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CytoDyn is in financial and clinical distress, newly filed annual report shows

By Adam Feuerstein[2] @adamfeuerstein[3]

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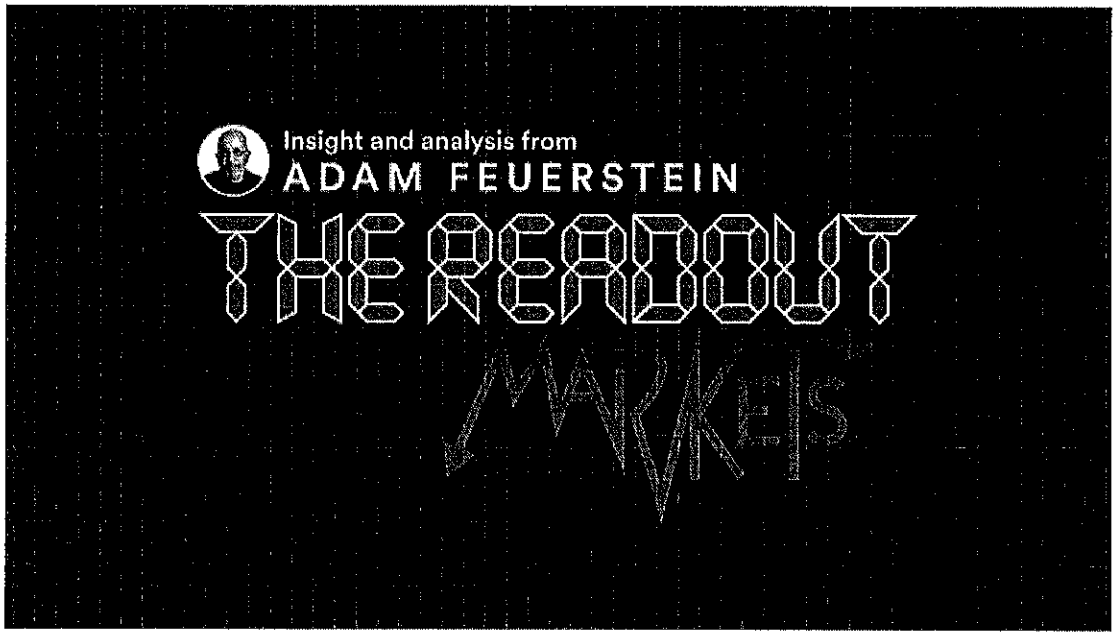

An annual report disclosed by CytoDyn on Friday night describes a drug maker in distress. It's a more troubling summary of CytoDyn's current situation than the boom times described by company executives in innumerable press releases, conference calls, and YouTube videos.

CytoDyn's financial losses are growing and its balance sheet is deteriorating, according to the year-end report, also known as a 10-K, filed with the Securities and Exchange Commission. Cytodyn's fiscal year ended on May 31.

The company is also burning more cash, the new filing shows. Clinical trials involving its lead (and only) drug have suffered setbacks and delays, while several efforts to secure either an approval or preferential regulatory status with the Food and Drug Administration have been denied.

"We stand by all our statements and believe the results we have disclosed speak for themselves," CytoDyn CEO Nader Pourhassan said in an email to STAT, responding to questions about the new information contained in its 10-K.

Smart investors read 10-Ks because it's the document in which publicly traded companies are the most honest about their operations, lest they run afoul of SEC rules. Companies often use their 10-Ks to disclose the bad news, risks, and red flags that management doesn't want to talk about in public, unless forced to.

You'd be naive to believe that a 10-K offers total corporate transparency, but free of misleading spin, the document is indispensable reading for any investor seeking a more honest status report on a company's operations and outlook.

Here are some of the alarming new disclosures in CytoDyn's newly filed 10-K[7]:

Unchecked financial losses

Pourhassan boasts repeatedly that the company has never been on a stronger financial footing. The actual numbers suggest otherwise.

Cytodyn's net loss more than doubled to $124 million from the previous year. The company generated no revenue. Total operating expenses were $75 million, an increase of 34% year over year. CytoDyn employs 19 people but general and administrative expenses rose 67% to $20 million. The company's board recently handed Pourhassan a salary bump to $1 million per year. Research and development costs increased 26% to $53 million. The company has had a single drug in its pipeline for its entire existence.

The staggering net loss was exacerbated by financial mismanagement. CytoDyn was forced to take a $22.5 million, non-cash charge in the fiscal year due to a legal settlement related to a claim filed by the holder of a convertible note issued in 2019.

The company's total interest expense was $18 million, almost six times higher than the prior year. That includes an $8 million charge for "inducement interest" related to warrant exercises and debt conversion.

What does that mean? Simply put, CytoDyn's finances were in such desperate condition that it could only raise money by paying holders of its warrants and convertible notes to exercise their shares early.

Money problems

Pourhassan assures investors that CytoDyn has ample cash, and the ability to raise more at favorable and non-dilutive terms.

CytoDyn ended its May 31 fiscal year with $14 million in cash, less than its average quarterly cash burn of $17 million. So, CytoDyn was actually very close to being insolvent.

Cash used for the company's operations — its burn rate — totaled $69 million in the fiscal year, including $30 million in the fiscal fourth quarter, alone.

In June and July (after its fiscal year ended), CytoDyn raised an additional $44 million, all of it on unfavorable terms or a steep discount to the market price of the stock. The new financings increased Cytodyn's total cash to approximately $58 million.

But with its bumped-up burn rate, CytoDyn is at risk of running out of cash by December — the start of its fiscal third quarter. Even if CytoDyn reduces expenses, it doesn't have sufficient cash to operate for a full year or make required cash payments for its manufacturing contract with Samsung.

Nasdaq listing in jeopardy

CytoDyn's auditors issued a "going concern" letter because there is "substantial doubt" that the company "can continue as an ongoing business for the next 12 months."

At the end of its fiscal year, the company had a stockholder's deficit of $2.5 million, which means its liabilities are greater than its assets.

CytoDyn is trying to move to the Nasdaq from its current trading home on the OTC, but its deteriorating financial condition will make it difficult, if not impossible, to meet the Nasdaq listing standards.

FDA rebukes

CytoDyn has yet to meet with the FDA to sort out the refuse-to file-letter[8] issued in July against its drug leronlimab as a treatment for patients with HIV. The company has promoted leronlimab as a blockbuster HIV medicine, yet in reality, it wasn't even capable of submitting an application sufficiently complete for the FDA to review.

In its 10-K, CytoDyn said a resubmission of the leronlimab HIV application to the FDA will be filed by the end of the year — a longer delay than the company has previously suggested.

CytoDyn also asked the FDA to award leronlimab with a "breakthrough therapy designation" for HIV and cancer. The agency turned the company down both times.

Clinical trial tribulations

Here's how CytoDyn, in its 10-K, described the efficacy results from its Phase 2 clinical trial of leronlimab in patients with Covid-19:

"Enrollment was completed in July 2020 and the Company has recently reported positive safety results. The Top-line Report from the trial, including efficacy and safety data, is expected to be submitted to the FDA in August 2020."

Nowhere in CytoDyn's 10-K does the company say the leronlimab clinical trial in Covid-19 achieved its primary endpoint — or any positive efficacy outcome. That's notable[9], because in press releases and conference calls, CytoDyn has claimed leronlimab is benefiting patients with Covid-19. The company has described study results — efficacy, not just safety — as "positive," "impressive," "clinically significant" and "statistically significant."

Remember, companies are forced by the SEC to be more honest in their 10-Ks than they are in press releases.

On Monday, CytoDyn said the leronlimab results from the Covid-19 study were submitted to the FDA, seeking an emergency use authorization, or conditional approval. The company offered no explanation for why the FDA would approve leronlimab just because it says the Covid-19 study was a success, even though data disclosed show it was a failure.

Miscellania

On July 28, CytoDyn's board revoked certain executive stock performance awards because the FDA rejected the company's request to award leronlimab a breakthrough therapy designation in cancer. But three days later,

Pourhassan was given CytoDyn shares worth $828,000.

In December, CytoDyn said it had licensed HIV marketing rights to leronlimab to drugmaker Vyera Pharmaceuticals — Martin Shkreli's company — for $87 million in cash. But according to the 10-K, CytoDyn only received $400,000 upfront for the deal, the rest is contingent upon leronlimab achieving certain sales milestones, if the drug is ever approved.

Patents protecting leronlimab begin expiring in 2023.

About the Author

Adam Feuerstein[2]

Senior Writer, Biotech

Adam is STAT's national biotech columnist, reporting on the intersection of biotech and Wall Street.

adam.feuerstein@statnews.com[11]
@adamfeuerstein[3]

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