From: Jim Mattis
To: Bechtel, Riley; 'Elizabeth Holmes'; hking@theranos.com
CC: 'David Boies'
Sent: 10/18/2015 7:12:39 PM
Subject: RE: Statement from Theranos, 10/16/15 [*EXTERNAL*]

Riley,

My apologies for being late coming on line. I know the management team is moving in real time to address the points raised in the article and to counter them before their repetition becomes accepted urban myth. I concur with addressing each of the points you raise, Riley, plus every other one that is first order (brought up in the article) and second order (anticipating the WSJ's likely response to our counter-story).

I regret that I'm removed from keeping current on the state of play back in the states but I think the game plan discussed at our board meeting remains operant: be swift in response with unassailable truth, countering directly and persuasively each & every allegation point by point without revealing critical intellectual property.

I'll be off line for much of the next 24 hours and I'm trying to close out my work asap so I can fly back early from the Mid-East. Will keep you posted, but please know that my silence is due to lack of connectivity, for I have full faith in our plan and the outcome as we execute it rapidly, thoroughly, rapidly (X2) and in an anticipatory mode for the follow-on attacks we know are coming….

Best, Jim

From: Bechtel, Riley [mailto:rileyb@[redacted]
Sent: Saturday, October 17, 2015 10:30 AM
To: Elizabeth Holmes <eholmes@theranos.com>; hking@theranos.com
Cc: David Boies [redacted]; jimmattis@[redacted]
Subject: Fwd: Statement from Theranos, 10/16/15

Elizabeth and Heather,

For what it's worth, I think Sam's right with a couple supplements: right behind, in importance, the allegation that we've been intentionally misleading with regulators are: 1) the one that we've been intentionally noncompliant, 2) the insinuation that we got caught by the WSJ "investigation"- encouraged-FDA audit, and 3) the allegation that we've had to change our website marketing and stop testing on our equipment as result.

You might consider a statement or two soon fully puncturing these allegations/insinuations with facts and plain, compelling context like EH response to Dick K, and inluding more facts and explanation hammering WSJ ignorant and disengenuous refusal to:

1) reference the 1000 pages you delivered (explain significance of some of the key data in those pages as relates to their allegations and your refutation); and

2) let you prove up your test system to them.

I'd consider being quite specific (e.g. on latter point, what was offered when and what dismissive reply was when), unless facts less helpful here than I recall. For e.g., if I recall correctly, the WSJ response to #2 was to effect "we don't have time, we're on a

deadline". You could note here that you could have had gear & people in their offices w/in __ hours, your test results in their hands w/in __ mins, all compliant with FDA regs; you can't do anything about competitor's taking __ days or __weeks for comparative results; and in any event is a pub deadline more important that being truthful in article?

For what it's worth, I'd also suggest being careful about (too much) marketing theme and tone (e.g innovativeness) or PR cleverness (e.g. "simple as 1,2,3") in your statements. It's a fine line to avoid tripwire of folks dismissing your statements as spin. They will be most compelling when steering clear of all that and coming across, like EH response to Dick K, "just the facts, thank you".

Are you coming along with side-by-side analysis of WSJ allegations vs facts? That would likely be very helpful in prioritizing responses and getting baseline of understanding and related support from BoC members. Guess you'll need to extend it at some point to pick up other important pubs' allegations, too (e.g. Forbes and Fortune). For next few days, agree that WSJ is main story to concentrate on.

Hope this is helpful. Am copying Jim and David in case they feel differently.

Riley

Riley P Bechtel

Office: 01 415 768 1415

Email: rileyb@[redacted]

Begin forwarded message:

From: Sam Nunn [redacted]
Date: October 17, 2015 at 08:30:33 PDT
To: Elizabeth Holmes <eholmes@theranos.com>
Cc: "kovacedm@[redacted]" <kovacedm@[redacted]>, "rileyb@[redacted]" <rileyb@[redacted]>, "groughead@[redacted]" <groughead@[redacted]>, "wjperry@[redacted]" <wjperry@[redacted]>, "jimmattis@[redacted]" <jimmattis@[redacted]>, "kmatthews@[redacted]" <kmatthews@[redacted]>, "bfrist@[redacted]" <bfrist@[redacted]>, "Bill.Foege@[redacted]" <Bill.Foege@[redacted]>, "Susan.Schendel@[redacted]" <Susan.Schendel@[redacted]>, "[redacted]boies@[redacted]" <[redacted]boies@[redacted]>, Sunny Balwani <sbalwani@theranos.com>, Heather King <hking@theranos.com>

Subject: Re: Statement from Theranos, 10/16/15 [*EXTERNAL*]

Thanks Elizabeth for your reply to Dick-very helpful. Thanks also to Riley for sending us your Kramer interview which was well done. From my perspective the most serious WSJ allegation is that Theranos has intentionally mislead the regulatory agency and this is the one I think we need to respond to in every interview and every statement. Even the reasonably well informed public does not know the difference between CLIA and FDA in terms of their jurisdiction over Lab testing so "full regulatory compliance and transparency" it seems to me must be the point we focus on in our public statements. Please let us know or have Heather call if we can be helpful. If someone at Theranos could send us all news that comes to company attention on this subject it would be helpful. Sam

Sent from my iPad

On Oct 17, 2015, at 2:15 AM, Elizabeth Holmes <eholmes@theranos.com> wrote:

Thanks for this Dick.

That's correct - we are at an exact moment in time right now where we've just transitioned from operating under the traditional laboratory framework (governed by a law called CLIA) to the FDA framework. This is what the laboratories have been threatening to sue FDA about to prevent such a transition from being required for them. We are the first lab to do this.

Part of this transition means moving all operations from the CLIA quality systems to the FDA quality systems. By definition, it is not possible to operate under both policies at the same time, as they have different requirements.

We are currently waiting on clearances for our nanotainers (all our data was submitted to FDA). In order to effect this transition, we voluntarily decided and communicated to them that we would temporarily not use the nanotainer under the CLIA lab framework until we received clearance, and bring it up under the FDA framework (which by definition means it starts being used only once clearance is complete).

We hope to see those clearances soon, but of course can never put a date certain on FDA timelines. The nanotainers were cleared as part of our previous FDA submission for use with our device and first cleared test, so we have been through this process before. We have advocated aggressively for FDA to become the new standard for lab testing, and we are now completing that transition ourselves.

During the time we are transitioning the nanotainers operations, we are still able to use all our proprietary technology, including our devices, which were approved for use this summer based on studies with ~900 patient samples. Note the name Edison was the name of the company's very first device (not our current systems) - this is one of many incorrect statements by the former employee who communicated this information to the WSJ reporter.

We do not have a good % number right now of how many tests will be done on our equipment during this temporary period, in addition to our first FDA-cleared test, as we are literally in the middle of having just completed this transition and mapping that out now, and this will likely continually evolve, including as we get additional clearances. The significant point is that every test Theranos does and is doing is now fully compliant with the FDA framework.

Let me know if you'd like more background on any of the above,

Elizabeth

From: kovacedm@[redacted] [mailto:kovacedm@[redacted]]
Sent: Friday, October 16, 2015 5:00 PM
To: rileyb@[redacted]; Heather King <hking@theranos.com>; groughead@[redacted];
wjperry@[redacted]; snunn[redacted]; jimmattis@[redacted];
kmatthews@[redacted]; bfrist@[redacted]; Bill.Foege@[redacted];
Susan.Schendel@[redacted]; [redacted]boies@[redacted]
Cc: Elizabeth Holmes <eholmes@theranos.com>; Sunny Balwani <sbalwani@theranos.com>
Subject: RE: Statement from Theranos, 10/16/15

That was well done.I am still confused,however,regarding my previous email.At this moment,how many of our customer submissions are being tested on lab equipment versus edison.?If I understand what is being said there is very little as we are focused on the FDA testing for edison and our nano tubes and not for active customers as we can't do both at the same time for some resaon

-----Original Message-----
From: Bechtel, Riley [rileyb@[redacted]
Sent: Friday, October 16, 2015 06:03 PM Central Standard Time
To: Kovacevich, Dick M.; hking@theranos.com; groughead@[redacted]; wjperry@[redacted]
snunn[redacted]; jimmattis@[redacted]; kmatthews@[redacted]; bfrist@[redacted]
Bill.Foege@[redacted]; Susan.Schendel@[redacted]; [redacted]boies@[redacted]
Cc: eholmes@theranos.com; sbalwani@theranos.com; hking@theranos.com
Subject: RE: Statement from Theranos, 10/16/15

Directors,

For those who missed it, Elizabeth did a superb job on CNBC's Kramer "Mad Money" yesterday. Here's link…http://video.cnbc.com/gallery/?video=3000432502.

Riley

Riley P. Bechtel

50 Beale St.

San Francisco, CA 94105

Email: rileyb@[redacted]

Ph; 415-768-1415

Fax: 415-442-1860

From: kovacedm@[redacted] [mailto:kovacedm@[redacted]
Sent: Friday, October 16, 2015 3:12 PM
To: hking@theranos.com; groughead@[redacted]; wjperry@[redacted]; snunn[redacted]
jimmattis@[redacted]; kmatthews@[redacted] bfrist@[redacted]
Bill.Foege@[redacted]; Bechtel, Riley; Susan.Schendel@[redacted]; [redacted]boies@[redacted]
Cc: eholmes@theranos.com; sbalwani@theranos.com
Subject: RE: Statement from Theranos, 10/16/15 [*EXTERNAL*]

So when blood is withdrawn in venous tubes do I understand correctly that the tests are then done on Lab like equipment and not Edison and those are sent to CLIA for testing while Edison is only being used for the FDA tests?

-----Original Message-----
From: Heather King [hking@theranos.com]
Sent: Friday, October 16, 2015 04:49 PM Central Standard Time
To: Kovacevich, Dick M.; 'groughead@[redacted]'; 'wjperry@[redacted]';
'snunn[redacted]'; 'jimmattis@[redacted]'; 'kmatthews@[redacted]';

'bfrist@[redacted]; 'Bill.Foege@[redacted]; 'rileyb@[redacted]
'Susan.Schendel@[redacted]; 'DB
Cc: Elizabeth Holmes; Sunny Balwani
Subject: Statement from Theranos, 10/16/15

Dear board members,

Please find below, attached and here (https://theranos.com/news/posts/statement-from-theranos-2 <https://theranos.com/news/posts/statement-from-theranos-2>) our statement that was recently posted.

Best,

Heather

Statement from Theranos

PALO ALTO, CA (October 16, 2015) - We are disappointed to see that The Wall Street Journal still can't get its facts straight.

Our focus is on providing lab tests at transparent, unprecedented low costs and in more accessible ways, so that people can afford them and get access to actionable health information in time to do something about it. Actionable health information means testing done in accordance with the highest quality standards - those standards are FDA quality standards and our standards.

Here are the facts:

There are just 3 steps to Theranos' groundbreaking finger-stick technology.

1. Take a few drops of blood.
2. Put the blood in the Nanotainer™ tube.
3. Analyze the blood.

That's it. 3 simple steps. 1, 2, 3.

We sought out and asked FDA to review those steps for everything we do - like no lab before us. We asked for that engagement, and are glad to have it. We believe the model for the lab of the future is to take all tests through FDA review, and we have been working with them to do that for quite some time. Because we've always been committed to quality, to the best science, and to ensuring that innovation comes to health care. We are the lab of the future, not the lab of the past. It's about quality, it's about rigor, it's about clearly defined standards, it's about access for everyone - it's about your health.

Our current work with FDA is focused on the Nanotainer™ tube - the tube that collects those few little drops of blood in order to be able to run tests on tiny finger-stick samples: Step 2.

The FDA is putting our tube that transports the blood for our devices through its rigorous review process. That's what we are advocating for. During this process, we also made the decision to move our existing quality systems operations over to FDA quality systems completely, while we work with FDA for clearance on our tubes. This has been a long-term transition which we've now completed.

And here is one more fact. The Nanotainer™ and our devices have already been cleared by FDA for use with our HSV-1 test. FDA had to review and clear all our proprietary systems - including the Nanotainer™ tubes - in order to clear even this one test. Why? Because we're innovative. Because we are doing things differently. Now we're working with them on clearance of just the Nanotainer™ tubes across all tests. But it's the same tube. We've already met their rigorous standards in our first submission on our systems, and we'll continue to do so.

Our decision to engage with FDA at these unprecedented and transparent levels is, in and of itself, innovative. It is not possible to operate under the CLIA lab quality systems for Lab Developed Tests (LDTs) and the FDA quality systems at the same time. There is evolving policy and debate on this topic of regulating LDTs. Most companies would fight it, and they do. Big

labs are threatening to sue the FDA over it. But we didn't. We said, we agree. We said, let's do this right. If we are going to advocate for the FDA regulatory framework, we should live by it as well. So we are.

As we continue with our transition to all FDA cleared or approved tests, we are now operating only under full FDA quality standards and systems. It's the right choice and the highest standard. And as of this exact moment, that means temporarily using a different tube - tubes for venous blood - so we can maintain the quality standards we have in our labs as we complete the clearance process on the Nanotainer™. Still smaller tubes, smaller samples, lower costs. So right now we are taking samples, transporting them, and running the tests. That is an FDA cleared process. That is our process.

Unprecedented transparency - in price and in submitting our data to FDA. Groundbreaking technology. Gold standard review. 1, 2, 3.

<https://theranos.com/news/posts/statement-from-theranos-2> # # #