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Veru Inc (NASDAQ:VERU): More Data, More Problems

We are short Veru Inc ("VERU", "the Company"). We released an initial report on VERU on May 2, 2022. In it, we criticized the Company's Phase III study for sabizabulin (VERU-111) in hospitalized COVID-19 patients ("the Study") as being, in our view, plagued by design flaws. We further highlighted that multiple VERU insiders have been associated in the past with clinical frauds and failures. The Company's July 6, 2022 publication[1] in NEJM's *Evidence* revealed more granular data which confirms our view that the Study was plagued by anomalies, which in sum led to a Placebo group which was not in fact "similar" to the treatment group, and instead was much sicker. As such, we continue to believe that Veru has little to no hope of obtaining an Emergency Use Authorization ("EUA") based on these results as called for by management and ever-obsequious sell-side analysts.

At Baseline, the Study's Placebo Group Was Markedly Sicker than the Sabizabulin Group

Veru has claimed its placebo and treatment groups contained "similar baseline characteristics", yet we find this claim totally empty in light of the major differences in blood oxygen saturation (SpO2) levels shown in the through the newly-published data. See per Table 1 that while blood oxygen saturation levels appeared to have similar mean and median values, the placebo group saw both (a) a significantly higher standard deviation and (b) a significantly lower minimum level as compared to the treatment group. As such, the placebo group holds a massive left tail of sick patients which were not found in the treatment group:

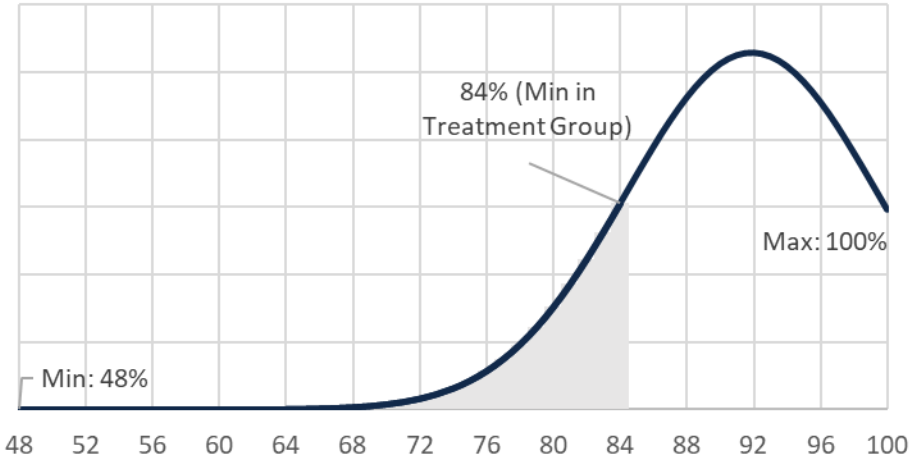
Baseline Oxygen Saturation	sabizabulin	placebo	Difference
Number of Patients	98	52	n/a
Mean (%)	92.7 (3.43)	91.9 (7.53)	+0.8
Median (min, max)	93.0 (**84**, 100)	94.0 (**48**, 100)	-1.0

Veru chose not to disclose patient data on an individual level, but basic statistical tools allow us to estimate that **an astounding 14% of patients (approximately 7 of 52 placebo patients) were altogether worse off (i.e., worse than 84% blood oxygen saturation) than the single worst patient in the treatment group, even as the treatment group was nearly twice as large.**[2] See Veru's new data illustrated by us below:

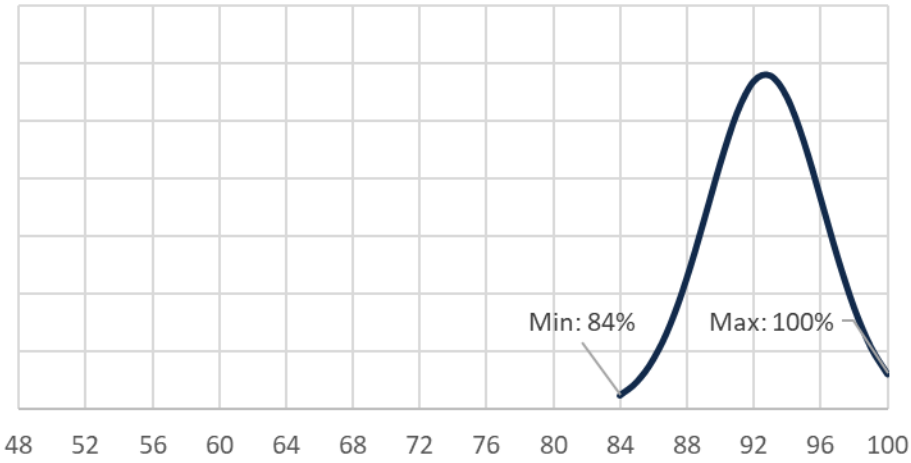
[1] Readers can find the full study protocol, disclosures, and supplemental appendix linked here. We also note that *Evidence* is a new monthly journal from NEJM, which "presents innovative research and fresh, bold ideas in clinical trial design and clinical decision-making."

[2] We assume a normal distribution, as we don't have full data. The actual data is unlikely to perfectly match this distribution, making our estimates just that. In our view, this remains the best method by which to model the data, given Veru has not offered individualized data.

Baseline Oxygen Saturation: Placebo Group



Baseline Oxygen Saturation: Treatment Group



The same basic statistical tools allow us to estimate[3] the percentage of each group which had baseline oxygen saturation levels below 90%. Our analysis of Veru's data suggests that:

- **Just 20.1% of patients in the treatment group (20 of 98 patients) had SpO2 levels below 90%,**
- **While 42.2% of patients in the placebo group (22 of 52 patients) had SpO2 levels below 90%.**

We find this highly problematic for Veru's claims of "similar baseline characteristics" between groups, given that numerous studies have found lower blood oxygen saturation levels contributes to increased mortality rates:

- A June 2020 study of 140 patients at Union Hospital in Wuhan, published by the Mayo Clinic, found that "Higher SpO2 levels after oxygen supplementation were associated with reduced mortality independently of age and sex…"

[3] Placebo group of -1.9% difference vs. mean / 3.43% standard deviation = -0.25; treatment group -2.7% difference vs. mean / 7.53% standard deviation = -0.78; reference 0.05.

- A December 2020 study of 369 hospitalized COVID-19 patients in Peru found, "By multiple Cox regression, oxygen saturation (SaO2) values of less than 90% on admission correlated with mortality, presenting 1.86 (95%CI: 1.02–3.39), 4.44 (95%CI: 2.46–8.02) and 7.74 (95%CI: 4.54–13.19) times greater risk of death for SaO2 of 89–85%, 84–80% and <80%, respectively, when compared to patients with SaO2 >90%."

- A May 2021 study of 1,095 hospitalized COVID-19 patients found that "…oxygen saturation <92% or a respiratory rate >22 breaths per minute—were each associated with elevated mortality in hospitalized COVID-19 patients."

- An April 2022 study of 236 hospitalized COVID-19 patients at King Edward VIII Hospital in South Africa found that "Multivariate logistic regression revealed a significant relationship between age and oxygen saturation with in-hospital mortality (OR 1.047; 95% CI 1.016–1.080; p = 0.003 and OR 0.922; 95% CI 0.880–0.965; p = 0.001 respectively)."

Moreover, see that once again despite Veru's claims of "similar" baseline characteristics between groups, the sabizabulin group was advantaged vs. placebo in numerous key factors.[4] Even if one were to assume that each difference was not significant in isolation – even the 12.7% difference in Pneumonia – we view the differences as having potentially further influenced results when considered in their entirety.

Factor	sabizabulin	Placebo	Difference (Absolute)	Difference (Relative)
Age category (over 65)	45.9%	50.0%	4.1%	8.2%
BMI under 35	64.9%	72.5%	7.6%	10.5%
Pneumonia	46.9%	59.6%	12.7%	21.3%
Diabetes	35.7%	40.4%	4.7%	11.6%
Received Dexamethasone	83.7%	80.7%	3.0%	3.7%
Received Remdesivir	34.7%	28.8%	5.9%	20.5%
Non-vaccinated	54.1%	57.7%	3.6%	6.2%

These stark differences in patient profiles between groups also begs the question as to how such a large group of low-saturation patients happened to be placed in the placebo group. When we take a closer look at US vs. Rest of World patients, we see further anomalies.

New Data Reveals Implausibly High 62% Mortality Rate in US Placebo Patients

We find Veru's US placebo group mortality rate of 62% implausibly high, to the point of raising questions regarding the composition of the US-based placebo group, which effectively appears stacked with near-death patients. Our initial report suggested that Veru's consolidated (i.e., both the US and Rest of World) placebo group mortality rate of 45% appeared artificially high, given that numerous data points suggested mortality rates ought to have been in the 20% to 25% range. Our research suggested that this massive disparity could have been skewed by

[4] See Veru's Table 1 for the full list.

international sites with low standards of care. However, CEO Steiner talked past such a suggestion in the Company's May 2022 Jefferies conference presentation, instead stating that the US patient mortality rate was in fact higher than the Rest of World mortality rate. Yet we find this merely replaces one set of concerns with another, as **Veru's updated data now show that US-based placebo group patients experienced what we view as an outrageous 62% mortality rate.** Per the study:

> "In the United States, a 34.4% percentage point absolute reduction in mortality at day 60 (55.5% relative reduction) was observed in the sabizabulin group compared with placebo. In the rest of the world (Brazil, Bulgaria, Mexico, and Argentina), a 18.5 percentage point absolute reduction in mortality at day 60 (55.6% relative reduction) was observed in the sabizabulin group compared with placebo."

We derive the 62% mortality rate using simple algebra as shown in the table below:

Phase III Mortality Rates	Absolute Reduction	Relative Reduction	Implied Mortality: Placebo	Implied Mortality: Sabizabulin
United States	34.4%	55.5%	62.0%	27.6%
Rest of World	18.5%	55.6%	33.3%	14.8%

This incredibly inflated mortality rate suggests to us that the US patients were not representative of a broader hospitalized population, and instead suggest to us that US-based enrollment contained critical flaws. Indeed, look no further than **Veru's own protocol, in which the Company itself relied on the assumption of a 25% mortality rate in the placebo treated group**:

9.0 STATISTICAL ANALYSIS

9.1 Sample Size Calculation

In the Phase 2, the VERU-111 treated group showed a 5.3% mortality rate compared to a 30% mortality rate in the Placebo group in the same patient population.

Approximately, 210 subjects are planned to be randomized at a 2:1 ratio into two treatment arms (140 subjects in the VERU-111 treated group and 70 subjects in the Placebo treated group). Randomization will be stratified by baseline WHO Ordinal Scale score of 4, 5 and 6 such that subjects with a WHO Ordinal Scale of 4, 5 and 6 at baseline will be approximately equally distributed between the treatment groups. Assuming a rate of mortality of 5% in the VERU-111 treated group and 25% in the Placebo treated group, the above sample sizes will yield 95% confidence interval of [--0.308, -0.092] for the risk difference between treatment groups. Other scenarios are shown in the table below.

We've already established that the Study's placebo group contained a fat left tail of sick patients, yet in seeking to explain exactly how these patients got into the study, CEO Mitchell Steiner's comments appear helpful. At the 2022 Jefferies conference, Steiner stated:

> "You could have a situation where somebody is just not doing well in the ICU, [and the doctor might say] 'Oh, we have a study that's open. Well he's been out on the vent for two weeks, so he's been on forced oxygen for two weeks. **There's no limit on how long they have to have a symptom before you put them on drug,** let's just put them on drug.'"

Veru chose not to disclose data regarding patients' pre-treatment length of hospitalization, and we don't find anything in the Study that would suggest that the Study controlled for this factor. As such, the door has seemingly been left open that a large cohort of patients in near-death conditions could have been tossed into the trial as a last resort, then disproportionately placed into the Study's placebo group.

Veru's Phase III Principal Investigators: Same Group Seen at Past Blow-Ups

We also find Veru's selection of Principal Investigators concerning, given their association with multiple past COVID-19 biotech failures. While Veru's newly disclosed US-based Principal Investigators appear at first blush an independent selection, a group of these investigators[5] have also worked for or received funding from at least two additional past COVID-19 biotech stock promotions.

***Phase 3 COVID-19 clinical trial Principal Investigator Listing**

PI	Institution	City, State, Zip/Province	State	Country
Gordon, Michael	Honor Health	Scottsdale, AZ 85258-4548	AZ	USA
Dasgupta, Samaresh	Inspira Medical Center Vineland 1505 W. Sherman Ave ATTN: Pharmacy	Vineland, NJ 08360	NJ	USA
Dawson, M. Scott	Inspira Medical Center Mullica Hill 700 Mullica Hill Road	Mullica Hill, NJ 08062	NJ	USA
Skolnick, Alan	HD Research (Memorial Hermann - Memorial City Medical Center)	Houston, TX 77024	TX	USA
Rafiq, Adnan	HD Research (Memorial Hermann Southeast Hospital & Memorial Hermann Pearland)	Houston, TX 77089	TX	USA

See as per the above, that while Michael Gordon and Alan Skolnick – who are also listed as authors of Veru's *Evidence* publication – work separately at Honor Health and HD Research, respectively, the two authors collaborated on work for RedHill Bioscience (RDHL). RedHill aimed to use its opaginib candidate to treat COVID-19, yet in September 2021, the company's Phase II/III trial failed to meet its primary endpoint. RDHL shares have lost 91% of their value from highs, and the company is currently laying off one-third of its workforce.

Alan Skolnick's coworker at HD Research is Harold Minkowitz, also an author of the RedHill study. In this study's disclosures, Minkowitz also disclosed funding from Veru, InMune Bio (INMB), and Sorrento Therapeutics (SRNE),

[5] Snippet shown; see hyperlink for the full list.

each of which also touted COVID-19 solutions, but have now left shareholders with massive losses.[6] The below table illustrates significant overlap between Veru's US-based Principal Investigators with those who have also received funding, grants/contracts, consulting arrangements, or authorships for other companies touting COVID-19 solutions:

Individual	InMune Bio (INMB)	RedHill (RDHL)	Sorrento (SRNE)	Veru (VERU)
Michael Gordon	NO	YES	NO	YES
Alan Skolnick	NO	YES	NO	YES
Adnan Rafiq	YES	YES	YES	YES
Harold Minkowitz	YES	YES	YES	YES
RESULT	**Shares down 67% from highs.**	**Shares down 91% from highs.**	**Shares down 84% from highs.**	**???**

VERU Made Unexplained Changes in Trial Protocol, Reducing Number of Patients

Finally, Veru's full study protocol also revealed a set of changes in protocol which we think deserve further explanation by the Company:

- On January 9, 2022, "The planned interim analysis was changed from the first 200 patients randomized into the study to the first 150 patients randomized into the study."

- Similarly, on March 18, 2022, "The number of planned subjects was reduced from approximately 300 to approximately 210."

Recall that Veru's independent data monitoring committee halted the Phase III study early after just 150 patients were treated, yet these protocol changes were made prior to these patients having been fully-treated. Yet we wonder why Veru did not prefer a larger study size so as to sufficiently power the study. But instead, it appears to us more that the Company may have been focused more on their ability to issue a promotional headline touting supposed success rather than to ultimately secure FDA approvals. We continue to believe, based on this updated data, that Veru has no hope of obtaining an EUA based on these results, and we are short.

[6] In May 2020, Sorrento Therapeutics was also subject to criticisms by Hindenburg Research.