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## Veru, Inc (VERU): Trials and Errors

We are short Veru, Inc. (“VERU”, “the Company”), a female condom maker now touting a COVID-19 drug we view as another attempted stock pump by a team of alleged frauds and failures. We think the Company’s Phase III trial for sabizabulin (VERU-111) in hospitalized COVID-19 patients – which released results without full data – is plagued by design flaws and compounded by management misdirection, which renders the Company’s application for an FDA Emergency Use Authorization (“EUA”) based on this data a non-starter. Our research further uncovered a historical pattern of alleged sham science, repeated failure, and misrepresentation among VERU’s top ranks:

- VERU’s EVP of Clinical Affairs Robert Getzenberg was previously sued for allegedly faking the development of a prostate cancer test funded by biotech startup Onconome. Getzenberg claimed his test had nearly 100% accuracy, yet researchers attempting to recreate his work found the tests a total sham. The now-settled lawsuit and depositions of Getzenberg’s colleagues lay bare a pattern of Getzenberg having done just about everything one should never do in clinical research: failing to keep accurate records, making false statements, exaggerating statistical associations, throwing out data that didn’t agree with his thesis, breaking the blind on samples, and publishing a sham paper in a urology journal. Getzenberg retracted his associated paper as part of the sealed settlement.
- VERU CEO Mitchell Steiner previously presided over the collapse of GTx, Inc (now ONCT), which over almost two decades failed to launch a single drug. Instead – much like we believe of VERU today – GTx was criticized for poorly designed trials and faced constant FDA rebukes. For example, GTx’s Phase III trial for toremifene in prostate cancer was called out by the FDA for “clinical deficiencies”. GTx’s follow-up trial then also failed. GTx also tested enobosarm – now a VERU-owned asset – for lung cancer. This trial was criticized for disproportionately randomizing patients and only including half of enrolled patients in the efficiency analysis. The subsequent Phase III trial then failed. GTx ruthlessly diluted shareholders to the tune of \$464 million in accumulated deficits, yet we estimate Steiner earned at least \$7.7 million in total compensation and dumped \$12.3 million in stock leading up to his resignation. Shares fell ~90% from their February 2004 IPO through Steiner’s April 2014 resignation.
- Then from 2014 to 2016, Steiner was Head of Urology at OPKO Health, where, in his own words, he “worked closely” with Dr. Phillip Frost, who settled securities fraud charges in 2018 for his alleged role in various pump and dump schemes.

At VERU, Steiner has now reassembled the same executives who presided over GTx’s collapse, including Chief Science Officer K. Gary Barnette, EVP of Clinical Operations Domingo Rodriguez, SVP of Quality Oversight Gary Bird, and EVP of Clinical Affairs Robert Getzenberg.

In April 2022, VERU released Phase III results for (VERU-111) for the treatment of hospitalized COVID-19 patients, claiming a 55% reduction in mortality, from 45% in the placebo group to 20% in the treatment group. However, we think that – much like insiders’ past ventures – VERU’s Phase III trial contains glaring issues, compounded by management misrepresentations:

- VERU’s placebo group mortality rate of 45% fails to pass a sanity check: numerous other studies, as well as real-world data, suggest to us that we ought to expect a placebo group mortality rate of 20-25%. For example, Gilead’s Phase III trial for remdesivir used the same patient population<sup>1</sup> of hospitalized patients

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<sup>1</sup> Trial protocols called for patients on Levels 4, 5, and 6 on the ordinal scale. Level 4 patients are hospitalized, but freely breathing without oxygen, Level 5 patients are on oxygen by mask, Level 6 patients are on oxygen by NIV or high flow.

in levels 4, 5, and 6, yet Gilead reported mortality rates of just 4.8%, 12.7%, and 20.4%, respectively. This suggests to us that VERU's patients ought to be in the same range. Instead, we think VERU's comparably sky-high mortality rate was due to glaring flaws in trial design.

- First, VERU's Phase III trial did not include any requirement that patients be co-administered standards of care including remdesivir, dexamethasone, or IL-6 inhibitors, only that these were "allowed." As such, even though VERU continually suggests that VERU-111 performs well above current standards of care, the trial results don't necessarily suggest any incremental benefit to patients. Given VERU's site selection – with over half of trial sites located in Argentina, Brazil, Bulgaria, Columbia, and Mexico – we doubt that many patients received adequate care.
- The Phase III trial also contained no control or stratification for site nation. We consider this particularly problematic given VERU's site selection. 37 of 57 total sites were outside the US, in: Argentina, Brazil, Mexico, Bulgaria, and Colombia, where standards of care are widely recognized to fall well below those of the US. For example, one site is a small allergy clinic in Brazil, whose own website states it only has a single "procedure room", with no hospital beds pictured. Meanwhile, Bulgaria has the worst life expectancy in the EU.
- VERU management has also made, in our view, blatantly misleading claims about underlying mortality rates. For example, Steiner claimed "by the time you get into the hospital and you're on oxygen, you have a fifty-fifty chance of surviving..." and that "patients in the ICUs and in hospitals...half of them will go on to die anyway." However, VERU's Phase III trial patients were not necessarily in the ICU or on oxygen; they were only hospitalized; and [less than 13%](#) of currently hospitalized COVID-19 patients in the US are in the ICU. As such, Steiner paints the picture that the 45% placebo group mortality rate is due to patients' underlying disease severity, rather than the trial's poor design.
- Finally, VERU's Phase III included just 150 total patients (52 in placebo, 98 in the treatment arm), across 57 sites – less than 1 placebo patient per site. Not only does this make the trial extremely susceptible to influence by just a handful of patients, but in our view makes the prospect of an EUA based on this data a non-starter. In comparison, each of the COVID-19 drug EUAs we've seen granted over the past 2 years has been supported by far larger studies, ranging from 966 participants in Eli Lilly's BLAZE-2 trial to over 10,000 patients in Regeneron's COV-2069 trial.

In our view, these results, continually paraded without full data, seem designed to generate fervor for VERU stock rather than an FDA approval.

VERU reminds us of other failed COVID-19 promotions such as CytoDyn, Humanigen, and Kintor, which touted supposedly robust decreases<sup>2</sup> in mortality rates, only to see collapsing share prices amid regulatory rebukes. In May 2022, we find VERU's promotion a bit long in the tooth.

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<sup>2</sup> In March 2021, CytoDyn reported that leronlimab led to an 82% reduction in 14-day mortality. Humanigen reported that lenzilumab led to a 54% greater likelihood of survival, and Kintor reported that proxalutimide cut mortality risk by 92%.

## We Find VERU's Phase III Trial for COVID-19 Plagued by Design Anomalies and Management Misdirection

In April 2022, the Company announced results from its Phase III COVID-19 study, and management took to touting the Company's EUA prospects based on this data. We think an EUA is a non-starter due to what we view as numerous study anomalies, the study's relatively small size compared to other granted EUAs, and management's continual misrepresentation of the study's context.

### 45% Mortality Rate in Hospitalized Patients Defies Common Sense Sanity Checks

We think VERU's witnessed 55% decrease in mortality rates (from 45% in the placebo group to 20% in the treatment group) is driven in large part by an artificially high placebo mortality rate, which is inexplicably higher than the rate seen in comparable patient populations. Consider for example:

- Gilead's [Phase III study for remdesivir](#) saw placebo group mortality rates of just 4.8% in Level 4 patients, 12.7% in Level 5 patients, and 20.4% in Level 6 patients – the same patient population as VERU's Phase III.
- Humanigen's [Phase III study for lenzilumab](#) saw a rate of just 22.1% of either mortality or progression to mechanical ventilation for hospitalized COVID-19 patients.
- CytoDyn's [Phase III study for leronlimab](#) in severe COVID-19 patients saw a 21.6% mortality rate in the placebo group.
- A [pooled study among 10,815 COVID-19 patients](#) who already had acute respiratory distress syndrome ("ARDS") – i.e., patients already in far worse condition than those merely hospitalized as per VERU's Phase III – saw a 39% mortality rate.

Further consider that in the US, COVID-19 related hospitalizations peaked at 154,540 in early 2022. Rolling 10-day deaths<sup>3</sup> then peaked weeks later at 35,222. This data suggests that at the peak of the "third wave" – which occurred during VERU's Phase 3 trial – hospitalized COVID-19 patients experienced a mortality rate of just 22.8%, again roughly half of the 45% witnessed in the Company's Phase 3 trial.

As such, our view is that VERU's 45% placebo group mortality rate will fail to hold up under a broader sample of hospitalized COVID-19 patients. Indeed, if we consider a normalized placebo mortality rate of 20% to 25% as per the studies above, the difference between VERU's placebo group and treatment group disappears.

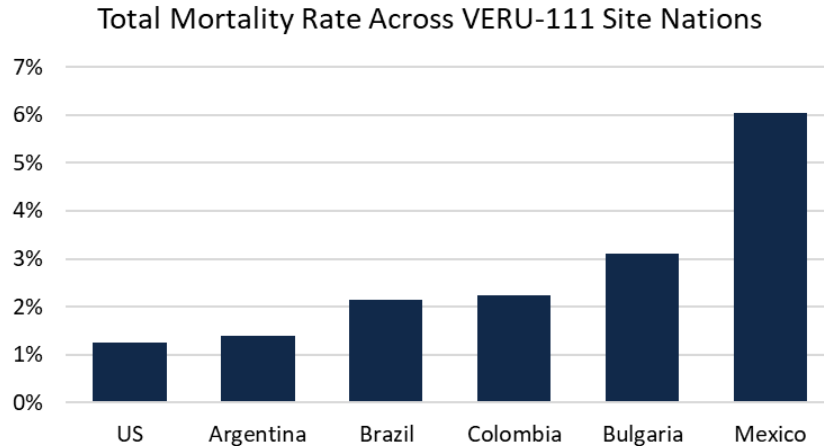
### No Stratification or Control for Site Selection

We think this artificially high mortality rate likely originated from two glaring flaws in VERU's study design, beginning with the Company's site selection and lack of control for such site selection, despite the well-recognized fact that standards of care vary widely across nations. See per the chart below that mortality rates from initial COVID-19 infection vary widely among VERU trial participant locations, with Mexico holding a 5x worse rate than the US, for example:<sup>4</sup>

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<sup>3</sup> We assume that each hospitalized patient spends about 10 days in the hospital.

<sup>4</sup> The Phase III included 20 sites in the US, 15 in Brazil, 9 in Colombia, 5 in Bulgaria, 5 in Argentina, and 3 in Mexico.



VERU’s site selection doesn’t inspire much confidence that these patients were receiving a high standard of care. For example, Bulgaria – which recruited patients at 5 sites – is regarded poorly for its quality of healthcare:

- A [2019 OECD report](#) on Bulgaria’s “State of Health” shows that the nation has the lowest life expectancy in the EU and the highest hospital admission rate in the EU, at double the EU average.
- A [2019 paper](#) surveyed Bulgarian medical specialists and found that the vast majority of them weren’t even aware of the existence of ethics committees in various clinical settings, including research. The paper concluded that “Despite the positive trends seen in some of the responses, the awareness level in regard to the existing ethics committees in the country still remains low and unsatisfactory.”

We are further puzzled by VERU’s [individual site selection](#). For example, see Brazil-based “Clinica de Alergia Martti Antila S/S LTDA”, which appears to be a small allergy clinic run by an allergist and immunologist. Its [website](#) claims the facility has just a single “procedures room” and 6 “medical service offices.” It’s unclear to us if the facility has any hospital beds, as none are pictured on their website:





Given that VERU's placebo group had just 52 patients amid 57 trial sites – less than 1 patient per site – a handful of patients or trial sites are liable to create drastic influences in results.

### Trial Held No Standard of Care Requirements

VERU's Phase III protocol also did not require patients to be co-administered existing standards of care, such as remdesivir, dexamethasone, and IL-6 inhibitors. Instead, protocols only stated that such treatments "are allowed". As a result, our view is that VERU's Phase III doesn't conclusively demonstrate that VERU-111 had any impact above and beyond existing treatments, despite what VERU management continually states.

Given these dynamics, we're not surprised that VERU has yet to publish the full results of the trial. Instead, management has, in our view, made numerous misdirected comments.

### VERU Commentary Then Conflates Disease Severity, ICU Admissions with Hospital Admissions

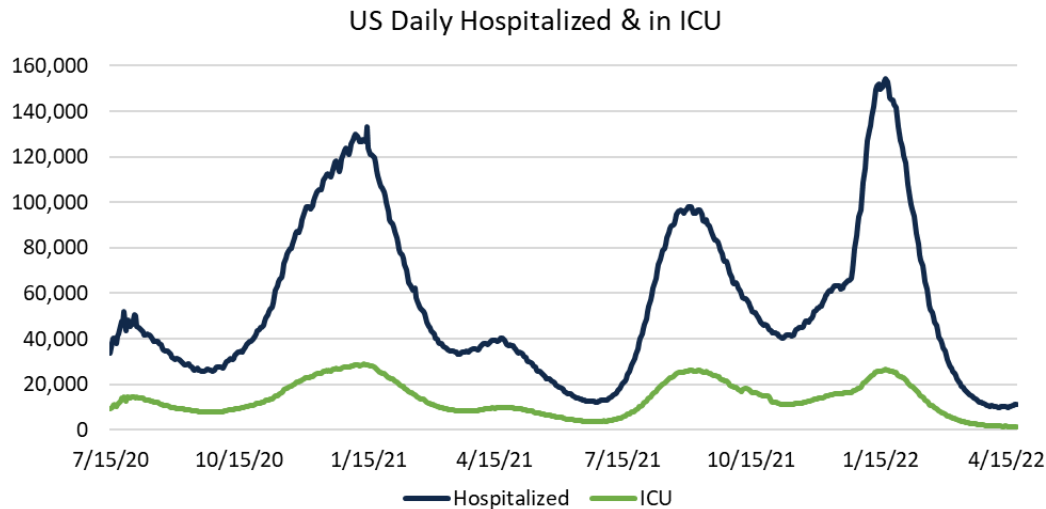
Against this backdrop of what we view as an artificially high mortality rate, VERU CEO Mitch Steiner appears to further the misdirection by making, what we believe to be reckless comments regarding disease severity. For example, Steiner stated that:

"This is [a] reduction in deaths in patients in the ICUs and in hospitals that are requiring tremendous resources to keep them alive. And unfortunately, half of them will go on to die anyway."

"That's scary to think, that by the time you get into the hospital and you're on oxygen, you have a fifty-fifty chance of surviving ... This takes some of the scariness out of going to the hospital."

"The placebo group rate of 45% -- placebo group death rate of 45% underscores how sick these patients really are. The poor outcomes demonstrate the inadequacy of the current standard of care, which could have included dexamethasone, remdesivir and anti-IL-6 receptor antibodies and JAK inhibitors."

However, VERU's Phase III protocol called only for hospitalized patients, not just those on oxygen or in the ICU as suggested by Steiner's comments. As shown below, only a fraction of hospitalized COVID-19 patients are in the ICU in the US<sup>5</sup>:



In our view, these misleading comments from Steiner appear designed to eschew concerns that a 45% mortality rate is in fact a ridiculous claim to make about the broader patient population.

### VERU's Paltry Study Size Renders an EUA a Non-Starter, in Our View

VERU has touted these Phase III results as sufficient to obtain an FDA Emergency Use Authorization, yet we think the above issues, as well as VERU's relatively small sample size, make an EUA a non-starter. See recently granted COVID-19 drug EUAs in the table below. In each case, the studies supporting authorization were conducted with a far higher number of patients than VERU's Phase III:

Date of First EUA	Drug	Sponsor	Trial Title	Participants
2/11/22	Bebtelovimab	Eli Lilly	BLAZE-4	1,634
12/22/21	Paxlovid	Pfizer	EPIC-HR	2,246
12/8/21	Evusheld	AstraZeneca	PROVENT	5,197
6/24/21	Acterna	Genentech	RECOVERY	4,116*
5/26/21	Sotrovimab	GSK	COMET-ICE	1,057
2/9/21	Bamlanivimab and Etesevimab	Eli Lilly	BLAZE-2 Part 1	966
11/21/20	REGEN-COV	Regeneron	COV-2069	10,078
11/19/20	Baricitinib and Remdesivir	Eli Lilly	ACTT-2	1,033

Unlike the pharmaceutical giants who obtained EUAs, VERU reminds us of promotional companies which announced "robust" headlines of large reductions in mortality rates, only to ultimately leave investors holding the bag. For example:

<sup>5</sup> We calculate, based on [data from the IMHE](#) and [the EU's Centre for Disease Prevention and Control](#) that VERU's other host nations hold ICU rates of: 12% in Mexico, 12% in Colombia, 64% in Brazil, 36% in Argentina, and 12% in Bulgaria.

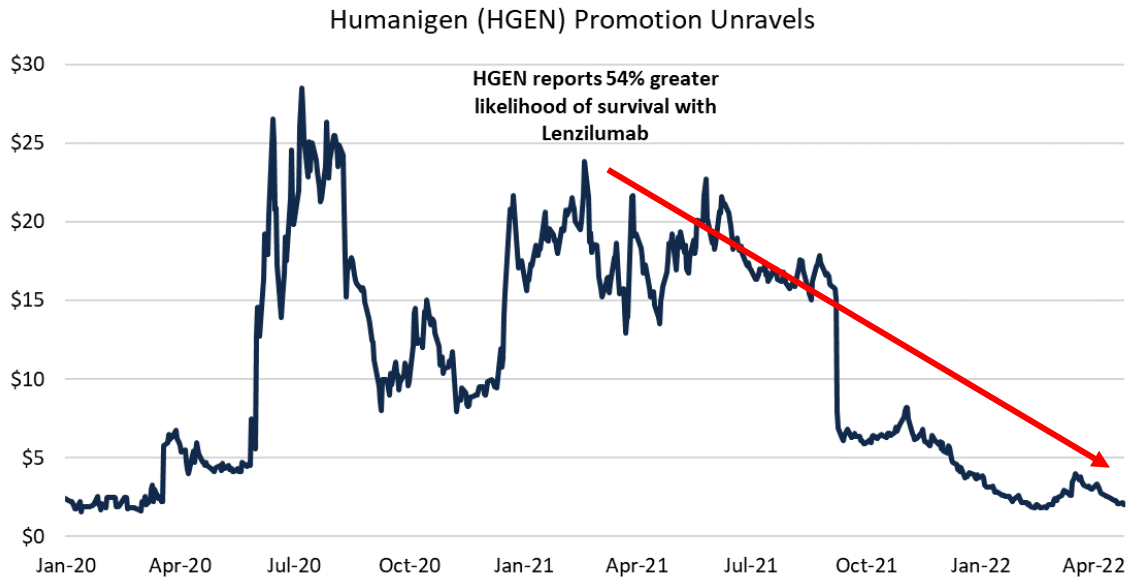
- In March 2021, CytoDyn (CYDY)<sup>6</sup> [announced](#) a statistically significant 82% reduction in 14-day mortality for a subcutaneous injection of Leronlimab (n=62). Nevertheless, 2 months later, the FDA took the extraordinary step of [rebuking CytoDyn](#) and leronlimab for COVID-19 use.
- In March 2021, Humanigen (HGEN) [reported statistically significant results of a 54% greater](#) likelihood of survival with lenzilumab and other treatments as compared to placebo and other treatments.
- In March 2021, [Kintor Pharmaceuticals](#) claimed that its proxalutimide cut mortality risk by 92%. The trial was [later called](#) “among the worst medical ethics violations in Brazil’s history” by Brazil regulators.

As shown below, investors buying these headlines have fared extremely poorly in the following months. We think VERU is set to end in similar fashion.



<sup>6</sup> We first wrote about CytoDyn in February 2020. Shares have declined roughly 80% since then, while the company has received an FDA rebuke, SEC and DOJ investigations, and CEO Nader Pourhassan has resigned. Leronlimab remains unapproved for any indications.





## VERU’s “Dream Team” – Producers of (Allegedly) Fake Research and Stock Collapses

We find these clinical anomalies even more concerning considering that VERU’s insiders were accused of performing fraudulent science, attested to “working closely with” charged security fraudsters, and have received multiple FDA rebukes.

### VERU’s EVP of Medical Affairs Was Previously Accused of Sham Research Over 5+ Years

VERU’s now-EVP of Medical Affairs Robert Getzenberg – who was also with Steiner at GTx – was [sued for allegedly](#) conducting sham research for the development of prostate cancer tests.<sup>7</sup> Steiner’s work was funded by a biotech startup Onconome, which alleged that Getzenberg’s work was “imaginary”, as the nearly-100% accurate cancer tests he claimed to have developed were in reality no better than a coin flip. The suit was settled, and Getzenberg, who had published his work in a urology journal, [retracted](#) the associated paper. We find not only the complaint but the depositions by Getzenberg’s colleagues particularly enlightening, describing allegedly fraudulent research which permeated Getzenberg’s operation:

<sup>7</sup> US District Court for the Western District of Pennsylvania (Case 2:09-cv-01195-AJS)

5. Dr. Getzenberg repeatedly represented to Onconome that the data from his laboratory showed “amazing” results for his immunoassays for prostate and other cancers, and showed the assays were working consistently, reproducible and demonstrated “sensitivities” (meaning few false negatives) and “specificities” (few false positives) approaching 100 percent.

6. But these representations were false. Dr. Getzenberg misrepresented the research results and data from his lab in order to claim these spectacular results. Even in the last year of his research for Onconome, Dr. Getzenberg’s researchers recorded, in laboratory records that Onconome only recently obtained: “the assay didn’t work as expected. . . . Because we don’t have the whole peptide sequence, all of this work may mean nothing”; “Everything has fallen apart. The CV values are very high for almost every sample”; “I’m having to throw out samples”; “Results A) EPCA 2.22 didn’t work.” Notwithstanding the spectacular (and false) results proclaimed by defendants, the Getzenberg assay was no more accurate in distinguishing cancerous tissue from normal tissue than flipping a coin.

7. Despite the many historical assertions to the contrary, the Getzenberg laboratory now admits that their immunoassay worked just once in late 2005, for one run, for one researcher alone, and never worked before or since for either this researcher or anyone else. The laboratory also confirms that this researcher “forgot” to keep hard copy records of this one special run, despite federal law requiring such records. In short, the assay was not and is not real.

Interested readers can find the original complaint, as well as the declaration of Onconome’s attorney and declaration of Onconome’s CEO (which include segments of depositions) [here](#) (Case No.2:09-cv-01195-AJS).

## VERU CEO Mitchell Steiner: Former Colleague of Phil Frost

From 2014 to 2016, VERU CEO Mitchell Steiner was President of Urology at OPKO Health, run by SEC-charged pump-and-dump artist Phil Frost. In Steiner's [own words](#), he "worked closely with Dr. Frost". In 2018, Frost was [charged by the SEC](#) for his alleged role "long-running" market manipulation schemes.<sup>8</sup>

## As CEO of GTX, Steiner Sold Millions Prior to the Stock's Collapse

From 1997 to 2014, Steiner was CEO of GTX, Inc, which continually paraded a series of "promising" trials only for GTX stock to decline more than 90%. We estimate that from 2005 to 2012, Steiner dumped approximately \$12.3 million in GTXI shares, with large sales near the highs:



For example, in February 2006, Steiner and his wife [entered into a 10b5-1 plan](#) which provided for the sale of 500,000 shares. In August 2006, the plan [was terminated](#) with Steiner appearing to have [sold 306,800](#) shares.<sup>9</sup>

In December 2006, Steiner [sold 193,200 shares](#) for proceeds of \$3.5 million after GTX announced [positive Phase II results](#). Just 5 days after this announcement, GTX announced a [\\$60.8 million share offering](#), and Steiner dumped [another 193,000 shares at \\$18.20](#) for proceeds of \$3.5 million.

In February 2007, Steiner transferred 400,000 shares from LD, Jr., LLC, which controlled the majority of his GTX holdings, to an account jointly controlled by his wife. GTXI held its Q4 2006 conference call that very same day, wherein Steiner told analysts that "the next 12 months should be transformational for GTX." Just 3 weeks later, this jointly controlled account [sold 200,000 shares](#) for proceeds of another \$4.4 million. Steiner nearly top-ticked this sale; a few weeks later, GTXI began its ~90% decline over the following 7 years until Steiner's resignation.

<sup>8</sup> Frost and OPKO settled the suits, paying \$5.5 million to the SEC, and Frost was permanently barred from participating in penny stock offerings.

<sup>9</sup> The filing shows 193,200 shares remaining in the joint account.

### Steiner Has Reassembled the GTx “Dream Team” at VERU

Despite GTx having ended in shambles for shareholders, we find that the team has reassembled at VERU where the Company is touting enobosarm once again.

Individual	Role at GTx	Role at VERU
Mitchell Steiner	Chief Executive Officer (Sept 1997 to Apr 2014)	Chief Executive Officer (Oct 2016 to Present)
Gary Barnette	VP, Clinical Development Strategy (2001 to 2012)	Chief Scientific Officer (Sept 2018 to Present)
Gary Bird	VP, Quality Assurance (Oct 2003 to Sept 2013)	SVP, Quality Oversight (Oct 2020 to Present)
Robert Getzenberg	Area Lead, Prostate Cancer (Jul 2012 to Apr 2017)	EVP, Medical Affairs (Apr 2017 to Present)
Domingo Rodriguez	VP, Clinical Operations (Nov 2004 to Nov 2013)	EVP, Clinical Operations (Apr 2018 to Present)

The University of Tennessee Research Foundation (“UTRF”) first licensed the rights to enobosarm to GTx in 1997, and over the course of over 2 decades, enobosarm failed to be proven out in any GTx clinical trials. GTx then [unsuccessfully tried to sublicense enobosarm](#), as apparently no one wanted it. GTx then abandoned the drug in late 2019 and terminated its agreement with UTRF in March 2020.

In December 2020, [VERU licensed enobosarm](#) just months after the drug candidate was dropped by GTx.

We find it telling that in February 2022, VERU decided to suspend further development of the sabizabulin and enobosarm combination in triple-negative breast cancer (“TNBC”). VERU said the decision was based on prioritization of other programs rather than a lack of belief in the opportunity. We think enobosarm is a worthless drug candidate merely being recycled by VERU to promote itself with a “new” story, yet we already know how this story ends.

### GTX Was Also Criticized for Poor Trial Design

We also find GTx’s legacy instructive as the company was not only criticized for enobosarm’s trial failures, but for poor trial designs, which we again see at VERU today. For example, from 2007 to 2008, GTx conducted a Phase IIb trial of enobosarm for muscle loss in non-small cell lung cancer patients. However, the full results, which weren’t published until April 2013, faced skepticism for a trial design which appeared to favor enobosarm over placebo at the outset. Among other issues, [critics highlighted](#) biased randomization, using mean values rather than median values (as is more common), and inclusion of only a fraction of patients in the efficacy analysis.

Nevertheless, GTx marched onto Phase III trials, obtained an FDA fast-track [designation](#), and continued to parade promotional press releases. However, in August 2013, GTx [disclosed](#) the Phase III trial ultimately failed, and its stock fell over 60% in a single day. GTx then laid off half of its employees and Steiner resigned in April 2014.

### Vice Chairman Fisch Employs His Son as EVP of Investor Relations

For his part, VERU's Vice Chairman Harry Fisch also moonlights as a "Medical Advisor" to the Dr. Oz Show – the same show which has: [faced lawsuits](#) for alleging that imported olive oil is fake, promoted the use of [colloidal silver](#) – a possible health hazard, falsely [claimed that apple juice](#) contains dangerous levels of arsenic, and promoted hucksters such as Lindsey Duncan, [charged by the FTC](#) for promoting false weight-loss benefits of green bean coffee extract.

Harry Fisch's son Samuel Fisch – who graduated from Elon University in 2018 and has less than 1 year of outside business experience – [is VERU's Executive Director of Investor Relations](#). VERU fails to disclose this relationship as a related party relationship in its filings, nor does the Company disclose Fisch's pay as is common practice.

At \$11.72 per share and 80.1 million shares outstanding, VERU holds a market cap of \$938 million. However, the Company also holds 12.7 million options with an exercise price of \$3.79. We thus estimate a fully diluted market cap at \$1.1 billion, and an enterprise value at \$923 million. VERU burns cash, and we view the Company's two highly touted assets in VERU-111 and enobosarm as effectively worthless.

