



Disclaimer

By downloading from or viewing material on this website you agree to the following Terms of Service. Use of Culper Research's ("Culper") research is at your own risk. In no event should Culper or any affiliated party be liable for any direct or indirect trading losses caused by any information on this site. You further agree to do your own research and due diligence, consult your own financial, legal, and tax advisors before making any investment decision with respect to transacting in any securities covered herein. You should assume that Culper (possibly along with or through our members, partners, affiliates, employees, and/or consultants) along with our clients and/or investors has a position in any securities covered herein. Following publication of any research, we intend to continue transacting in the securities covered herein, and we may be long, short, or neutral at any time hereafter regardless of our initial recommendation, conclusions, or opinions. Research is not investment advice nor a recommendation or solicitation to buy securities. To the best of our ability and belief, all information contained herein is accurate and reliable, and has been obtained from public sources we believe to be accurate and reliable, and who are not insiders or connected persons of the securities covered herein or who may otherwise owe any fiduciary duty or duty of confidentiality to the issuer. However, such information is presented "as is," without warranty of any kind – whether express or implied. Culper makes no representation, express or implied, as to the accuracy, timeliness, or completeness of any such information or with regard to the results to be obtained from its use. Research may contain forward-looking statements, estimates, projections, and opinions with respect to among other things, certain accounting, legal, and regulatory issues the issuer faces and the potential impact of those issues on its future business, financial condition and results of operations, as well as more generally, the issuer's anticipated operating performance, access to capital markets, market conditions, assets and liabilities. Such statements, estimates, projections and opinions may prove to be substantially inaccurate and are inherently subject to significant risks and uncertainties beyond Culper's control. All expressions of opinion are subject to change without notice, and Culper does not undertake to update or supplement this report or any of the information contained herein. You agree that the information on this website is copyrighted, and you therefore agree not to distribute this information (whether the downloaded file, copies / images / reproductions, or the link to these files) in any manner other than by providing the following link — <http://www.culperresearch.com> The failure of Culper to exercise or enforce any right or provision of these Terms of Service shall not constitute a waiver of this right or provision. If any provision of these Terms of Service is found by a court of competent jurisdiction to be invalid, the parties nevertheless agree that the court should endeavor to give effect to the parties' intentions as reflected in the provision and rule that the other provisions of these Terms of Service remain in full force and effect, in particular as to this governing law and jurisdiction provision. You agree that regardless of any statute or law to the contrary, any claim or cause of action arising out of or related to use of this website or the material herein must be filed within one (1) year after such claim or cause of action arose or be forever barred.

CytoDyn (CYDY): Where the Drugs are as Convincing as the Dreamcatchers

“Dreams feel real while we're in them. It's only when we wake up that we realize something was actually strange.”

Dominick Cobb, *Inception*

We believe CytoDyn (“CYDY”, “the Company”) is an \$860 million enterprise value stock promotion kept alive by CEO Nader Pourhassan, a two-time felon who has moved on from selling falsely labeled Native American dreamcatchers to selling grossly inflated CytoDyn shares to unsuspecting minority shareholders.

We believe CytoDyn is a press release machine that exists to grossly overstate the clinical potential of its sole drug, PRO 140, in every way possible. From HIV, to cancer, to coronavirus, we’ve found that Pourhassan has alternated between demonstrable falsehoods and misleading innuendo regarding PRO 140 for years. Meanwhile, the Chief Medical Officer was fired in August 2019 and sued the Company, alleging dangerous trial design practices, abuse of authority, and concerns regarding Pourhassan’s pathologically false statements to investors and regulators alike. On the back of these statements, CytoDyn has conducted numerous predatory capital raises, putting cheap equity in the hands of insiders and their cronies, while making a mockery of the Company’s responsibilities to common shareholders. Moreover, this has created a shadow valuation of the Company that is much higher than the basic market capitalization.

However, we reckon that Pourhassan’s back is now pressed firmly against the wall in trying to keep this scheme alive. The Company has burned \$46 million of cash in the LTM and SEC filings disclose that it has not even paid its bills on time. Even after CytoDyn’s near-incessant equity raises over the past two months, culminating in a sizable \$7.6 million financing, we estimate the Company has just 38 days before running out of cash. We are short CytoDyn and believe shares are worthless.

Numerous other questions swirl around the business: a criminally linked commercialization partner currently being sued by the federal government; a virtually no-name auditor whose next largest public account has a \$38 million market capitalization; a previously fined, suspended, and bankrupt bookrunner; and a suspect entity participating in the Company’s heavily discounted private placements.

Through the course of our research, we engaged 6 experts in the fields CytoDyn claims to be revolutionizing: (1) a 30+ year physician and 10+ year practicing oncologist and founder of a community-based practice; (2) a 25+ year director of the HIV program at one of the world's leading medical centers; (3) a 15+ year practicing infectious diseases physician and professor; (4) a 10+ year practicing infectious diseases physician; (5) a breast cancer director at a leading cancer research organization with 10+ years of experience; and (6) a 20+ year surgical breast cancer oncologist at one of the world's leading cancer centers. We occasionally cite their commentary.

The Chief Promotion Officer: Nader Pourhassan

In addition to having zero pharma experience, Pourhassan’s criminal history is a unique one. Pourhassan declared personal bankruptcy – twice – was convicted of a third-degree felony of theft by deception, a felony domestic violence court order violation, and was charged by federal prosecutors for allegedly claiming that his handmade dreamcatchers were in fact made by Native Americans. They were not.

Pourhassan then took up the CytoDyn CEO role in September 2012. In October 2012, CytoDyn acquired its now key asset, PRO 140, for \$3.5 million in upfront payments, agreeing to licensing fees of 5% of any future sales. Since 2012, CytoDyn has paid Pourhassan a total of \$7,919,979 for his services, which we find have primarily been in promoting CytoDyn stock. Despite over 7 years of supposedly groundbreaking clinical efforts, the Company has yet to obtain a single FDA-approved indication for PRO 140.

Nevertheless, CytoDyn's website boasts that, "To advance the drug development of Leronlimab, Dr. Pourhassan raised capital for CytoDyn of approximately \$200 million over the last 5 years." We believe much of this capital has been – and, unless investors act, will continue to be – raised under a set of highly questionable premises across the Company's winding promotions of HIV, cancer, and most recently, coronavirus.

The Promotion Du Jour: Coronavirus

On January 28, 2020, the Company announced it would explore PRO 140 to combat coronavirus. The press release was notably absent of named partners, steps the Company had taken to study PRO 140's potential in coronavirus, or any other indication that this was anything more than a puff release reminiscent of the bitcoin era's Long Island Blockchain. Indeed, PRO 140 is an entry/fusion inhibitor that works on the CCR5 receptor, while the most recent coronavirus studies, on the other hand, indicate that the virus infects via the ACE2 receptor. Thus, CytoDyn's press release is akin to showing up at a house fire and volunteering a fruit cake as an extinguisher; no one needed it before, and it certainly won't help the current situation. Coincidentally, on February 4, 2020, the SEC [issued](#) an Investor Alert "to warn investors about investment frauds involving claims that a company's products or services will be used to help stop the coronavirus outbreak."

The Pivotal Promotion: Cancer

Over the past several months, CytoDyn has barraged investors with press releases pertaining to its Phase 1b/2 breast cancer trial, most recently characterizing interim results as "stunning." However, we find the trial design, interim results, and the Company's associated claims regarding this data to be highly questionable.

The trial has enrolled just three patients who have been inexplicably been diagnosed with two distinct cancers: mTNBC and HER2+. In addition to the absurdly small sample size, per the opinion of one physician we engaged, such a design "is comparing apples to oranges ... there's no reason to design a trial this way unless you're just wanting to show investors something positive." Moreover, one of the patients is highly conflicted, as she is Pourhassan's own mother-in-law.

Reported interim results, in our opinion, also fail to withstand even a modicum of scrutiny. CytoDyn frequently cites circulating tumor cells (CTCs) as an indicator of PRO 140's efficiency, as Pourhassan himself unashamedly stated on Proactive Investors just last week: "CTCs: that's what kills people." Put plainly, we believe this is a gross mischaracterization of the nature of cancer itself, which becomes deadly not with the presence of CTCs, but when tumors interfere and overtake the normal functioning of the body's organs. As one physician put it to us bluntly, "having no detectable circulating tumor cells doesn't mean anything" and "there's nothing here at all to convince anybody that the drug has efficacy in breast cancer." Similarly, the Company reports tumor shrinkage, yet this is also unindicative of patient improvement or ultimate survival. Per one physician, "I can't make any sort of therapeutic judgement [based on reported tumor shrinkage]." All that said, in addition to PRO 140, patients received standard therapy: the mTNBC patient received carboplatin, one of the most widely recognized chemotherapy drugs in the world, while the HER2+ patient also received radiation therapy. As such, it is extremely

difficult to attribute the patients' supposed improvements to PRO 140 without relying on the hearsay of the Company's highly conflicted Key Opinion Leaders.

Nevertheless, akin to his characterization of CTCs, Pourhassan continues to make statements regarding PRO 140 that, in our view, lack grounding in clinical reality. In a January 2020 interview, Pourhassan said, "It looks like Leronlimab could have 32 different indications, and thank God we filed for triple negative breast cancer protocol, because now it seems that we're saving people's lives and this is going to be a very powerful agent." The reality is that the drug has never been proven to save lives, let alone demonstrate effectiveness in breast cancer or any other cancer.

Moreover, this same line of reasoning was used as a justification for Pourhassan's January 31, 2020 claim that "our regulatory team is reaching out to the FDA to organize an emergency Type C meeting to discuss the data evidenced in our clinical trials." Despite the sly wording on the Company's part, the FDA does not hold "emergency type C meetings", only "type C" meetings. Moreover, we find the Company's flippant language – specifically, that "it is reaching out" to the FDA – to be questionable, as the FDA's draft guidance denotes that the request itself contains of 11 separate parts.

Finally, Pourhassan stated of this hypothetical future meeting that, "I'm hoping that the FDA will immediately allow this product to be approved on a breakthrough designation status, do a phase 4, and let everybody come in and as soon as everybody is getting the product, the data can be accumulated more for support." Given that CytoDyn's only claim to PRO 140's efficacy in breast cancer is based on 4 months of highly conflicted data in just 3 patients, we believe the probability of breakthrough FDA approval to be extremely improbable, to be kind. Not only do these statements create a false sense of progress ("Stunning Data", "Emergency Type C Meetings", "Breakthrough Approvals", Oh My!), but the Company's actions instead demonstrate a muddled and incoherent approach to pursuing a cancer indication.

First, in March 2018, the Company issued a [press release](#) stating that "CytoDyn Form[ed a] Scientific Advisory Board to Advance PRO 140 Development in Immunological Disorders." The press release contained names of 6 individuals on the board. However, an August 2019 lawsuit filed against the Company by former Chief Medical Officer Dr. Richard Pestell alleges that this board was never in fact formed. We searched publicly available biographies of the individuals named in the press release, but found zero public affiliations with CytoDyn's supposed Scientific Advisory Board. Second, the same complaint also alleges that the Company cancelled its statements of work for preclinical trials with its oncology research laboratory, which were "essential for the development of the Company's programs in oncology and cancer metastasis." Finally, in connection with the above, CytoDyn's Chief Medical Officer, who one board member characterized as the Company's "only claim to expertise in cancer", left the Company last summer.

The Original Promotion: HIV and the Most Successful Drug that Never Was

In a series of statements from at least June 2018 to the present, the Company has continuously claimed to be on the verge of obtaining a BLA (biologics license application) for HIV combination therapy. For example, in June 2018, the Company claimed that, "Our BLA filings may start as early as the end of 2018", while in February 2019, Pourhassan definitively stated, "Our BLA will be submitted in second quarter." Pourhassan again stated on January 22, 2020, that "in 9 days we should be able to file the clinical section of the BLA." This again came and went without results. With respect to the BLA filing itself, we conclude that either Pourhassan is highly deluded, or that these statements were intentionally false and misleading. Neither solution should be particularly comforting for CytoDyn investors.

Moreover, we believe investors may be confused as to the overall BLA process, especially given Pourhassan's comments. The [median time](#) from BLA **filing** to BLA **approval** is 8 to 10 months under priority or standard review, respectively. As such, the data suggests that even if CytoDyn were to complete its **BLA filing** in full tomorrow, the Company would be hard-pressed to obtain a **BLA approval** prior to year-end 2020. We believe this delay is a function of both the Company's feeble clinical package and its shoddy management.

In concert with the BLA approval required prior to the sale of any biologics (i.e., PRO 140 injections), the Company has also put forward an aggressive commercialization timeline. For example, in [October 2015](#), Pourhassan claimed that "we [PRO 140] could be commercialized in the first half of 2017." More recently, Pourhassan claimed in an April 2019 Proactive Investors interview that, **"We will be having revenue by the end of first quarter of 2020. Imagine having close to half a billion dollar worth of sales hopefully in 2020. That just transforms this Company."**

On December 17, 2019, the Company announced a commercialization agreement with Vyera Pharmaceuticals – the former company of now-jailed securities fraudster Martin Shkreli. In short, we view this as a co-promotion, as Vyera's "investment", in the form of cheap warrants, paid off when CytoDyn shares rallied on the news. However, STAT+ reports that Vyera's sales are falling rapidly, while it is burning cash, and on January 20, 2020, the company was indicted by the FTC and the NY Attorney General, thus placing any theoretical future commercialization plans into jeopardy.

Finally, despite the Company's continued inability to commercialize PRO 140 in HIV, our view is that even in a "Dream State" wherein CytoDyn were to penetrate 20% of the entire HIV combination therapy market – disregarding the multiple competitors with commercialized products and/or bigger pockets in the process – the Company would generate just \$59 million in run-rate revenues. This is, of course, a far cry from Pourhassan's claim to generate "half a billion dollar worth of sales hopefully in 2020."

The Minority Shareholder Con and Current Solvency Crisis

In a January 23, 2020 Proactive Investors video, Pourhassan claims that during the week of January 13, 2020, he met with 18 different investors, at least some of whom discussed the potential of a debt financing. We cannot confirm nor deny that these meetings actually happened, yet Pourhassan stated, "I believe we are going to get quite a bit of term sheets to try to get \$40 to \$50 million of non-dilutive financing. This is something we always promised the shareholders and now we are able to hopefully able to deliver in the next few weeks."

We remain dumbfounded as to why CytoDyn would consider the addition of \$40-50 million of debt to its already bloated balance sheet to be a positive development. Nevertheless, despite the potential for "quite a bit of term sheets," just 2 weeks later on January 31, 2020, the Company announced a highly dilutive equity raise in which insiders received discounted stock at the expense of minority shareholders, merely the latest in CytoDyn's long running scheme.

Even given recent highly dilutive, insider-enriching financings, we estimate the Company has less than 2 months before it again runs out of cash. Over the past 3 years, share count has more than tripled, while additional warrants and convertible securities have created a shadow enterprise value of \$860 million, far greater than the \$642 million basic market capitalization. We believe this absurd valuation is set to unwind as investors wise up to the Company's history of gross exaggerations, mistreatment of minority shareholders, and current solvency crisis. We are short CytoDyn and believe shares are worthless.

CytoDyn, Chief Promotion Officer Nader Z. Pourhassan, and PRO 140

CytoDyn was formed in May 2002 under the name RexRay Corporation and reincorporated in August 2015. Based in Vancouver, Washington, the Company's key asset is PRO 140, also known as Leronlimab. PRO 140's pre-clinical and clinical development began with Progenics Pharmaceuticals, Inc. in 2011.

In [September 2012](#), Nader Z. Pourhassan became the CEO of CytoDyn. Pourhassan has a Ph.D., but the degree is in Mechanical Engineering; we were unable to find any drug development experience, or in fact any medical or pharmaceutical experience whatsoever prior to his involvement with CytoDyn. The only academic / clinical paper we were able to with Pourhassan's name on it was his Ph.D. [thesis](#) on the mechanics of jets, a topic well outside the realm of drug development, cancer, or infectious diseases. Pourhassan's additional non-biotech experience includes authoring three books, [per](#) the Company. Apparently CytoDyn finds this noteworthy, as it's featured prominently on the Company's website. We were only able to find two of them, entitled "[The Corruption of Moslem Minds](#)" and "[God's Scripture: A Faithful Comparison -- What Jews, Christians, and Muslims Must Know.](#)"

In 1986, Pourhassan was convicted of a third-degree felony of theft by deception and placed on one-year probation. In 1991, Pourhassan filed for Chapter 7 bankruptcy in Salt Lake City, Utah (case: 91-24348). In 2001, Pourhassan again filed for Chapter 7 bankruptcy in Portland, Oregon (case: 01-36712-elp7). 2001 was a busy year for Pourhassan, as he was also charged by federal prosecutors who alleged violations of the Indian Arts and Craft Act after Pourhassan falsely claimed – for four years – that his own handmade dreamcatchers were in fact made by Native Americans. Finally, in 2006, Pourhassan was convicted of a felony domestic violence court order violation. He performed community service, paid a fine, served 24 months of probation, and was ordered to comply with the protection order (Superior Court of Washington Clark County case: 204227D).

Our kudos go out to Pourhassan for managing through the 2010's without another charge or personal bankruptcy. Instead, Pourhassan has been busy running the CytoDyn promotion machine.

In [October 2012](#), just one month after Pourhassan took up the CEO position, CytoDyn acquired PRO 140 for an up-front payment of \$3.5 million, \$1.5 million upon commencement of a Phase III clinical trial, \$5.0 million on approval, and 5% royalty payments upon commercialization. This nominal acquisition underpins the Company's entire promotion and its resulting \$860 million enterprise valuation. Since 2012, CytoDyn has paid Pourhassan a total of \$7,919,979 for his services:

Fiscal Year	2012	2013	2014	2015	2016	2017	2018	2019	TOTAL
Total Comp (\$000s)	\$1,094	\$808	\$448	\$615	\$1,324	\$1,143	\$967	\$1,521	\$7,920

While such a sum would suggest that Pourhassan has executed brilliantly on PRO 140's development, we are left flummoxed as, despite numerous claims [such as](#) the one in October 2015 that, "We could be commercialized in the first half of 2017," CytoDyn has yet to sell a single dose of PRO 140, let alone secure FDA approval in a single indication. Instead, Pourhassan has been on a rigorous promotion tour; the Company's own website boasts that, "To advance the drug development of Leronlimab, Dr. Pourhassan raised capital for CytoDyn of approximately \$200 million over the last 5 years", while Pourhassan's time appears to be spent at such venerable outfits as "[Proactive Investors](#)", which [indicates that](#) it "receives from said issuer annual aggregate cash compensation in an amount equal to Twenty Five Thousand dollars (\$25,000)."



CytoDyn Inc. (OTMKT: CYDY)
Proactive • Updated 5 days ago

CytoDyn reports early but strong clinical responses for two patients • 6:10
20-001 CytoDyn Inc Short • 0:51

VIEW FULL PLAYLIST (66 VIDEOS)

In some cases, Pourhassen has even broadcasted from what appears to be a living room sofa:



In addition to Proactive Investors, Pourhassen has also made appearances on:

[WallStreetReporter](#): January 7, 2019

[American Medicine Today](#), November 7, 2019

[CEORoadshow](#): November 21, 2019

[MoneyTV](#) with Donald Baillargeon: January 10, 2020. Note that Pourhassen introduces CytoDyn with, “this company has a product that could be the next Humira.” For those unfamiliar, Humira generated \$20 billion of revenues in 2018. CytoDyn has yet to receive a single indication through Pourhassen’s 7+ years with the Company.

[Most recently](#), Pourhassen took to the “NEXT SUPER STOCK Live” conference on January 23, 2020.

Moreover, since May 13, 2019, the Company has issued a remarkable 50 press releases, or a press release every 5.2 calendar days. Indeed, it appears that **Pourhassen’s increasing diligence to his role as Chief Promotion Officer has coincided with CytoDyn’s increasingly desperate solvency situation, as the Company had just \$409,452 in cash on the as of Q3 2019, equivalent to just 5 days of cash burn at the Q3 rate.** The scope of this promotion has shifted from breast cancer to the Coronavirus, and back to breast cancer again. We begin with Coronavirus.

The Promotion Du Jour: Coronavirus

On January 28, 2020, the Company took a page from the bitcoin era playbook of Long Island Blockchain and Kodak Coin, announcing it would explore Leronlimab to combat Coronavirus. Per Pourhassan's comment:

"We support efforts to identify new and potential treatments to limit the spread of the 2019-nCoV, which is affecting people on a global scale at an accelerating rate. We look forward to advancing discussions with potential partners to study leronlimab as a treatment option for this deadly virus."

This is what the announcement **did not** indicate: there was no sign that the Company had formed a partnership with any entities actively fighting Coronavirus, or even that it would extend its own resources to explore PRO 140's potential in fighting Coronavirus. The release only offered the limp hope that CytoDyn would "look forward to advancing discussions with potential partners." One 30+ year practicing oncologist offered sarcastically that when he read the press release, he thought it was "very interesting, to be blunt." We believe this goes a considerable step further; namely, that the press release was a blatant stock promotion tactic.

We suspect that this abject lack of substance provided by the Company reinforces the notion that PRO 140 is highly unlikely to be effective in the prevention or treatment of Coronavirus. The prevailing evidence to date regarding coronavirus suggests that it infects patients via the enzyme-2 (ACE2) receptor. This link was discovered when a team in Wuhan [isolated](#) the virus, backed by additional work published by the [American Society for Microbiology](#) and [The Lancet](#). We checked with a 15+ year practicing infectious disease physician, who confirmed this mechanistic understanding of coronavirus.

As such, since PRO 140 acts on CCR5, rather than ACE2, it would be found ineffective. In the very act of making this statement, the Company hoisted itself by its own petard, demonstrating just how absurd this promotion has become. Coincidentally, on February 4, 2020, the SEC [issued](#) an Investor Alert "to warn investors about investment frauds involving claims that a company's products or services will be used to help stop the coronavirus outbreak."

The Pivotal Promotion: Cancer

Amid the Coronavirus promotion, the Company has been promoting PRO 140 for potential treatment of CCR5-positive metastatic triple-negative breast cancer (TNBC). In May 2019, the FDA granted a fast-track designation to PRO 140 for TNBC, and the Company has ceaselessly touted its breast cancer efforts ever since. Note that we restricted the press releases to only those concerning cancer:

Date & Time	Press Release
Aug 02, 2019 6:00am EDT	CytoDyn Sponsored Research Reaffirms the Role of CCR5 in Cancer Biology and Provides a New Potent
Aug 06, 2019 6:00am EDT	Patient Treated with Leronlimab (PRO 140) for Metastatic Triple-Negative Breast Cancer under Emerge
Aug 08, 2019 6:00am EDT	CytoDyn Files a Phase 2 Protocol with the FDA for Leronlimab (PRO 140) and Regorafenib as a Combin
Sep 09, 2019 6:00am EDT	CytoDyn Announces FDA Clearance to Proceed with Phase 2 Study of Leronlimab (PRO 140) and Regor
Sep 27, 2019 10:30pm EDT	CytoDyn Treats First Patient in Phase 1b/2 Clinical Trial with Leronlimab (PRO 140) for Patients with Tr
Nov 11, 2019 8:02pm EST	First Patient in CytoDyn's Triple-Negative Metastatic Breast Cancer Trial Shows Significant Reduction in
Nov 12, 2019 10:14pm EST	CytoDyn Receives IRB Approval To Proceed With Compassionate Use Of Leronlimab For Patients With
Nov 19, 2019 6:00am EST	CytoDyn's Lead Product Candidate Leronlimab (PRO 140) Inhibits Colon Carcinoma Metastases to Liver
Dec 03, 2019 8:00am EST	CytoDyn Reports Early Results from First Patient in its Phase 1b/2 CCR5+ Metastatic Triple-Negative Br
Dec 23, 2019 6:00am EST	CytoDyn Reports Early, But Strong Positive Clinical Responses for Two Patients, One in Metastatic Brea
Jan 13, 2020 5:00am EST	CytoDyn Files for Breakthrough Therapy Designation with the FDA for the Use of Leronlimab for the Tr
Jan 22, 2020 5:00am EST	Impressive Results Continue from CytoDyn's Clinical Trials Evaluating Two Patients with Leronlimab, O
Jan 31, 2020 6:00am EST	CytoDyn Announces Stunning Results from Clinical Trials Evaluating mTNBC and MBC with Leronlimab

In analyzing the releases, we uncovered a multitude of ways in which investors could be significantly misled, both by what was said and what was left unsaid. These concerns can be broadly grouped into two buckets: (1) trial design and (2) interpretation of results and associated commentary. Investors ought to keep in mind that CytoDyn's track record in fulfilling Company-stated clinical and regulatory expectations is abysmal.

Trial Design

- (1) The Company has recruited all of three patients to undergo treatment. Needless to say, this sample size makes it extremely difficult to draw conclusions regarding broad populations. Per a physician at one of the leading cancer research organizations in the US, "I would definitely not rely on three patients ... Statistically, there's not enough power to say whether or not this is beneficial over placebo or standard patient therapy."
- (2) Moreover, while one of the patients has in fact been diagnosed with stage IV triple-negative breast cancer, the second patient was diagnosed with HER2+, which is entirely different. Per one 30+ year physician and practicing oncologist we engaged, "this is comparing apples to oranges."
- (3) We suspect that the rationale for the HER2+ patient's inclusion stems from the fact that the patient is Pourhassan's mother-in-law, as he [freely admits](#). Agnostic of Pourhassan's potential benevolence, the inclusion is an obvious conflict of interest, which we understand the FDA would tend to look unfavorably upon. The same oncologist expressed his view that **if the Company were serious about obtaining a breast cancer indication for Leronlimab, they wouldn't have proceeded in this manner**. Another physician at a leading cancer institution noted optimistically that, "I would hope the CEO would be honest in reporting what the outcomes are. If we could see some images, that would be helpful."
- (4) Further on the topic of conflicts of interest, the Company employs two Key Opinion Leaders who frequently offer commentary on the Company's efforts in breast cancer. The first is Bruce Patterson, CEO of IncellDx. In December 2018, IncellDx also [partnered](#) with Zomedica (Ticker: ZOM), a development-stage, zero revenue pharmaceutical company. Since the announcement, ZOM shares have fallen over 80% and trade at a valuation of just \$20 million today, which hardly inspires confidence in Patterson's partner

selection criteria. The Company's second KOL is Dennis Burger, who was CytoDyn's Chief Science Officer from January 2016 to July 2018.

Interpretation of Results

- (1) Throughout the Company's numerous press releases, it frequently touts circulating tumor cell (CTC) levels as implicit proof of efficacy. For example, in the most recent January 31, 2020 release:

"New data from the first patient enrolled in the Company's mTNBC Phase 1b/2 trial showed no detectable levels of circulating tumor cells (CTC) with leronlimab in combination with carboplatin at 16 weeks of treatment."

Then, Pourhassan stated in a February 1, 2020 interview that, "CTC, that's what kills people." We find this to be a gross mischaracterization. In the vast majority of cases, cancer kills after tumors become metastatic, interfere with, and overtake the normal functioning of the body's organs. Not only are circulating tumor cells not the "killer", as Pourhassan portends, but our conversations with practicing oncologists affirm that changes in CTCs are not necessarily even indicative of underlying efficacy or patient improvement. As one oncologist put it to us bluntly, **"no detectable circulating tumor cells doesn't mean anything" and "there's nothing here at all to convince anybody that the drug has efficacy in breast cancer."** Per a second oncologist, "[regarding] the diminishment [in CTCs], I haven't seen any data to suggest that diminishing CTC's improves function" and in response to Pourhassan's claim that, "CTC, that's what kills people", he stated that, "I would be a little skeptical of that statement ... It's the complete metastatic process that is typically fatal to the patient."

In the same February 1 interview, Pourhassan also claimed that "Our product has 4 different mechanism of action [sic] on tumors." This is the first we've heard such a claim, and is highly perplexing given that PRO 140 has been long classified merely as a CCR5 inhibitor. Unsurprisingly, Pourhassan declined to name the 3 other supposed mechanisms of action.

- (2) Similarly, the Company's reports of tumor shrinkage, or even "disappearance" do not imply a clinical or practical improvement in the patient. Per the same physician, "50% shrinkage makes for solid PR, but it may not necessarily improve survival or functionality."
- (3) Notwithstanding (1) and (2), these results lose legitimacy, in our view, when considering that the trial included 2 treatment-naïve patients, who then received well-proven and effective treatments in addition to PRO 140. One patient who was diagnosed with TNBC – concurrent to his PRO 140 treatment, was taking carboplatin, a chemotherapy drug, that [per the WHO](#), is one of the most safe and effective medicines in the world. As such, we are left unsure as to whether the changes observed are due to the existing, well-proven drug, or to PRO 140.

Similarly, the Company's January 31, 2020 press release indicates that the second HER2+ patient – Pourhassan's mother-in-law – has been on radiation therapy concurrent with her PRO 140 treatment. As such, the Company relies on hearsay from the patient's radiologist who ostensibly "cancelled the suggested new round of radiation due to results that he believes is due only to Leronlimab."

That said, **it's easy for readers to be misled by these statements given that Pourhassan continues to make numerous claims that, in our view, simply aren't supported by the data.** For example, Pourhassan again took to Proactive Investors in January 2020 to claim:

"It looks like Leronlimab could have 32 different indications, and thank god we filed for triple negative breast cancer protocol, because **now it seems that we're saving people's lives** and this is going to be a very powerful agent."

To again analogize, it's one thing for a 12-year-old to tell his parents that he's going to try out for the NBA. It's another for that same child to claim that he in fact has already been playing for the Lakers and scored 40 points last night. Pourhassan's Leronlimab promotion is akin to claiming that not only did he score 40 points for the Lakers last night, but because of this, he is now going to play quarterback in the Superbowl. **In reality, Pourhassan has yet to make a layup in his 7-year tenure at CytoDyn's helm, and PRO 140 has never been demonstrated to have saved a single patient's life.**

Furthermore, on January 31, 2020, concurrent with the most recent breast cancer "data", the Company [announced](#) that it "is reaching out to the FDA to organize an emergency type C meeting":

"Today, we have heard from over 50 individuals who are waiting to be treated with leronlimab and our regulatory team is reaching out to the FDA to organize an emergency Type C meeting to discuss the data evidenced in our clinical trials."

First, there is no such thing as an "emergency type C meeting", as the Company has slyly put it. Type C meetings, [per the FDA](#), merely refer to meetings that do not qualify as type A (to help an otherwise stalled product development program proceed) or type B (commonly pro-IND meetings, phase 1/2/3 meetings, pre-NDA or pre-BLA meetings). Moreover, the Company's flippant language regarding its "reaching out" to the FDA calls into question whether or not CytoDyn is fully aware of the meeting request process. The FDA's own [draft guidance](#) for formal meeting requests makes clear the substantial burden of work involved merely in submitting a request, to say nothing of one being granted:

The meeting request should include adequate information for the FDA to assess the potential utility of the meeting and to identify FDA staff necessary to discuss proposed agenda items.

The meeting request should include the following information:

1. The application number (if previously assigned).
2. The product name.
3. The chemical name, established name, and/or structure.
4. The proposed regulatory pathway (e.g., 505(b)(1), 505(b)(2)).
5. The proposed indication(s) or context of product development.
6. The meeting type being requested (i.e., Type A, Type B, Type B (EOP), or Type C).
7. Pediatric study plans, if applicable.
8. Human factors engineering plan, if applicable.
9. Combination product information (e.g., constituent parts, including details of the device constituent part, intended packaging, planned human factors studies), if applicable.
10. Suggested dates and times (e.g., morning or afternoon) for the meeting that are consistent with the appropriate scheduling time frame for the meeting type being requested (see Table 2 in section VI.B., Meeting Granted). Dates and times when the requester is not available should also be included.
11. A list of proposed questions, grouped by FDA discipline. For each question there should be a brief explanation of the context and purpose of the question.

Nevertheless, that didn't stop Pourhassan from claiming on a same-day Proactive Investors [interview](#) that he hopes this theoretical, future, yet-to-be-requested, let alone scheduled meeting could lead to immediate PRO 140 approval in TNBC:

Question: What kind of outcome would you expect to receive out of that Type C meeting with the FDA?

Pourhassan: "I'm hoping that the FDA will immediately allow this product to be approved on a breakthrough designation status, do a phase 4, and let everybody come in and as soon as everybody is getting the product, the data can be accumulated more for support."

In our view, such a proposition borders on absurdity, to be kind. To contrast, coincidentally, the [last drug of 2019](#) to be approved in breakthrough designation was Daiichi Sankyo's ENHERTU, designated for treatment of adults with unresectable or metastatic HER2+ breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting. The [clinical underpinning](#) for this approval was a multi-center phase II trial evaluating the drug in 111 patients. Its investigators reported an objective response rate of 60.3%, a median duration follow-up of 11.1 months, and median response duration of 14.8 months.

On the other hand, CytoDyn has offered incomplete, highly conflicted data on just three patients who have undergone a mere 4 months of treatment. **One of the physicians we engaged, when asked about the possibility of an immediate approval, responded, “Absolutely not. I don’t think that’s ever happened in the history of the FDA.”** In summary, we agree that the suggestion that the FDA would approve PRO 140 via breakthrough designation at this yet-to-be-scheduled meeting is ridiculous.

August 2019 Suit Illuminates Oncology Retreat and Further Underlying Issues

Despite CytoDyn’s numerous public assurances, the Company’s actions behind the scenes appear entirely unconcerned with building a breast cancer / oncology infrastructure. Much of this is laid bare in the August 2019 lawsuit (1:19-cv-01563-RGA) filed against the Company by former Chief Medical Officer (CMO) Richard G. Pestell, MD, Ph.D. In short, Pestell alleges he was wrongfully terminated after having brought up substantial concerns about CEO Pourhassan’s actions, notably with respect to public statements, among other things. Note that the complaint also corroborates our concerns with many of the Company’s public statements and Pourhassan’s commentary:

63. In his capacity as CMO and a director of the Company, Dr. Pestell worked closely with the CEO. From time to time, Dr. Pestell raised concerns regarding certain actions taken by the CEO, including but not limited to actions in connection with public representations, regulatory submissions, program safety, hiring of consultants and advisors, contract execution, strategic planning, and program delays.

128. Dr. Pestell previously recommended to the CEO and the Board that all cancer-related press releases be reviewed by the CMO and by CytoDyn’s legal counsel prior to release, to avoid unnecessary risk to the Company due to statements which are inaccurate or cannot be substantiated. This recommendation was not followed.

Dr. Pestell’s unwillingness to toe the CytoDyn party line clashed with Pourhassan’s promotion-first approach. According to the complaint, Pourhassan directed that the Company continue with a treatment protocol that Pestell and other medical experts deemed would put patients at a direct risk of harm. Nevertheless, Pourhassan pushed the protocol forward over Pestell’s head:

64. Although Dr. Pestell and the CEO initially maintained a cordial working relationship, their relationship rapidly deteriorated following Dr. Pestell's objections in late June 2019 to the CEO concerning an investigational new drug application ("IND") and protocol to be submitted to the FDA despite the fact that Dr. Pestell, as the CMO, and another expert had determined that the protocol, as then drafted, was not safe for the study subjects.

65. Specifically, on June 20, 2019, the CEO, who has no medical training, demanded that the clinical trial office at Amarex Clinical Research LLC ("Amarex") "submit the IND and protocol that you had made for colon cancer for submission to the FDA by tomorrow and let [Professor] John [Marshall, Consultant to CytoDyn] know that we are not waiting for him any longer."

66. Dr. Pestell pushed back on the CEO's attempts to rush the submission because, the week prior, on June 12, 2019, Dr. Pestell had determined that the protocol was unsafe because it would likely lead to a higher incidence of side effects, placing patients at unnecessary risk. For those reasons, Dr. Pestell and Professor Marshall, a colon cancer subject matter expert who had previously worked with Dr. Pestell from 2002 to 2005 and is currently a consultant to CytoDyn, agreed that changes should be made to the protocol.

68. Despite this recommendation from experts in the field, and despite Dr. Pestell's authority for leading and implementing the Company's clinical programs, the CEO instead proposed submitting the original protocol with Dr. Pestell's name removed. This interference with Dr. Pestell's authority and performance of his duties constituted a breach of Section 2.2 of the Employment Agreement.

In the end, the complaint states that the clinical research laboratory itself also agreed that the proceeding would be unsafe and forced the Company to alter the protocol, hence validating Pestell's concerns. Nonetheless, Pestell alleges that these concerns led to his firing. Notably, the suit also claims that one board member characterized

Pestell, among other things, as “our only claim to expertise in cancer,” thus implying that the Company’s supposedly growing body of clinical evidence could not speak for itself:

115. At least one Board member, Carl Dockery, pushed back on this improper attempt to fire Dr. Pestell, highlighting the imprudence of hastily firing “our public face of the cancer program, our largest shareholder, a fellow board member, and our only claim to expertise in cancer” without first conducting a fair, independent, and impartial investigation.

116. No such investigation was conducted.

Moreover, CytoDyn did not only dismiss Pestell for his concerns, but pulled back on its preclinical studies in metastatic cancer, cancelling its statements of work with its laboratory partner just 2 months after establishing the relationship:

78. On May 6, 2019, two Statements of Work were initiated under the Master Sponsored Research Agreement, for preclinical studies relating to the effectiveness of leronlimab (PRO 140) for metastatic cancer. Staff, including researchers recruited from other countries, were hired to carry out these preclinical studies.

79. On July 8, 2019, however, Dr. Pestell learned that the Company – apparently at the direction of the CEO – had decided to cancel these studies.

Pourhassan was apparently unsure of his decision, as he rescinded the termination just one day later, then again terminated the agreements another 19 days after that:

84. On July 9, 2019, the Company sent a letter to Blumberg terminating the contracts.

85. The next day, July 10, 2019, the Company sent a second letter to Blumberg “rescind[ing]” its termination from the day before and advising that the Statements of Work “remain in effect” (the “Rescission Letter”).

92. On July 29, 2019, the Company once again terminated the Statements of Work with Blumberg (despite having rescinded its prior termination). The Company’s CFO sent a

Finally, the suit alleges that CytoDyn failed to create a Scientific Advisory Board (SAB):

95. Despite the Company's representation to the public in March 2018 that a SAB would be created, the SAB members still had not, as of Dr. Pestell's termination, received contracts or payments relating to their membership. In response to Dr. Pestell's requests for funding of the SAB, the CEO stated, on July 5, 2019, that no SAB would be formed "until after September [2019]."

We searched the resumes, CVs, and LinkedIn profiles of the 6 individuals noted in the March 2018 [press release](#), excluding CytoDyn's own Richard Pestell. We were unable to find a single example of any of these members holding out a public affiliation with a CytoDyn Scientific Advisory Board, hence corroborating this allegation.

The Original Promotion: The Most Successful HIV Drug that Never Was

For years, CytoDyn has offered the prospect of a wildly successful HIV combination therapy indication, with Pourhassan touting "half a billion dollar worth of sales hopefully in 2020" as recently as April 2019. Not only has the Company thus far failed to obtain FDA approval or a BLA, but PRO 140's potential in HIV has been usurped by more effective competing treatments. Furthermore, CytoDyn's suspect bedfellows in this venture include Martin Shkreli-tied Vyera Pharmaceuticals, which, we understand, is not the first port of call for a legitimate drug development business. Even should CytoDyn's "Dream Case" occur, we demonstrate how the Company would stand to generate just \$59 million in peak run-rate revenues.

Failure to Obtain BLA is Illustrative of CytoDyn's String of Broken Promises

The HIV indication was the first act of Pourhassan's promotional performance. Take, for example, his commentary regarding the process of obtaining a biologics license application (BLA), which is a prerequisite for any company seeking to introduce a biologic product into interstate commerce. On June 22, 2018, the Company issued a press release stating:

"CytoDyn Announces Productive Pre-BLA Meeting with FDA for PRO 140 Combination Therapy ... "Our pre-BLA meeting with the FDA was productive and provided specific guidance for meeting the FDA's requirements for a BLA" stated Nader Pourhassan, Ph.D., CytoDyn President and Chief Executive Officer, "Understanding the FDA's concerns and requirements for the BLA submission puts the Company on a solid footing to move forward with filing our first BLA for PRO 140. **Our BLA filings may start as early as the end of 2018** and the FDA review process will start when the full BLA submission is completed and the FDA has accepted the BLA for review."

After failing to obtain a BLA in 2018, Pourhassan then took to Proactive Investors on February 5, 2019, stating, among other things:

"We are very close to very major milestones, which is getting approval ... **Our BLA will be submitted in second quarter.**"

On April 15, 2019, Pourhassan stated:

“We will submit the BLA by the end of July ... **Worst case scenario, end of September.** Either way, we will be having revenue by the end of first quarter of 2020. Imagine having close to half a billion dollar worth of sales hopefully in 2020. That just transforms this Company.”

On October 28, 2019, Pourhassan stated:

“We were told by the FDA that you have success with 700mg, give us more data ... 50 patients they asked for in the next 3 days we will have 52 patients. We will submit it to the FDA in early November and hopefully have **the BLA all done with clinical and manufacturing in December.**”

“we believe we can do that [generate revenue] in 2020.”

On December 17, 2019, the Company stated:

“CytoDyn plans to seek FDA approval for leronlimab in combination therapy and **plans to complete the filing of a Biologics License Application (BLA) in 2019** for that indication.”

On January 22, 2020, Pourhassan [stated](#):

“We believe in 9 days we should be able to file the clinical section of the BLA.”

On January 31, 2020 – spoiler alert – the Company stated:

“CytoDyn plans to seek FDA approval for leronlimab in combination therapy and **plans to complete the filing of a Biologics License Application (BLA) in the first quarter of 2020** for that indication.”

Needless to say, the Company still has not publicly indicated that it has filed the BLA. Moreover, we believe investors may be confused as to the **separate processes** of (1) filing and (2) obtaining a BLA. Even after the BLA has been filed, the [median time](#) from BLA filing to approval is 8 to 10 months. As such, even if CytoDyn managed to file the BLA in full tomorrow – which we view as highly unlikely given the Company’s track record – the Company would remain hard pressed to **obtain** the BLA, and hence be permitted to sell PRO 140, prior to year-end 2020. 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.

Vyera Partnership a Co-Promotional Ploy

On December 17, 2019, CytoDyn [announced](#) it signed agreements with Vyera Pharmaceuticals to commercialized Leronlimab in the U.S. for the treatment of HIV:

“In exchange for the exclusive right to market and distribute leronlimab in the U.S. for HIV-related indications, Vyera will pay upfront and regulatory and sales-based milestone payments of up to \$87.5 million, as well as a royalty of 50 percent on net sales. Vyera will also make an investment in CytoDyn of \$4 million in the form of registered CytoDyn common stock

CytoDyn will maintain responsibility for the development and FDA approval of leronlimab for all HIV-related and other indications.”

While investors might cheer on an agreement with the likes of Gilead, Merck, Pfizer, or AstraZeneca, CytoDyn was only able to secure Vyera Pharmaceuticals, formerly known as Turing Pharmaceuticals, run by now-convicted and jailed security fraudster Martin Shkreli. Moreover, we believe the royalty agreement stipulating 50% of sales is especially punitive for CytoDyn, and again serves as a reflection of PRO 140’s unattractiveness. To contextualize, a 2013 Medtrack [report](#) reviewing nearly 400 drugs across 14 major therapy areas and 6 phases of development noted a 13% median royalty rate for Phase III drugs, and a 19% median royalty rate for drugs which have completed Phase III and are pending approval.

In our view, CytoDyn’s inability to secure more attractive terms with a more reputable partner, such as those listed above ought to tell investors everything they need to know about Leronlimab’s feverishly touted promise. From Vyera’s perspective, we believe the agreement was merely an opportunity to capitalize on CytoDyn’s desperation rather than create a route to PRO 140 commercialization in HIV. Simply put, Vyera paid \$4 million for a CytoDyn PIPE at a valuation of ~\$0.30 per share. In this way, Vyera created its own catalyst, as CytoDyn shares rocketed higher on the press release.

That said, while Shkreli remains in jail for securities fraud, Vyera’s business has fallen apart, and the government lawsuit that hit Vyera in January 2020 put further distance between PRO 140 and any theoretical commercialization plans.

In September 2019, STAT News [reported](#) that Vyera’s parent company, Phoenixus AG, has gone from making money (\$2.5 million in the first 6 months of 2017) to losing money (-\$7.2 million in 2018 alone), while sales fell 18% on a quarter-over-quarter basis. Moreover, “In August, [Phoenixus AG CEO Averill] Powers told the company’s 20 Daraprim sales reps that their collective bonus for the second quarter was being cut by more than 20%” which was characterized from one Phoenixus rep as a “breach of trust is unheard of in the industry. Basically, this is a company stealing from its own employees.”

On January 27, 2020 the Federal Trade Commission (FTC) and the New York Attorney General (NY AG) filed a complaint in federal court against Vyera alleging “an elaborate anticompetitive scheme to preserve a monopoly for the life-saving drug, Daraprim ... The complaint seeks equitable monetary relief to provide redress to purchasers who have overpaid for the drug. The complaint also seeks remedial injunctive relief to restore competitive conditions to the market, halt any ongoing anticompetitive conduct, and prevent the defendants from engaging in similar conduct in the future.” Given Vyera’s already precarious state, we believe the government’s complaint puts the CytoDyn partnership into severe jeopardy.

Despite Pourhassan’s near-daily appearances on Proactive Investors, we are surprised that we have yet to see an update from the CEO on these events, since Vyera is supposedly so important to the Company’s future.

We believe the foregoing fact pattern further confirms CytoDyn is a stock promotion. However, even if we ignore the voluminous body of evidence and assume that CytoDyn (1) obtains a BLA, (2) achieves FDA approval in HIV combination therapy, and (3) penetrates a substantial portion of the TAM, we see massive downside to the shares.

HIV “Dream State” Remains a Nightmare

To introduce readers to HIV treatment, the current standard across the HIV spectrum (i.e. regardless of age, time since diagnosis, severity, etc.) is referred to as antiretroviral therapy (ART). ART is typically conducted by combining drugs from two or more classes of drugs so as to avoid developing resistance to a single drug. Classes include NNRTIs, NRTIs, PIs, entry/fusion inhibitors, and integrase inhibitors. PRO 140 is an entry/fusion inhibitor, blocking HIV’s entry into CD4 T cells, which are critical to the body’s immune system. Specifically, PRO 140 binds to the CCR5 receptor, preventing HIV infection in healthy cells. While PRO 140 acts prior to a cell’s infection, other drug classes work after the cells have already been infected. As such, as well as due to the substantial cost of PRO 140 discussed below, PRO 140 would likely be a third-line therapy reserved for patients with multiple existing drug class resistances.

Even in what we believe to be the highly-unlikely event of FDA approval and successful commercialization, it is nearly impossible for PRO 140 to live up to the claims CytoDyn has made on its behalf. For example, in April 2019, Pourhassan [stated](#):

“We will be having revenue by the end of first quarter of 2020. Imagine having close to half a billion dollar worth of sales hopefully in 2020. That just transforms this Company.”

Q: “You mentioned you’re paying all of your bills. Are you pursuing non-dilutive financing to do this?”

Pourhassan: “Absolutely...”

We view the assumptions underpinning this theoretical “half a billion dollar worth of sales” as highly questionable. CytoDyn claims to hold a \$1.7 to \$3.4 billion TAM in HIV combination therapy:

Initial approval **Combination Therapy**

- HAART failures: ~ 70,000* patients with 2 or more drug class resistances
- 70,000 – 150,000 patients x 70% (R5-HIV strain) = 49,000 -HIV patient R5 eligible
- 50,000 -100,000 patients x **\$35,000** = ~ **\$1.7 to \$3.4 billion**

Note that the Company calculates 49,000 -HIV patient R5 eligible patients, then in the very next line claims 50,000 to 100,000 patients, effectively doubling the high-end of the TAM range. We are unclear as to where the Company derives the grounds for this claim.

CytoDyn’s fuzzy math aside, an infectious disease physician we engaged confirmed that approximately 5% of HIV patients will be resistant to multiple drug classes, implying just 47,300 patients given the latest HIV.gov data.

On the other hand, Theratechnologies (Ticker: THTX) is a publicly traded company that has a \$233 million market capitalization. THTX has already commercialized Trogarzo, which we view as comparable to what CytoDyn aspires to create with PRO 140 in HIV. Trogarzo is indicated “for human immunodeficiency virus-1 (HIV-1) infection in heavily treated adults with multidrug-resistant infection failing their current antiretroviral therapy (ART) regimen; use in combination with other ART drugs.” [Per Theratechnologies](#), which has an obvious incentive to promote Trogarzo’s growth prospects, “**Up to 25,000 patients have multidrug-resistant HIV**, and approximately 12,000 are in “dire need of a new treatment option.” Thus, our “dream case” model below utilizes a 30,000 patient figure.

We also believe PRO 140's hypothetical \$35,000 price tag is an aggressive assumption. Pfizer's Maraviroc has been approved since August 2007 for the treatment of CCR5-tropic (R5) HIV in treatment-experienced adults. 150mg of Maraviroc currently [retails](#) for \$1,820 per month, or just \$21,840 per year.

In our view, CytoDyn's chief claim to advantageous treatment vs. existing options are its form, being a once-weekly injection as opposed to once or twice-daily pills. It remains unclear to us whether or not self-administration of injections would in fact improve adherence, but in either case, major pharmaceutical companies such as GlaxoSmithKline are [already besting](#) CytoDyn's once-weekly injection with a once-monthly injection.

In summary, we believe PRO 140 would have a very difficult time competing with these alternatives in what is already a third-line HIV therapy. As such, we believe a penetration rate of 20% of the market is a generous "Dream state" scenario. At a comparable \$21,840 per patient and a 30,000 patient TAM, we calculate a more realistic TAM at just \$873.6 million. That said, recall that the Company has already licensed out 50% of potential future PRO 140 sales to Vyera and 5% to Progenics. Thus, **even if investors assume that PRO 140 were to be approved, commercialized, and gained 20% of the market tomorrow, CytoDyn would generate just \$59 million in run-rate annual revenues, a far cry from the "half a billion worth of sales hopefully in 2020" per Pourhassan:**

PRO 140 "Dream State"		Notes
Therapy-resistant HIV patients	30,000	<i>THTX states 25,000 multi-drug resistant</i>
Annual price	\$21,840	<i>In line with Maraviroc</i>
TAM (millions)	\$655	
PRO 140 share / penetration	20%	<i>Maraviroc and Torgarzo already selling</i>
Gross revenues (millions)	\$131	
Progenics Royalties	5%	<i>Initial purchase agreement</i>
Vyera Royalties	50%	<i>December 17, 2019 agreement</i>
CYDY Revenues (millions)	\$59	

Insider Enrichment via Private Raises and the Question of Cool Blue Capital, LLC

Given that the Company burns gobs of cash, its continued existence necessitates access to the capital markets. Like we have shown with man of Pourhassan's public statements, what is said is far different than what transpires in reality. In a recent Proactive Investors video, Pourhassan claimed that during January 2020's JP Morgan healthcare week (note the Company did not attend the JP Morgan conference), he met with 18 different investors, at least some of whom discussed the idea of a \$40 to \$50 million debt package:

"I believe we are going to get quite a bit of term sheets to try to get \$40 to \$50 million of non-dilutive financing. This is something we always promised the shareholders and now we are able to hopefully able to deliver in the next few weeks."

We believe this remains highly unlikely to transpire, as \$40 to \$50 million of debt at a generous 10% interest rate would equate to \$4 to \$5 million of interest expense, a burden the Company's already strained balance sheet and \$46 million of LTM cash burn cannot hold.

Of course, as we noted, what Pourhassan says is often far different than what he does, which once again shown through just three days ago. At that time, the Company filed an 8-K disclosing that on January 31, 2020, it issued newly created Series D Preferred Stock, in addition to warrants priced well below the current share price:

Item 1.01 Entry Into a Material Definitive Agreement.

On January 31, 2020, CytoDyn Inc. (the "Company"), issued in private placements to accredited investors an aggregate of 7,570 shares of its newly authorized Series D Convertible Preferred Stock, par value \$0.001 per share, with an initial stated value of \$1,000 per share (the "Series D Preferred Stock"), together with warrants to purchase an aggregate of up to 3,785,000 shares of its common stock, par value \$0.001 per share ("Common Stock"), with an initial exercise price of \$1.00 per share (the "Series D Warrants") for aggregate gross proceeds to the Company of approximately \$7,570,000 million (the "Series D Offering").

The shares of Series D Preferred Stock are convertible into shares of Common Stock at an initial conversion price of \$0.80 per share (the "Conversion Price") and will carry dividends at a rate of 10% per annum (subject to adjustment as provided in the Certificate of Designation of the Rights, Preferences, Privileges and Restrictions of the Series D Convertible Preferred Stock (the "Series D Certificate of Designation")) and have the preferences, rights and limitations set forth in the Series D Certificate of Designation. The Series D Warrants have a five-year term and are immediately exercisable. Pursuant to the subscription agreements entered into with each of the investors (the "Subscription Agreements"), the Company has agreed to use commercially reasonable efforts to prepare and file with the United States Securities and Exchange Commission within 120 days following the closing of the Series D Offering, but not later than April 30, 2020, a registration statement under the Securities Act of 1933, as amended, covering the resale of all of the Common Stock issuable to the investors upon the conversion of the Series D Preferred Stock and the exercise of the Series D Warrants.

Note that the preferred stock is immediately convertible into shares of common stock at \$0.80 per share – a remarkable 47% below the current share price – yet investors have the option to either convert their shares or collect dividends of 10% per year. In addition to the 47% discount, investors also received an **immediately exercisable warrant** for every two shares of preferred stock with an exercise price of \$1.00 per share, 33% below the current share price. The Company's recent 10-Q [indicates](#) (page 24) that insiders participated in these transactions.

Thus, while Pourhassan talks up non-dilutive financing in what is merely another deflection, these slugs of equity are injected into this insider enrichment scheme at substantial discounts to the current share price. Yet, minority investors have missed the fact that they continue to be the butt of this inside joke. Namely, that certain shareholders have benefited from participating in these highly discounted offerings, dumping their cheap stock mere weeks after receiving it.

Importantly, on Friday, January 31, 2020, the Company filed a form S-3 for the sale of up to 16,033,500 shares of common stock, entirely by existing shareholders. 14,413,500, or **89%, of these shares were issued to shareholders just two months ago in the Company's December 2019 private placement.** The remaining 1,620,000 shares were acquired through the Company's November 2018 transaction. In total, this takes the shareholders in question from 40.8 million shares to just 24.8 million shares owned:

Name of Selling Stockholder	Shares Beneficially Owned Pre-Offering(1)	% Owned Pre-Offering(2)	Common Stock Offered in this Offering	Warrant Shares(3) Offered in this Offering	Number of Shares Post-Offering	% of Shares Post-Offering(2)
Cool Blue Capital, LLC	4,993,500	1.1%	1,050,000	1,312,500	2,631,000	*
Elias De La Torre III	1,350,000	*	600,000	750,000	—	—
Flying S Ranch Trust	3,474,000	*	690,000	862,500	1,921,500	*
Francesco Tosco	3,452,250	*	736,000	920,000	1,796,250	*
Martin Krytus	3,817,500	*	930,000	1,162,500	1,725,000	*
Paul and Maureen Hydok	1,772,917	*	200,000	250,000	1,322,917	*
Paulson Investment Company, LLC (4)	2,802,063	*	384,750	—	2,417,313	*
Christopher Clark (5) (6)	4,273,642	*	405,000	—	3,868,642	*
Malcolm A. Winks (5)	20,250	*	20,250	—	—	—
Robert Setteducati (5)	4,004,947	*	405,000	—	3,599,947	*
Thomas Parigian (5)	4,073,954	*	405,000	—	3,668,954	*
The Thomas C. Mollick Insurance Trust	450,000	*	200,000	250,000	—	—
Thomas C. Mollick	6,300,000	1.4%	2,000,000	2,500,000	1,800,000	*
Total	40,785,023	*	8,026,000	8,007,500	24,751,523	*

We also note that one of the largest selling shareholders is an entity named “Cool Blue Capital, LLC”. We [searched](#) the SEC’s database of EDGAR filings from the past 4 years and found only four filings in which Cool Blue Capital, LLC was mentioned, each of which pertained to CytoDyn’s S-3 offerings:

Search For Text: [Advanced Search Page](#)

1 - 4 of 4 results [Printer Friendly Version](#)

Previous 1 Next

Date Filed Title

01/31/2020 [S-3 for CytoDyn Inc.](#)
COMPANY NAME(s) - [CytoDyn Inc (CIK - 1175680 /SIC - 2834)]
As filed with the Securities and Exchange Commission on January 31, 2020 Registration No. 333- UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549 FORM S-3 REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933 CYTODYN INC. (Exact
[Exhibits List->](#) | 1 | 2 | 3 | 4

09/30/2019 [424B3 for CytoDyn Inc.](#)
COMPANY NAME(s) - [CytoDyn Inc (CIK - 1175680 /SIC - 2834)]
Filed Pursuant to Rule 424(b)(3) Registration No. 333-233526 Prospectus 17, 526, 200 Shares of Common Stock This prospectus relates to the offer and sale by the selling stockholders identified in this prospectus of up to 10, 000, 000 shares of our common stock, par value \$0.001 per share,

09/27/2019 [S-3/A for CytoDyn Inc.](#)
COMPANY NAME(s) - [CytoDyn Inc (CIK - 1175680 /SIC - 2834)]
As filed with the Securities and Exchange Commission on September 26, 2019 Registration No. 333- 233526 UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549 Pre- Effective Amendment No. 1 to FORM S-3 REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933
[Exhibits List->](#) | 1

08/29/2019 [S-3 for CytoDyn Inc.](#)
COMPANY NAME(s) - [CytoDyn Inc (CIK - 1175680 /SIC - 2834)]
As filed with the Securities and Exchange Commission on August 29, 2019 Registration No. 333- UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549 FORM S-3 REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933 CytoDyn Inc. (Exact
[Exhibits List->](#) | 1 | 2

1 - 4 of 4 results

The August 29, 2019 offering also indicates that Cool Blue was the owner of 6,139,000 shares at the time, yet sold its entire stake down to zero in the offering:

Name of Selling Stockholder	Shares Beneficially Owned Pre-Offering(1)	% Owned Pre-Offering(2)	Common Stock Offered in this Offering	Warrant Shares(3) Offered in this Offering	Number of Shares Post-Offering	% of Shares Post-Offering(2)
Andrew D. Cooper	80,000	*	50,000	30,000	—	—
Aurelia Cure	160,000	*	100,000	60,000	—	—
Baylor Buck	41,600	*	26,000	15,600	—	—
Baylor Buck Roth IRA	48,000	*	30,000	18,000	—	—
Brady Buck	41,600	*	26,000	15,600	—	—
Brady Buck Roth IRA	32,000	*	20,000	12,000	—	—
Brent and/or Lyndee Orr	2,184,000	*	990,000	1,094,000	100,000	*
Brian Baalman	160,000	*	100,000	60,000	—	—
Cass Baalman	160,000	*	100,000	60,000	—	—
Chris or Kari Didier	80,000	*	50,000	30,000	—	—
Christopher Kennedy	80,000	*	50,000	30,000	—	—
Coby Buck	41,600	*	26,000	15,600	—	—
Coby Buck Roth IRA	32,000	*	20,000	12,000	—	—
Cody McDaniel	80,000	*	50,000	30,000	—	—
Collins Family Trust f/b/o Jody Buck	192,000	*	120,000	72,000	—	—
Cool Blue Capital, LLC	6,139,000	1.6%	3,508,000	2,631,000	—	—
CZB Development LLC	80,000	*	50,000	30,000	—	—
Daryl South	480,000	*	300,000	180,000	—	—
David R. Baker Trust	320,000	*	200,000	120,000	—	—
David T. Mortell	80,000	*	50,000	30,000	—	—

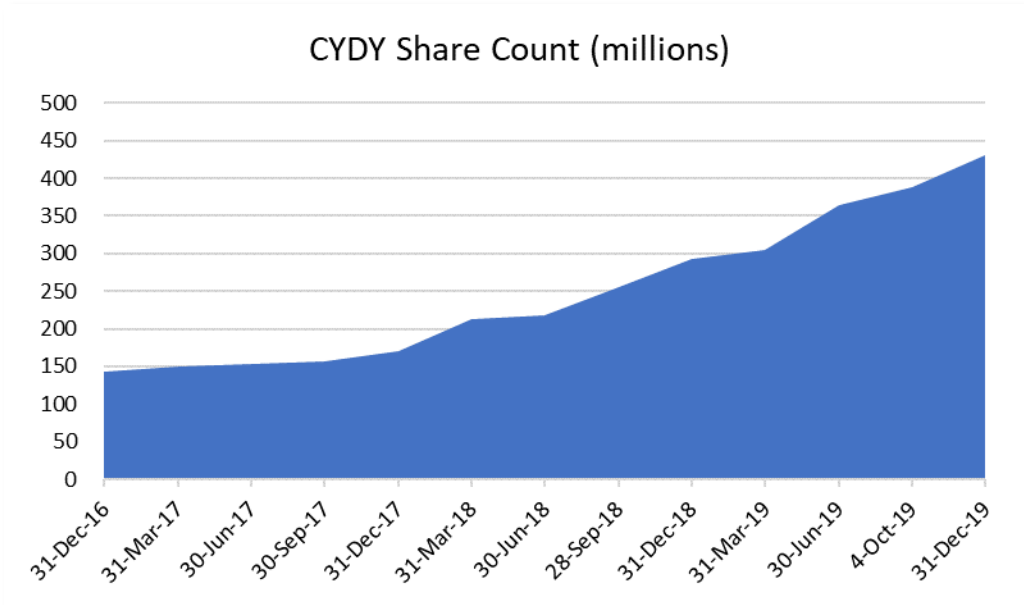
Despite having sold its entire previously held stake in August 2019, in the most recent offering dated January 31, 2020, this owner of 4,993,500 new shares is yet is again selling nearly half of its cheap shares, indicating both that (1) Cool Blue has been participating in the Company's private placements, hence obtaining shares at below-market prices, and (2) has been promptly selling these shares through the S-3 offerings, hence benefiting at the expense of minority shareholders.

In addition to the SEC search, we also conducted a Google search for the entity, which was fruitless. Finally, we conducted a search of state-by-state registration filings for "Cool Blue Capital" to determine potential members. **We discovered an entity in Oklahoma that was formed on August 19, 2019, notably just 10 days prior to the Company's first S-3 offering that mentioned Cool Blue Capital, LLC:**

COOL BLUE CAPITAL LLC	
Details	
Filing Number:	3512777931
Name Type:	Legal Name
Status:	In Existence 
Corp type:	Domestic Limited Liability Company
Jurisdiction:	Oklahoma
Formation Date:	19 Aug 2019

While we cannot directly demonstrate that CytoDyn insiders are also beneficial members of Cool Blue, we considered it worthwhile to flag to readers, given the otherwise notable absence of information on the entity.

After the market close on January 31, 2020, the existing CYDY shareholders [offered](#) to sell up to 16 million shares through a combination of preferred stock, common stock, and warrants issued as recently as December 2019. In the past year alone, shares outstanding have grown from 292.9 million to 430.8 million (+47%), while over the past 3 years, share count has more than tripled:



In fact, the Company's dilution has gotten so out of hand that it was necessary to call a special shareholder meeting in order to increase the number of authorized shares from 600 million to 700 million. When asked to [comment](#), Pourhassan first stammered to imply that the amendment was merely a technicality based on convertible notes. He then conceded that the change would be "the maximum dilution we'd do pre-revenue." Dilution notwithstanding, as of November 30, 2019, the Company held 177.5 million options and warrants outstanding at a \$0.65 strike price, short-term convertible notes and accrued interest that could convert into 10.0 million shares, and Series B and C convertible preferred stock that could convert into 17.6 million shares. As such, the current \$1.49 share price represents a fully diluted enterprise value of \$860 million.

CYDY Market Cap	millions
Share price	\$1.49
Common shares O/S	431
Market cap displayed	\$642

CYDY Enterprise Value	millions
Common shares O/S	431
Convertible note shares converted	10
Series B & C shares converted	18
Total shares	458
Share price	\$1.49
Sub-total valuation	\$683
Net dilutive value of warrants	\$149
Fully diluted value	\$832
Net tangible liabilities	\$28
Total CYDY Enterprise Value	\$860

In addition to the compendium above, there are multiple other red flags worth highlighting for investors.

Additional Red Flags

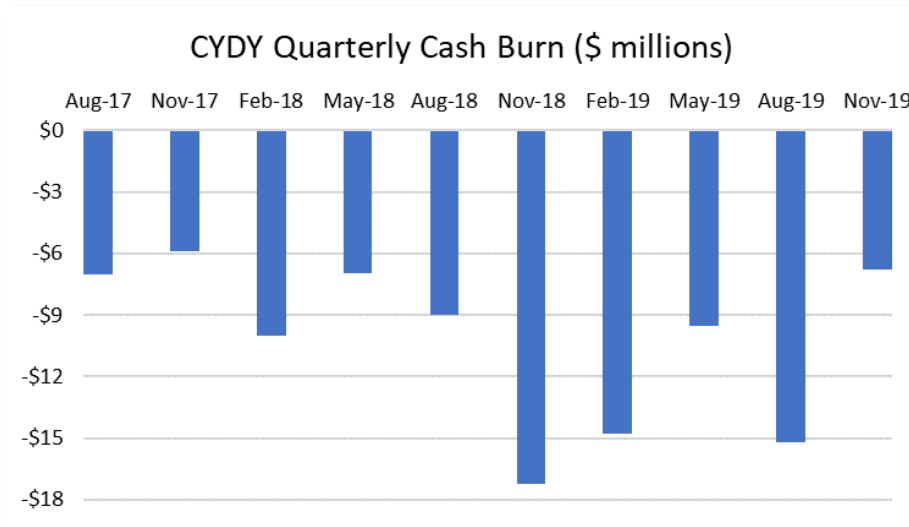
In 2016, the Company partnered with Charlie Sheen to promote PRO 140 in HIV. This included an appearance on the Dr. Oz show, where Pourhassan sat next to Charlie Sheen, who stated that his viral load was undetectable. Per Arlene Weintraub of [Forbes](#), “Seeing as the FDA often frowns on companies with overly enthusiastic CEOs, this might not be a smart course of action for CytoDyn.” We can only speculate whether Pourhassan’s promotion is a contributing factor to the Company’s inability to secure a BLA or FDA approval for PRO 140.

Second, the Company has conducted its constant fundraising through Rodman & Renshaw, a broker that has been subject to multiple fines and regulatory events [involving](#) (1) failing to separate the investment banking and research functions, (2) failing to correctly report transactions to exchanges, (3) failing to submit required information to the order audit trail system, and (4) failing to comply with securities laws concerning firm quote rules. Accordingly, R&R’s parent company declared [bankruptcy](#) in 2013. More broadly, R&R is often recognized as a key enabler of the systemic China-based securities fraud of the past decade plus.

Finally, the Company’s [auditor](#) is Warren Averett, LLC. Warren Averett is a relatively small firm, whose next-largest public company client after CytoDyn is National Security Group (NSEC), which has a \$38 million market capitalization. CytoDyn’s engagement partner lives in Birmingham, Alabama, approximately 2,100 straight miles from the Company’s Vancouver, Washington headquarters.

CytoDyn’s Current Solvency Crisis

Unsurprisingly, given CytoDyn’s stagnant clinical efforts on all fronts, the Company has continued to generate zero revenues and burn substantial cash:



Court documents show this cash crunch has been felt for some time: per the August 2019 complaint, the Company was in default of its payments to the Blumberg Institute, its laboratory partner. As we noted earlier, this fractured relationship and failure to pay led to the termination of the Company's preclinical studies oncology with Blumberg:

86. However, the contracts were not secure, as the Company remained in default of its payment obligations to Blumberg.

87. Blumberg's President Timothy Block responded to the Rescission Letter on July 12, 2019, explaining that "[p]erhaps it can be appreciated how disturbing and threatening the events of the past week have been to the overall program stability and operations within [Blumberg], and in particular, to those working on the project (several scientists have been recruited and relocated to the area expressly for this work)." Dr. Block also noted that the Company owed \$71,428.00 to Blumberg for work performed but not yet paid for. For these reasons, Blumberg requested (1) immediate payment for all funds owed, (2) 1-year notice for termination going forward, and (3) 6 months of advance payment for future work.

CytoDyn's inability or unwillingness to pay its bills isn't an anomaly; over the past 3 years (quarter-ended November 2016 to November 2019), the Company's accounts payable have ballooned from \$5.9 million to \$18.7 million. Moreover, the interest expense associated with these past-due accounts payable has become more burdensome. Per the most recent form 10-Q (emphasis ours):

"Interest expense for the six months ended November 30, 2019 totaled approximately \$7.1 million, as compared to approximately \$1.9 million for the similar period in 2018. The components of interest

expense **include finance charges on certain past due accounts payable balances**, non-cash inducement interest expenses incurred on warrant exercises and debt conversion, along with the amortization of debt discount and debt issuance costs.”

As such, the Company has become increasingly desperate to execute its highly dilutive equity fundraising scheme, as explained above. See the following, compiled from the Company’s November 30, 2019 form 10-Q and recent announcements:

Description	Cash Impact
December 2, 2019 convertible cash redemption	(\$0.35)
December 6, 2019 Series C conv pref equity raise	\$0.38
December 9, 2019 registered direct offering	\$0.75
December 13, 2019 registered direct offering	\$0.73
December 16, 2019 convertible cash redemption	(\$0.35)
December 23, 2019 Vvera equity investment	\$4.00
December 30, 2019 warrant exchange	\$1.00
January 31, 2020 Series D conv pref equity raise	\$7.57
Total	\$13.73

Despite the above incessant fundraising, in our view, it’s simply too late. Given the Company’s cash burn of ~\$12 million per quarter, we estimate that the Company will again run out of cash in the next 38 days:

CytoDyn's Solvency Crisis	millions
Cash as of November 30, 2019	\$0.41
Interim fundraising	\$13.73
Pro forma cash balance	\$14.14
Daily cash burn	\$0.13
Days since November 30, 2019	106
Cash crunch date	3/15/2020
Days until out of cash	38

We believe CytoDyn’s continued existence, parasitic as it is, is predicated on diluting unsuspecting minority shareholders. We believe this will prove disastrous to investors who have been on the receiving end of saccharin, empty promises for years. Moreover, as alleged in the August 2019 lawsuit, management has demonstrated its increasing willingness to take increasingly drastic measures – including putting human lives at risk – in the name of Pourhassan’s promotional self-enrichment campaign. As such, we believe that it’s time the capital markets finally say sweet dreams to CytoDyn. We are short and believe the shares are worthless.