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CytoDyn: Misrepresentation Measured in Minutes

"If you tell the truth, you don't have to remember anything."

Mark Twain, *Notebooks*

The Company has responded not by disputing the content of our report – as we believe it simply cannot – but by continuing on its promotion tour. Despite just 6 calendar days and 4 trading days having passed since our original report, we believe the Company has continued to make numerous false and misleading statements across each of coronavirus, breast cancer, and HIV. We lay these bare below. We remain short CytoDyn.

The Coronavirus Promotion Tour Continues

On February 6, the Company held an investor update call. On that call, the Company disclosed for the first time that it had signed a "non-binding agreement to explore licensing out Leronlimab for cancer and potential use of leronlimab for coronavirus with one of the largest leading distributor of health product in China."

This "non-binding agreement" implies simply that two parties have stated their intention to negotiate potential terms of a future agreement. As was stated later on the call, the Company has yet to actually finalize an agreement; "All of those [details] will be announced in a press release and any agreement that is finalized, which will take some time, those will also be announced." As such, we view this announcement, and this morning's press release, as a non-event, merely another blatant promotional tactic in the Company's playbook. However, despite the already noncommittal nature of this non-binding agreement, additional details that CEO Nader Pourhassan offers on the February 6 call create an even more disorienting picture. See below:

> Analyst Question: So just [to] clarify, you're saying that the Chinese partner could very rapidly move Leronlimab into clinical trials for the corona[virus]?
>
> Pourhassan: Oh, that's why we chose them, **they own eight Tier 1 hospitals in China. And Tier 1 hospitals are the top hospitals in all of China, which have the resources and the sophistication to be able to conduct these trials expeditiously get data quickly and move on from there.** But like I said, we're going through the proper channels, we're doing this in very defined clinical studies, but that doesn't mean the timeline has to be long.

First, we find that Pourhassan's characterization of Chinese Tier 1 hospitals is – like much of his commentary – demonstrably false. Tier 1 hospitals are not "the top hospitals in all of China"; rather, they are the nethermost hospitals in China. Per IHS Markit (as well as many other readily available sources which readily refute this claim):

> "A three-tier system is used to classify China's hospitals: Hospitals with over 500 beds are classed as Tier 3 and provide the top level of care; Tier 2 hospitals are medium-sized city or county institutions; and Tier 1 institutions are township hospitals."

Moreover, there are thousands of these Tier 1 hospitals, and their roles have been relegated in recent years to those of zombie-like institutions. Per a 2016 paper published in China Perspectives entitled "Evolution of the Health System," Tier 1 institutions "collapsed" years ago:

> With the advent of economic reforms and decollectivisation (at the beginning of the 1980s), the people's communes that funded public services were dismantled. The community medical system found its funding cut dramatically, and sometimes this funding even disappeared completely. Existing public establishments were either replaced by private ones, or put into competition with them. As a result, Tier-1 public establishments began to collapse due to a lack of funding, leaving rural areas without public healthcare treatment.

This is confirmed by a June 2019 article in the South China Morning Post, which states that, "Around 2,300 top tier public hospitals are at capacity, while 950,000 lower-tier hospitals, community health centres and clinics struggling to attract patients." Thus, while Pourhassan's claims intend, in our view, to conjure images of the Chinese equivalents of Johns Hopkins, Mayo Clinic, Cleveland Clinic, or New York Presbyterian, the reality is that these 8 facilities are akin to defunct, 25-bed rural hospitals, which is entirely dissatisfying to CytoDyn investors.

We put the question to readers: if Pourhassan is willing to lie about the details of an already suspect non-binding agreement, what else is he willing to lie about?

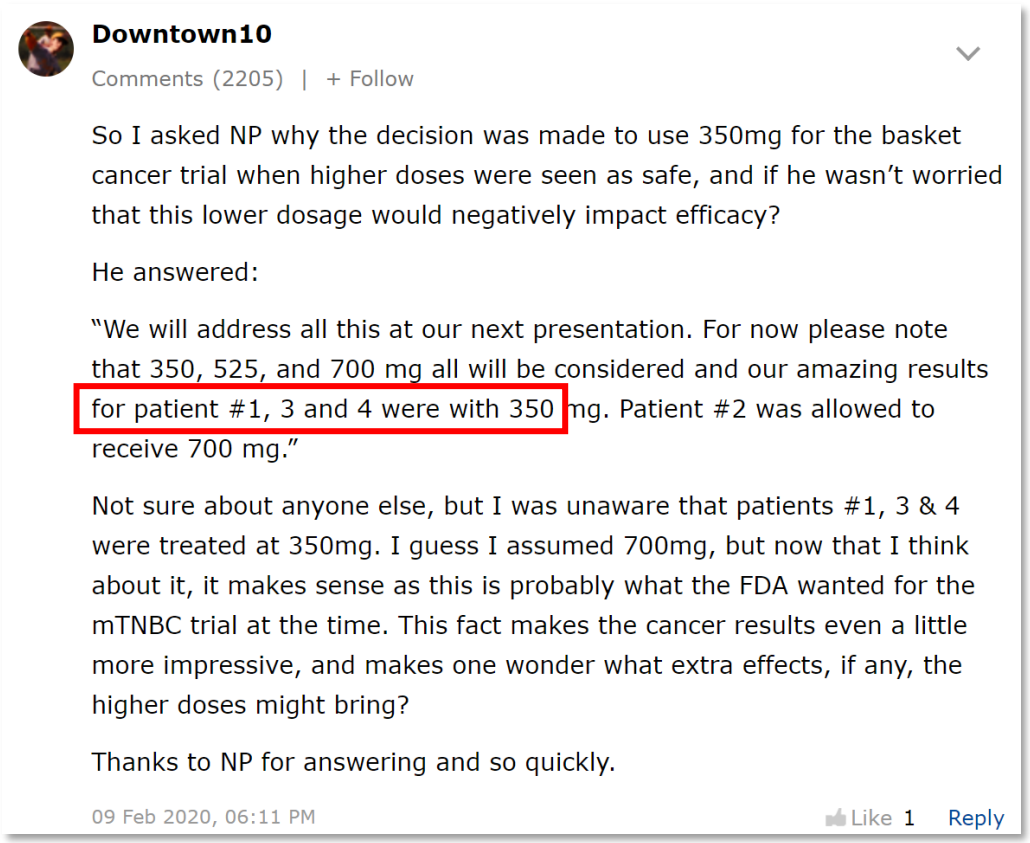
Nevertheless, Pourhassan claims that this distributor is "one of the largest leading distributors of health product in China." In a February 11 conference presentation, around the 39th minute, Pourhassan characterized the partner as, "a very great pharmaceutical company, or health space company that has hospitals and access to that sort of thing." To be clear, the Chinese drug distribution market is extremely fragmented, with thousands of distributors. Per Research in China, "By the end of 2018, there had been 13,146 drug wholesalers competing fiercely in China, showing a low market concentration." Thus, we view Pourhassan's characterization of this single distributor supplying eight Tier 1 hospitals as "leading" to be highly misleading.

On February 12, the Company issued a press release with respect to this Chinese partner. We make no representations about the legitimacy of the partner, Longen China Group, but note that this press release indicated once more that CytoDyn merely signed a "non-binding letter of intent," the same language contained in the January 28 press release. By contrast, just days ago, Pourhassan stated that "any agreement that is finalized, which will take some time, those will also be announced." As such, today's press release is perplexing, given that this "non-binding letter of intent" makes no legal strides towards finalization of a binding commitment, which seems to us to be what Pourhassan had implied.

Pourhassan's earlier comment that this partner "owns eight Tier 1 hospitals in China" contrasts markedly with the sparse, garbled information offered on Longen in the Company's February 12 press release, namely that, "At the same time with a number of well-known domestic third-class first-class hospitals to carry out clinical research and transformation [sic]." It remains unclear to us the exact nature of this entity's operations. In tandem with what we view as the Company's track record of misdirection, we struggle to assign any credibility to CytoDyn's statements regarding coronavirus and believe that they are promotional tactics.

Breast Cancer

In breast cancer, the Company continued to make claims across its February 6 and February 10 public presentations that simply aren't supported by the data, in our view. That said, we have discussed this at length in our original report, and refer readers to that document. In addition, we note the following Seeking Alpha comment, which alleges that CEO Pourhassan stated to an investor in a private email that "Patient #1 … [was prescribed] 350 mg."



Downtown10

Comments (2205) | + Follow

So I asked NP why the decision was made to use 350mg for the basket cancer trial when higher doses were seen as safe, and if he wasn't worried that this lower dosage would negatively impact efficacy?

He answered:

"We will address all this at our next presentation. For now please note that 350, 525, and 700 mg all will be considered and our amazing results for patient #1, 3 and 4 were with 350 mg. Patient #2 was allowed to receive 700 mg."

Not sure about anyone else, but I was unaware that patients #1, 3 & 4 were treated at 350mg. I guess I assumed 700mg, but now that I think about it, it makes sense as this is probably what the FDA wanted for the mTNBC trial at the time. This fact makes the cancer results even a little more impressive, and makes one wonder what extra effects, if any, the higher doses might bring?

Thanks to NP for answering and so quickly.

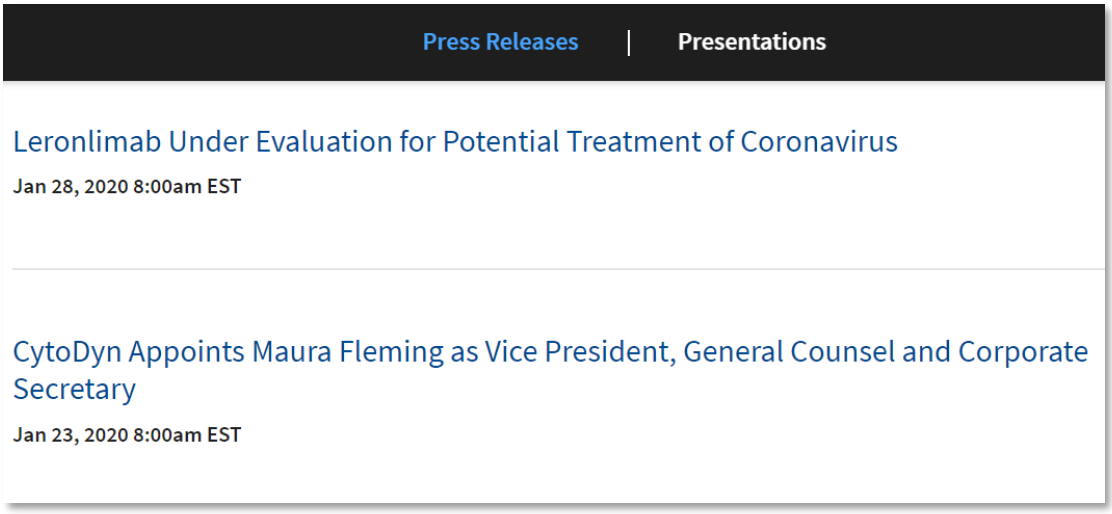
09 Feb 2020, 06:11 PM Like 1 Reply

Note from the Company's December 3, 2020 press release that the first patient was prescribed 700mg:

> "The first patient in the open label study was given a weekly injection of leronlimab at 700mg along with carboplatin. The patient was enrolled in the trial with CCR5-positive, mTNBC and naïve to chemotherapy in metastatic setting."

If indeed this communication came from CytoDyn's CEO, notwithstanding the potential selective disclosure issues, we ask: if the Company's CEO can't be expected to keep these figures straight, how ought investors to be expected to rely on their authenticity, let alone draw conclusions regarding them?

On the topic of disclosures, we also note that the Company issued a press release on January 27, 2020 stating, "CytoDyn Announces CROI's Acceptance of Late-Breaking Abstract by Dr. Jonah Sacha for use of Leronlimab as PrEP." However, when we tried to search for the abstract on the CROI's website, we could not find the presentation listed. Further, the Company's website also removed the press release:



Finally, we searched for the abstract title, and did not find a single instance of the presentation's existence, apart from CytoDyn's mention of it in the now buried press release. Thus, much like the Company's supposed Scientific Advisory Board, supposedly formed in March 2018, we believe this phantom abstract is merely another in the Company's series of public statements that we are unable to reconcile with reality.

HIV

The White House

In HIV, the promotion tour has continued unabated. On the February 11 presentation at the 11th minute mark, Pourhassan states:

> "Prevention, also, we are very happy have some discussion currently with the White House doctors about how we can change the new HIV transmission to hopefully go to zero. In the last 15 years, it's always 40,000…"

Then, at the 48th minute, Pourhassan is questioned regarding the supposed White House conversations, and his reply is quite perplexing:

> "So please make sure that – what we say here is recorded – I did not say we are talking to [the] White House, I said that in [the] past we are talking to senators, one senator. That senator has now reached out to the HIV person at the White House and we are now gonna have a talk with them, directly. So we haven't had that talk, we're supposed to set up that time and talk…"

While in the past, we have measured the pace of Pourhassan's promotional misrepresentations in days, it appears these can now be measured in mere minutes.

The BLA

Regarding the Company's BLA non-filing, per our original report:

> "We expect that during today's 4:00 PM EST investor conference call, the Company will once again kick the can down the road with respect to BLA filing. We suspect that Company has likely left the BLA unfiled so as to stall the revelation of deficiencies in the Company's clinical data package and/or manufacturing."

On the February 6 conference call, the Company disclosed another delay in its BLA application, citing deficiencies both in clinical data package and in manufacturing, as we predicted:

> "Clinical sections because FDA requested all of our CD03, which is our monotherapy data not just the 50 that was – we were under the impression to intro -- to give to this FDA, we now going to be delayed to the end of February, and that's what I have been given the information, I've been given from Amarex [ph]. And with our CMC manufacturing package, that also is due to be completed by the end of February."

We continue to believe that the longstanding BLA delays hint at deeper problems within the Company. In a RedChip interview uploaded on February 10, 2020, Pourhassan claims that the Company will now have the BLA filed by the end of February. To remind readers, the Company has claimed numerous times over the past ~18 months that the BLA is on the brink of filing. Why ought investors to expect that this time is any different? Nevertheless, Pourhassan then claims,

> "Then 6 months later [after filing], because we have accelerated approval, instead of one year standard, 6 months later we should have approval."

In contrast to this comment, the FDA's own data show that from 2014 through 2016 (latest available), the agency has a median priority approval time of 8.0 months, while the standard review time was 10.1 months in 2016. Thus, the most recent data suggests a timing difference between standard and priority review of 2 months in total, rather than the half-year difference stated by Pourhassan, while the Company's review ought to be expected to take 8 months, not 6.

We pose the question once more: If Pourhassan is so eager to lie about such seemingly trivial facts that are readily and easily disproved, why ought investors to trust the claims that the Company makes regarding more substantial matters?

Fundraising: The Real Business

On the topic of fundraising, Pourhassan continues to talk out of both sides of his mouth. Recall that in early January, Pourhassan claimed that the Company was expecting to receive 14 term sheets for $40 to $50 million in debt, yet executed an equity raise just days later. On the Company's February 6 call, he stated:

> "I mean, it's amazing how we raise money with this product from day one. And everything we told – **we continuously told the truth,** performed great, had great results from FDA always, always told how this product is amazing and you don't have selling pressure, people going to have exit now."

In light of our original report and the public statements we have attempted to reconcile above, we encourage investors to contemplate whether or not the Company has indeed "continuously told the truth." We remain short CytoDyn.