**From:** Daniel Edlin <dedlin@theranos.com>
**Sent:** Tuesday, April 3, 2012 2:51 PM
**To:** Victoria Sung <VSung@celgene.com>
**Subject:** RE: For our discussion this morning

---

Hi Vicki,

Thank you for this information and for reaching back out to your team. I think that it would be useful to briefly talk about the shipment model and address any questions or concerns that you may have. If you would, please give me a call when you can to touch base.

Thanks again,
Dan

**Daniel P. Edlin**
*Senior Product Manager*
Theranos, Inc.

Office: 650.470.0322
Mobile: 650.701.4739
dedlin@theranos.com

---

**From:** Victoria Sung [mailto:VSung@celgene.com]
**Sent:** Monday, April 02, 2012 12:16 PM
**To:** Daniel Edlin
**Cc:** Elizabeth Holmes; Daniel Young
**Subject:** RE: For our discussion this morning

Hi Daniel,

Thank you for your e-mail and ideas. At last week's project team meeting, we had decided to simply wait until your next-gen machines are ready and then deploy them to the three clinical sites which have prior experience with the Theranos platform. I will reach out to the team with your e-mail below, however, and will let you know if there is any change of plans.

Best wishes,

Vicki

---

**From:** Daniel Edlin [mailto:dedlin@theranos.com]
**Sent:** Monday, April 02, 2012 10:43 AM
**To:** Victoria Sung
**Cc:** Elizabeth Holmes; Daniel Young
**Subject:** RE: For our discussion this morning

Hi Vicki,

I hope you are well. Following on our last conversation, I'm writing to highlight a few thoughts on the upcoming trial and our proposed sample shipment model.

We are looking forward to the opportunity of deploying our next-generation systems in field for you. We should be able to do this in the coming months based on our current commitments. Until our systems are deployed, we would like to

propose gaining more experience with Theranos assays through our nanotainer shipping model for all collected samples. These samples will be shipped to Theranos' CLIA lab location via our courier service, at which point the analysis is performed. The only sample allocated for all Theranos assays would be the 1 ML of whole blood originally discussed. Most assays would be run on whole blood. For a couple of the analytes, we don't want to risk the stability issues, so we would pipette a few microliters of sample into a separate tube, spin it on a small Theranos micro-fuge for a few minutes, and then ship it together with the whole blood sample. Theranos assumes all cost and oversight of logistical operations associated with sample pick up and shipment, and our turn-around commitment for results remains within 24 hours for your and the clinical teams review.

This will allow us to accomplish several objectives:

1. Get more statistically significant experience with the performance of Theranos assays so that they can be effectively evaluated as an alternative to a central lab for future programs
2. Generate data on cost savings next to central laboratory-based testing
3. Generate performance data so that the systems could be used for real-time PK/PD monitoring in future programs, and/or, as originally discussed, evaluated as companion diagnostics

Recognizing that Celgene is also utilizing a non-Theranos lab for this trial, we feel it is important to continue performing the analysis on our platform to ensure an extremely high confidence and comfort level with our chemistries, especially in line with our previous exchanges. As Theranos evolves to the sole platform used by Celgene, we want to ensure there is a clear understanding of the integrity of our systems and data, and we see this trial as a necessary component to this process.

Please let us know if it is of value for us to support your conversations internally on this in any way. We would like to begin collecting samples immediately for analysis after sign off of the validation reports. We have additional validation reports we can provide this week. The remaining are targeted to be sent in the month of April or shortly thereafter depending on how fast we have the opportunity to begin receiving samples.

I will call you shortly to follow up on the above.

Looking forward to it,
Dan

---

**From:** Victoria Sung [mailto:VSung@celgene.com]
**Sent:** Friday, March 23, 2012 12:09 PM
**To:** Daniel Young; Nianhang Chen
**Cc:** Elizabeth Holmes; Daniel Edlin
**Subject:** RE: For our discussion this morning

Hi Daniel,
Thank you very much for your e-mail and follow-up to our discussion of the PK and PD results; we appreciate the time you have taken to review these data and will let you know if we have any further questions after reviewing that data again.

At this point, we really need to make a final decision in the next week or so about whether or not to include Theranos PD assays in PART 2. It would be great if you could send the information about when the new machines will be ready for deployment and which assays will be on the cartridges so that I can inform our clinical team asap. I think that we will forego the option to send samples to Theranos for processing at this point.

I look forward to hearing back from you soon.
Best regards,
Vicki

---

**From:** Daniel Young [mailto:dyoung@theranos.com]

**Sent:** Thursday, March 22, 2012 9:23 PM
**To:** Victoria Sung; Nianhang Chen
**Cc:** Elizabeth Holmes; Daniel Edlin; ronb@b2s-stats.com
**Subject:** RE: For our discussion this morning

Dear Vicki and Nianhang,

We wanted to follow-up regarding the PK and PD results that your recently sent to us for evaluation.

Regarding the PD assays, overall our analysis suggests good performance and concordance with ACM as detailed below:

- The feedback in our discussion was that for Estradiol, many Theranos results were out of range low (OORL). In fact, 10 of Theranos' reported measures were OORL; of these 10 time points, ACM reported 6 of these same time points as 10 pg/ml, 2 were not reported, and 2 were 56 pg/ml and 22.9 pg/ml. Note that 10pg/ml is ACM's limit of quantification, and likely they are reporting out of range values at their limit of quantification (this reporting method seems a little unusual to us). You may want to ask ACM if these measures were assumed or measured by ACM. Overall, our assessment is that the concordance for the Estradiol assay is strong.
- Also note that for Estradiol, overall 15 measurement values were reported by Theranos compared to only 5 measurement values reported by ACM.
- The feedback from Celgene regarding FSH was that the results between Theranos and ACM were largely comparable, and we agree.
- The feedback during our discussion was the there was a "major discordance" between Theranos and ACM. I pointed out during the call that the assay units used by Ron during the comparison were not correct, and Vicki noted that this was indeed an oversight. While, the conversion between ng/ml and IU/L for LH is not a universal standard, my analysis showed good concordance between ACM and Theranos results for this assay.
- Finally, for LH, Theranos reported four NA's out of the 26 time points, while ACM had 2 blank measurements for the same set of 26 time points. In at least two of these four Theranos cartridges, out of range values in the control tips caused us to report the assay results as "NA" (while not known for certain, these cartridges may have been mishandled by the study sites leading to control failures).

Regarding the ACE-011 PK assay, we wanted to reiterate a few points to correct Celgene's misunderstanding. First, additional dilutions are possible in our automated protocols to extend the assay range in Theranos devices. Second, we have a means to archive samples for regulatory purposes and re-runs, as mentioned on the call. Third, in our newly developed device being launched this year, Theranos can perform assays in plasma (in addition to or instead of in whole blood), so any possible confounding issues introduced by whole blood would not be a factor (whole blood possibly being a source of variance for this ACE-011 PK assay).

Regarding the ACE-011 PK assay performance, I compared all the matched samples from QPS to Theranos, and this comparison suggested to me that the QPS assay may be saturating (loosing linearity) at values between 1500 and 2000 ng/ml (their ULOQ is in fact 2000 ng/ml), while Theranos' ULOQ is 4000 ng/ml. Several significant differences between QPS and Theranos that I noticed were seen when Theranos reported values above 2000 ng/ml and QPS was consistently reporting lower values. While QPS's ACE-011 assay has limits of quantification between 40 to 2000 ng/ml, they report that additional dilutions can be used to extend their range above 2000ng/ml. We suggest that Celgene determine if QPS performed such additional dilutions for these measurements, and if so, for which particular samples/time points and if the corrections in the assay concentrations for any additional dilutions were correctly appropriately. We look forward to your feedback on this matter as we at Theranos strive to deliver the best assays in the most convenient and cost effective manner to Celgene.

Best regards,
Daniel

Daniel Young, PhD
Vice President, Theranos Systems
Theranos, Inc
3200 Hillview Avenue

Palo Alto, Ca 94304
650-470-6119 (office)
650-804-8185 (mobile)



---

**From:** Victoria Sung [mailto:VSung@celgene.com]
**Sent:** Monday, March 05, 2012 10:26 AM
**To:** Elizabeth Holmes; Daniel Edlin; Daniel Young; ronb@b2s-stats.com
**Cc:** Nianhang Chen
**Subject:** For our discussion this morning