but we already know that)
Overall, I think across the 3 regulatory/science calls I feel that there is small risk to implementation if the FDA chooses to exercise their authority, but this would be unusual. So, I would still stick to my low 10-20% chance that the implementation gets derailed by the FDA demanding more regulation and a decent chance that some of the tests may not pass the FDA 501K review. I continue to believe that this is an acceptable risk for a private investment as long as we believe upside in the base case scenario justifies taking the risk of an FDA action and/or rollout delay.

On a side note, I am not sure what Theranos is doing with my test, but I still have not gotten the results and I spoke to OneMedical and they did not get my results either.