

**To:** Elizabeth Holmes[eholmes@theranos.com]  
**From:** roger\_parloff@fortune.com  
**Sent:** Fri 6/6/2014 11:56:25 AM  
**Importance:** Normal  
**Subject:** Re: Additional Follow Up Items  
**Received:** Fri 6/6/2014 11:56:05 AM

Thanks for all this, Elizabeth! I'll ask some followup questions when we talk later today.

Best,  
Roger

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**From:** Elizabeth Holmes <eholmes@theranos.com>  
**Date:** Friday, June 6, 2014 12:22 AM  
**To:** "Parloff, Roger - Fortune <roger\_parloff@fortune.com>" <roger\_parloff@fortune.com>  
**Cc:** Daniel <dedlin@theranos.com>  
**Subject:** Additional Follow Up Items

Dear Roger:

please find some additional follow ups to our calls below. As always, do not hesitate to connect on any clarifications we can provide or questions we can answer on any of this.

With all my very best,  
Elizabeth

**Topic:** Names of pharmaceutical companies.

- OK to disclose Schering Plough and GSK. Awaiting permission from Pfizer – should get it in time.

**Topic:** How to describe the analytical systems.

- As you know, we want to generally keep the focus off the hardware. A way to do this if you are referring to it/the automation in our lab is to use the word analyzers, which is likely the best word to use beside analytical systems (rather than the word device). As you know, analytical systems is how we describe them. You can reference that in line with our FDA filing initiative you found the listing and registration of the analyzer on the FDA website. In that context, it is ok to say the analytical systems are about the size of a desktop computer (for reference off the record, this is the size of the system we're standardizing around for our next wave of production) if contrasting the size of our laboratory facility next to conventional laboratory facilities.

**Topic:** Proprietary technology and future plans if questioned/discussing the CAP article and DARPA references.

- The company is very focused on decentralization, and also very focused on maintaining our CLIA lab status, empowering pathologists with better data, and maintaining the oversight of pathologists. Your hypothesis if questioned after the article could be that we will be increasingly decentralized – as we discussed off the record re: the regulatory model for it, Theranos could do this in the form of many CLIA-certified locations. This avoids making the connection for people that most will not ever have made without insight into our proprietary plans that are obviously not public.

**Topic:** Software.

- Theranos leverages software automation to realize test integrity and oversight.

**Topic:** Laboratory comparison language.

- Our laboratory is designed to be automated, decentralize-able, and process much smaller volumes of samples. You asked a question at one point about number of analytical systems in the laboratory – let us know if this is on or off the record. We have further follow up on this.

**Topic:** Publications.

- No certified laboratory does publications for every lab test it brings up. Instead, the performance of those tests is demonstrated through ongoing proficiency testing with blinded samples. Theranos tests are for exactly the same analytes as are measured in traditional laboratory settings and not for new tests or methods around which other companies might do publications. Accreditation/certification of a lab is the means for demonstrating the integrity of the tests, in contrast to peer-reviewed publication of something like a novel test method or clinical application (you've seen the publications when, for example, a center of excellence advocates moving away from ELISA-based hormone assays to mass spec, but proficiency testing and accreditation, and not publication, is the way laboratory performance is demonstrated when LDTs are brought up, especially using conventional test methods like ELISA, for example). Of course you know we are filing all of our tests with FDA, and that we are focusing our publications around the clinical implications of our work (ie empowering pathologists and clinicians with richer longitudinal laboratory data).

**Topic:** Samples.

- Right now the majority of our samples come from our retail locations, however both through partnerships with our hospital systems as well as these physicians, the sample volume from physicians sending us samples will be scaling.

**Topic:** Venipuncture.

- We're scaling our infrastructure and working to make it possible to eliminate the need to have blood drawn from big tubes or through venipuncture for everyone. We've built and constantly update our infrastructure based on the tests we anticipate to be run in a given geography, but based on the combination of tests that are ordered we'll occasionally run them through venipuncture, with much smaller sample sizes as to what is traditionally collected.

**Topic:** Freezing capillary blood.

- We have validated multiple methods for freezing capillary samples, along with the associated tests that run on those samples in our high-complexity CLIA certified laboratory.

**Topic:** Data on performance of POC instruments in the context of existing finger-stick capability in conventional laboratory testing/"point of care".

- Lenters-Westra and Slingerland 2010 (Clinical Chemistry, *January 2010 vol. 56 no. 1 44-52*) studied eight different POC HbA1c analyzers and showed total-error estimates that ranged from -1.56% to +1.2% HbA1c units. At a 7% HbA1c, these total errors translate into relative errors of -22% to +17% in HbA1c, exceeding both the College of American Pathologists (CAP) acceptable limit for proficiency testing (+/- 6%) and the International Organization for Standardization currently used for glucose meters. Only two of the 8 POC analyzers studied were able to meet the total CV criteria of 3%.
- Blood glucose POC: only 50% of POC meters approved from 2009 to 2011 would meet +/-15% at >75 mg/dL criteria. (Patricia Bernhardt, M.T.(ASCP), Scientific Reviewer, FDA, 2011)
- Seven POC blood glucose meters involving four different manufacturers were compared to a reference method by Khan et al (Arch Pathol Lab Med. 2006;130(10):1527-32). Only one device met ADA 1996 performance requirements. Of major concern was the significant disagreement with reference values within the critical hypoglycemic range that could result in an adverse clinical decision. At the extremes of hyperglycemia and hypoglycemia, when compared to reference methods, 61% of values differed by more than 10% from the reference method with an alarming 57% of measurements differing by more than 20% in the hypoglycemic range. This study emphasizes the shortcomings for accurate detection and thus treatment of hypoglycemia with POC blood glucose meters.
- The performance of two POC devices that test for glucose, total cholesterol (TC), and high-density lipoprotein cholesterol (HDL-C) were compared to test results from a central laboratory (Simon J Whitehead, Clare Ford, and Rousseau Gama, Annals of Clinical Biochemistry, online first published July 23, 2013). In the first device, the total cholesterol test performance was 4.9% imprecision and a 24.76% bias, not meeting CLIA requirements. The second device for the glucose test imprecision of 2.1 to 3.7% and bias of 20.34% to 40%, not meeting minimal CLIA requirements.

**Topic:** Dr. Phelan video I referenced. Please follow the link below for an interview with Dr. Darren Phelan, for your reference in line with your discussion with him. Note that this footage is completely raw and unedited – I have not seen it yet but thought you'd find it of value.

LINK: <https://vimeo.com/97017816>

PASSWORD: Theranos

**Topic:** Additional Quotes.

Updated patient quotes

"I am normally a very hard venous stick, but I didn't feel a thing with the finger stick. This is amazing" – **Customer at 1182**

"I really like the convenience and privacy of your Wellness Center" – **Customer at 5453**

"That's IT?!? I am coming here all of the time"- **Customer at 5453 after experiencing the finger stick**

"I usually have to ask for a ride to get my blood work done, but with Theranos, I can conveniently get my lab work done without asking for a ride" – **Customer at 4139**

"My physician told me to use Lab Corp because it was cost \$61 to get my lab work done, with Theranos it cost \$6" - **Customer at 4046**

"Our six year old son had a great experience today because of how well the Theranos Phlebotomist handled things" – **Customer at 4139**

Updated physician quotes

Dr Perminster: "We're so glad to have a better testing option, especially one that is convenient, simple and affordable for our patients."

Dr Balderama (speaking to his assistant): "Why in the world are we not utilizing this in our office?"

Dr. Mengesha: "It's about time somebody came up with this!"

Dr. Milton Scharff: "This could change everything. It's great! Really great...Do you know the last time I said "This is great" to a detail person? It's been a really long time!"

Office Manager for Dr. Huang: "I love that this company is driven to have a huge impact on healthcare, it's challenging overpriced labs but has such a bigger potential than just cost savings. That goes right along with the mission of our practice."

Dr. Morton-Bours: "I think this is going to fit in so nicely with my practice. The draw station isn't at all what I imagined. You always think of it as a "Walgreens Wellness Center" with the accordion divider. This looks like a spa. It looks like my office . . . I'm emailing my EMR manager today and telling them that if they aren't working with you guys already, they need to be. This is the future".

Dr. Singh: "This is the future of healthcare - especially the price transparency part."

Dr. Zumarraga: "After reading about Elizabeth Holmes and learning more about her vision, I want to use you guys even more now ..."

April @ Derma Health: "This is amazing and not sure why someone hasn't brought this process to the market before. I have a lab order that I have had for 6 months that I haven't gone for but I will go get my labs this weekend!

Dr. Klee, Valley Hearth: "WOW....your PT/INR is how much?! How much are our strips...\$18 per strips? I would rather be doing something else in the office; let's start sending out patients over to these locations if patients are willing to travel! Once you get into Chandler, you can have them all!

Arthur McDonald, PA-C, GK Medical: "How in the world is this possible? . . . A vitamin D test for \$20. This is blowing my mind right now."

Dr. Lakin: "Really things have been good, I know you are accurate because I had a patient come back negative on measles that I just couldn't believe so I ran it through Sonora and it came back the same. I even had a phone call from your head of labs about a patient with unusually low triglyceride and that was accurate as well. I keep telling some of my colleagues back east about Theranos. You guys are definitely going to disrupt things."

Dr. Levy: "Great vision for the company. I'm bringing a copy of the Wired article home to my daughter so she can see what is possible when you work hard!"

Dr. Go: "Finally a lab with draw hours that make sense!"

Sonny (Dr. Fisher's MA): "Our patients reported they feel comfortable and were treated with respect from your staff."

Dolores Gonzalez (NP): "I am a patient advocate first. What Theranos is doing could really benefit many of our patients."

Dr. Gomez (agreeing with Dolores): "this is amazing."

Dr. Lawrence: "Wonderful! Wonderful! When can we sit down and talk?" (scheduled immediately; he & wife visiting WAG prior to appt.)

Dr. Courtney Hunt: "I want to work there I'm so excited about this!"

Dr Bernardo Tan: "This company is from Palo Alto which means it's new, innovative and everything they do is going to be cool."

Dr. Guyette to Theranos representative: "I want you to be the main driver of Theranos for me. Going forward, I want you to give out Theranos order forms instead of Sonora or LabCorp. In fact, can you start pre-filling some of the info for my patients this afternoon?"

**Topic:** Move in date for new space.

- November 1 is target move in date for new headquarters building on Page Mill Road.

**Topic:** Size and images of commonly used vacutainers.

- See attached. Representative tubes are 5 mLs.

**Topic:** Are we going to have further progress on NY cert by June 10<sup>th</sup>

- This is unlikely. Our team spoke with NY state last week and they are seeing if they can expedite this.

**Topic:** Sample volume.

- Best way to describe this is likely to say that we can run tens of tests from tens of microliters of blood.

**Topic:** Retail partnerships and exclusivity.

- Walgreens is our anchor partner, and our focus is around operationalizing that framework.

**Topic:** Certified lab.

- Theranos' high-complexity certified laboratory is located in Palo Alto, California.

**Topic:** Speaking to Medicare/Medicaid officials re: savings.

- Jon Blum contact information to follow. Mike Leavitt will be calling you tomorrow.

**Topic:** API quality certificate.

- This certificate is from participating in this proficiency testing program with API in addition to our other proficiency testing programs.

**Topic:** Video links of Elizabeth speaking on panels at the HEP Summit 2014 conference with the Labcor, UCSF, and BCBS Nebraska CEOs.

- These videos are not public yet but will be on our website.
  1. Theranos – Changing the Diagnostics Model to Improve Patient Compliance (Background about Theranos)  
<https://vimeo.com/user9029760/review/97191552/e5e8339742>
  2. Leveraging Diagnostics to Improve Patient Care in a Connected Healthcare System:  
<https://vimeo.com/user9029760/review/97190599/4ef5ce884b>
  3. Topic: A New Day In Diagnostics (Full Video): <https://vimeo.com/user9029760/review/96995028/4f31399297> (full video)

**Topic:** Description of any combination of tests being able to be done on our framework.

- Theranos can process and analyze samples in order to perform one more assays in parallel from a single micro-sample. These assays can be of the same assay method or of different assay methods.

**Topic:** Background on reflex panels across test methods from our lab order form.

- Below are 5 different testing scenarios where panels and/or reflex testing can aid in more rapid diagnosis and accurate decision making for patients and physicians. The testing volumes will not be too different if these tests are ordered all together or sequentially, but ordering them all together at one time will clearly transform the decision making process and mitigate sequential labs and prophylactic treatment.

#### **Anemia testing:**

Anemia is initially diagnosed hemoglobin values:

- o In men, less than 13 g/dL
- o In women, less than 12 g/dL
- o Reticulocyte index  $\geq$  2.5

Indications for anemia:

- Fatigue, weakness, pallor, dizziness, fainting

Types of anemia:

1. Iron-deficiency anemia
  - a. Is the most common form of anemia, and may be due to blood loss or poor absorption of iron
2. Vitamin-deficiency anemia
  - a. May result from low levels of vit-B12 or folate (poor diet) or poor absorption
3. Aplastic anemia
  - a. Rare form when the body stops making RBC
4. Hemolytic anemia
  - a. Occurs when RBC are broken up in the bloodstream or in the spleen
5. Sickle-cell anemia
  - a. Inherited hemolytic anemia when the hemoglobin protein is abnormal

Testing for diagnosis **Iron-deficiency anemia:**

- Iron deficiency is common in menstruating and pregnant women, children, and others with a diet history of excessive cow's milk or low iron-containing foods.
- Testing for diagnosis includes:
  - CBC
    - Low Hgb and HCT
    - Low MCV
  - Serum ferritin (low)
  - Iron (low)
  - Total iron binding capacity (high)
  - Transferrin (high)
  - Iron saturation (low)
  - Peripheral smear or blood slide
    - Small oval-shaped cells with pale centers
- In patients such as men, postmenopausal women, or younger women with severe anemia, the doctor may recommend additional testing. These tests may include the following:
  - Fecal occult blood test
  - Urine test for blood or hemoglobin
  - Endoscopy to look for gastrointestinal tract abnormalities
  - Gynecologic evaluation

Typical testing sequence, often through follow-on labs:

- 1) CBC with platelet count and automated diff and reticulocytes, then
- 2) Peripheral smear or blood slide, then
- 3) Evaluation of RBC indices from CBC test (looking at MCV, MCHC), then
- 4) Iron, Iron Binding Capacity, Ferritin, then
- 5) Vitamin B12 and Folate

Recommended panel:

- CBC / Auto Diff w/reflex to add'l tests:
  - Ferritin, Folate, Iron, Iron Binding, Smear Review, Vit B-12

#### **Celiac Disease Testing**

Theranos panel:

- 1) IgA, serum
- 2) Celiac-associated HLA-DQ Typing
- 3) Tissue Transglutaminase (tTG) IgA Antibodies, Serum
- 4) Gliadin (deamidated) Antibody, IgG, Serum
- 5) Endomysial Antibodies, IgA, Serum

A likely scenario with sequential testing requires three sequential visits, such as:

- 1) IgA, serum & Celiac-associated HLA-DQ Typing
- 2) Tissue Transglutaminase (tTG) IgA Antibodies, Serum
- 3) Gliadin (deamidated) Antibody, IgG, Serum & Endomysial Antibodies, IgA, Serum

Recommended panel:

- IgA, Celiac-associated HLA-DQ Typing, Tissue Transglutaminase (tTG) IgA Antibodies, Gliadin (deamidated) Antibody, IgG, Endomysial Antibodies, IgA

#### **Thyroid Screening:**

Recommended panel:

- 1) TSH (84443)
- 2) T4, free (84439)
- 3) T3, free (84481)
- 4) Thyroid hormone (T3 or T4) uptake or thyroid hormone binding ratio (THBR) (84479)

#### **Coagulation disorders:**

Prolonged coagulation results require further testing to differentiate factor deficiencies from circulating inhibitors

Possible for Coag Profile panel:

- 1) Automated platelet count (85049)
- 2) Prothrombin time (85610)
- 3) Thromboplastin time partial (85730)
- 4) Fibrinogen activity (85384)

#### **Trauma Panel: rapid response and decision making when reflex testing could take too long**

- Metabolic panel total ca (80048)
- Amylase (82150)

- Complete cbc w/auto diff wbc (85025)
- Prothrombin time (85610)
- Thromboplastin time partial (85730)
- Reflex to: Bl smear w/diff wbc count (85007)

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