UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) of the SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): August 11, 2022

VistaGen Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Nevada	**000-54014**	**20-5093315**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(IRS Employer Identification Number)*

343 Allerton Ave.
South San Francisco, California 94090
(Address of principal executive offices)

(650) 577-3600
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a -12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d -2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e -4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	VTGN	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR 230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR 240.12b-2)

Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act ☐

Item 7.01 Regulation FD Disclosure.

On August 11, 2022, VistaGen Therapeutics, Inc. (the "*Company*") hosted a conference call to report the financial results for the Company's first quarter of fiscal year 2023 ended June 30, 2022 and provide a corporate update. A transcript of the conference call is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K, including the information set forth in Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "*Exchange Act*"), nor shall Exhibit 99.1 filed herewith be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits Index

Exhibit No.	Description
99.1	VistaGen Therapeutics, Inc. Earnings Call Transcript, dated August 11, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

VistaGen Therapeutics, Inc.

Date: August 16, 2022

By: */s/ Shawn K. Singh*
Shawn K. Singh
Chief Executive Officer

VistaGen Therapeutics, Inc.

First Quarter Fiscal Year 2023 Results Conference Call

August 11, 2022

C O R P O R A T E P A R T I C I P A N T S

Mark Flather, *Vice President of Investor Relations*

Shawn Singh, *Chief Executive Officer*

Jerrold Dotson, *Chief Financial Officer*

C O N F E R E N C E C A L L P A R T I C I P A N T S

John, *William Blair*

Vijay Subramanian, *Jefferies*

Brian Skorney, *Baird*

P R E S E N T A T I O N

Operator

Welcome to the VistaGen Therapeutics First Quarter Fiscal Year 2023 Results Conference Call.

I'll now turn the call over to your host, Mark Flather, Vice President of Investor Relations. Mr. Flather, you may begin.

Mark Flather

Thank you, Erica. Hello, and welcome to VistaGen's conference call covering our first quarter of Fiscal Year 2023 financial results and business update. I'm Mark Flather, Vice President of Investor Relations at VistaGen. Thank you for joining us today, and welcome to our stockholders, analysts, and anyone taking an interest in VistaGen.

Joining me today are Shawn Singh, our Chief Executive Officer, and Jerry Dotson, our Chief Financial Officer.

The format for this call will consist of prepared remarks from Management, followed by a brief opportunity for questions. This call is being webcasted and will be available for replay. The link to access the replay can be found in the Investors IR Calendar section of our website, vistagen.com.

On today's call, we will make forward-looking statements regarding our business based on our current expectations and current information. The forward-looking statements speak only as of today, and except as required by law, we do not assume any duty to update in the future any forward-looking statement made today. Of course, forward-looking statements involve risks and uncertainties. Our actual results could differ materially from those anticipated by any forward-looking statements that we may make today.

Additional information concerning risks and factors that could affect our business and financial results is included in our most recent quarterly report on Form 10-Q filed earlier today with the Securities and Exchange Commission, or SEC, and in future filings that we make with the SEC from time to time, all of which are and will be available on our website and the SEC's website.

Now, I'd like to turn the call over to our CEO, Shawn Singh.

Shawn Singh

Thank you, Mark, and good afternoon, everyone. On behalf of our entire team here at VistaGen, thank you all for joining the call today.

VistaGen's working to address unmet mental health needs in communities all across the globe. We are focused on improving patient care in mental health, and our talented team is driving innovation to help patients live healthier and more enjoyable and productive lives. Our drug pipeline currently includes three central nervous system therapies that have the potential to fundamentally shift the treatment paradigm for anxiety and depression and other CNS disorders.

The prevalence of these disorders has grown considerably since the beginning of the pandemic, and it is crystal clear that currently approved treatments are underserving people struggling with these conditions. Individuals across a broad range of demographics need new, faster-acting treatment options without having to worry about the negative side effects and safety concerns often associated with currently approved medicines.

We know that we've had a recent setback, but we remain focused on getting PH94B back on track and maintaining our course of developing and commercializing new differentiated treatments with the potential to improve lives. In previous studies, PH94B has demonstrated potential efficacy as compared to placebo and a favorable safety profile when used acutely as needed before stressors at home, work or elsewhere. For this reason, we've decided to continue late-stage clinical development of PH94B as a potential treatment for social anxiety disorder, adjustment disorder with anxiety, and potentially other anxiety disorders.

As a result of the outcome of PALISADE-1, in addition to our interim analysis of PALISADE-2, we're currently assessing different study designs for submission to the FDA later this year. This includes study designs that may consist of multiple-administration, multiple-use assessments over an extended period of time, as well as the potential utilization of both the Liebowitz Social Anxiety Scale and the Subjective Units of Distress Scale as efficacy endpoints.

The Liebowitz Social Anxiety Scale, or LSAS, is a well-established 24-item questionnaire developed in 1987 by Dr. Michael Liebowitz while he was the professor of psychiatry at Columbia University. Historically, the LSAS has been the diagnostic gold standard for clinical assessment of social anxiety disorder. It was the primary efficacy endpoint supporting the approval of the three antidepressants currently approved by the FDA for the treatment of SAD.

Since our meeting with the FDA back in the middle of 2020, we have developed extensive new data, reinforcing our confidence in PH94B's potential to transform lives of millions of people suffering from the debilitating effects of SAD and other anxiety disorders. For example, preliminary data from nearly 200 subjects in our PALISADE open-label safety study suggests that as-needed use of PH94B over time has potential to help patients achieve cumulative functional improvement in the severity of social anxiety disorder as measured by the LSAS.

Based on a cohort of nearly 200 subjects who have completed three months of exposure, we saw increasingly reduced severity of SAD as measured by the LSAS at the end of each of months one, two, an three, with a greater than 20-point reduction on the LSAS compared to baseline at each of those time points. Importantly, at three months, over half of the subjects in that cohort had a greater than 20-point reduction on the LSAS.

A 20-point reduction on the LSAS is very important, and it's usually associated with functional improvement. This is similar to LSAS scores that we saw from multiple use assessments in the published randomized double-blind placebo-controlled Phase 2 study conducted by Dr. Liebowitz in a real-world outpatient setting. Also, preliminary data from the open-label safety study reflect that the level of severity of social anxiety disorder has dropped over time in many subjects with severe and very severe SAD.

These preliminary data further fortify our steadfast confidence that PH94B can help people struggling with SAD, help them reduce joy-stealing opportunities from the avoidance of situations and experiences that most of us lean into regularly to enrich the quality of our lives, and also help reduce fear, anxiety and avoidance of situations necessary for building relationships, academic achievements, and vocational successes.

Notably, we continue to see data showing PH94B's favorable safety profile, which has been consistent through all PH94B clinical studies conducted to date. PH94B is designed to reduce anxiety acutely as needed. Importantly, the findings from the multiple-use Phase 2 study, which was conducted, again, in a real-world environment rather than in a clinical setting, suggests that once a person with SAD experiences a benefit from PH94B, they may gain confidence in their ability to function in stressful situations, and that confidence can persist. That's our paramount goal for PH94B, and we're seeing similar results in a substantial percentage of subjects in the PALISADE open-label study.

Accordingly, we plan to meet with the FDA later this year to pursue consensus around a clearly defined development plan for further Phase 3 development of PH94B in SAD. This development plan will ideally maintain an emphasis on a multiple-use assessment study design, with the LSAS as a primary efficacy endpoint as it was for the three antidepressants previously approved by the FDA for the treatment of SAD, and with SUDS as a secondary end point.

Our randomized double-blind placebo-controlled exploratory Phase 2a study in adjustment disorder with anxiety is ongoing. The study involves daily use of PH94B in an outpatient setting for 28 days, and Dr. Liebowitz is the principal investigator of that study. As the need for safe and fast-acting treatments expands, we will continue to thoughtfully pursue PH94B's potential as a therapy for various anxiety orders, in addition to social anxiety disorder and adjustment disorder.

Our team continues to advance other CNS candidates in our pipeline. We're developing another pherine nasal spray, PH10, as a potential rapid-onset, stand-alone treatment for major depressive disorder and potentially other distinct depression disorders. We'll provide further guidance on our development plan for PH10 later this year.

AV-101 in combination with probenecid, we'll complete our Phase 1b trial as planned later this year. The study follows two positive preclinical studies showing that the combination of AV-1 and probenecid substantially increased the brain concentration of the active metabolite of AV-101, which is targeted reducing, rather than blocking, disordered NMDA receptor signal. We'll provide further guidance on our development plan for AV-101 later this year.

As you can see, there's a lot of work underway here at VistaGen to bring new therapies to patients who urgently need them.

I would now like our CFO, Jerry Dotson, to summarize some of the highlights from financial results for the first quarter of our Fiscal '23. Jerry?

Jerrold Dotson

Thank you, Shawn.

As Shawn mentioned, I'll highlight a few of the financial results from the first quarter of our Fiscal Year 2023. I would also encourage everyone to review our quarterly report on Form 10-Q that we filed with the SEC earlier this afternoon for additional details and disclosures.

Our research and development expenses increased by $9.8 million from $5.5 million to $15.3 million for the quarter ended June 30, 2021 and 2022, respectively. This increase is primarily due to expenses related to conducting our PALISADE Phase 3 program for PH94B, including PALISADE-1, PALISADE-2, the PALISADE open-label safety study, and the PH94B Phase 2 study in adjustment disorder with anxiety, as well as nonclinical development and outsourced manufacturing activities for both PH94B and PH10.

Our general and administrative expenses increased to approximately $4.8 million for the quarter ended June 30, 2022, compared to approximately $2.6 million for the first quarter of the fiscal year ended June 30, 2021. That increase was primarily due to the addition of senior management and other personnel during Calendar 2021 and the first half of Calendar 2022, as well as PH94B prelaunch commercialization market-research studies and analyses.

Our net loss attributable to common stockholders for the quarter ended June 30, 2022, was approximately $19.8 million versus a net loss attributable to common stockholders of approximately $8.1 million for the quarter ended June 30, 2021.

At June 30, 2022, the Company had cash and cash equivalents of approximately $52 million. As a result of the deferral of several research and development and pre-commercial activities involving PH94B, the Company anticipates a considerable reduction in our external spending to conserve cash and extend our cash runway for at least the next 12 months.

Again, please refer to our quarterly report on Form 10-Q filed today with the SEC for additional details and disclosures.

I'll now turn the call back to Shawn.

Shawn Singh

Thanks, Jerry.

While we'd hoped that PALISADE-1 would have been positive, we've long believed that the paramount potential benefit of PH94B to patients would come through acute as-needed use, but over time. The mean duration of SAD for most subjects is somewhere around 20 years, and the onset, as I've mentioned before, is typically in adolescence, between the ages of 8 and 15. But the use over time would allow patients to face anxiety-provoking situations and engage in the activities that they've long avoided in the past.

Given what we've recently learned from PALISADE-1 and the PALISADE open-label study, we believe LSAS measurements over time may be better suited to demonstrate efficacy and the true impact of PH94B on patients' lives. We've seen PH94B improve LSAS scores in both our Phase 2 study versus placebo, a published study after two weeks of use, and in our recent open-label study of a cohort of nearly 200 subjects by capturing the monthly change from baseline on the LSAS.

In both instances, we've seen rapid and robust improvement, and in the PALISADE open-label study, we've seen continued improvement over several months. All these studies reinforce our confidence in the potential of PH94B to help people, to help people in a world where SAD and other anxiety disorders are more and more prevalent every day.

Again, our mission's clear, and I'm confident in the potential of our pipeline and our team to accomplish it, and that's to radically change the trajectory of mental healthcare and improve the lives of millions of people around the world who battle mental health challenges, including anxiety and depression disorders, every day. We're thankful for that privilege, and we're also thankful for that powerful opportunity to make a difference.

Mark Flather

Thank you, Shawn. This concludes our prepared remarks.

Erica, we'd like to now open up the call for questions.

Operator

Our first question comes from Tim Lugo from William Blair. Please state your question.

John

Hi. This is John on for Tim. Thanks so much for taking our questions.

I just wanted to get a little bit more clarity on these preliminary results that you're seeing from the OLE. As patients are using the drug over time as needed, are you seeing improvement in their acute response to the drug or just in their overall anxiety regardless if they've just administered? Are you also evaluating SUDS in the open label, or just Liebowitz scale?

Sorry, a quick follow-up. For your upcoming anxiety disorder study, I think that the endpoint you have is the Hamilton Anxiety Scale. Can you just give us some color on how that compares to SUDS and the Liebowitz scale and how you're thinking about that endpoint in light of your most up-to-date knowledge from PALISADE? Thanks.

Shawn Singh

Yes, I'll work it backwards.

The adjustment disorder study has HAM-A as the primary endpoint, so a totally different disorder -totally different study design. In that study, the drug is given four times a day for 28 days, so it's a different type of disorder and a different type of scale that's necessary to assess potential benefit in that study – we're looking for a signal in that study, on HAM-A.

In terms of what we're seeing in the OLE cohort that I mentioned, it's nearly 200 subjects that have completed three months of use of PH94B and comparing their LSAS scores each month against their baseline. We're just looking at LSAS, and so we wouldn't be looking at HAM-A. In this case, these are just LSAS data, not SUDS-related data. But what we are seeing is, importantly, a significant number, even after one month, are showing a 20-point-plus reduction in SAD severity as measured by the LSAS, so that's an important point. Somewhere around one out of three of them is likely to see that kind of reduction based on this cohort's data after only one month.

John

Okay, thanks for the additional color.

Shawn Singh

You bet.

Operator

Our next question comes from Andrew Tsai from Jefferies. Please state your question.

Vijay Subramanian

Hi. This is Vijay on for Andrew. Thanks for taking our question.

Two questions on my part. Number one, the interim PALISADE-2 analysis, could you just give a little more detail on that? Where is that? Have you seen any data from the analysis? What you're looking to get out of the analysis.

Second question about the PALISADE-1 trial. What is your leading hypothesis in terms of what happened that drove the difference in the result between the Phase 2 and the Phase 3? Was there any separation with PH94B at all in the SUDS scores across the time points?

Shawn Singh

I'll answer the second one first. It sounds like this is like the San Francisco Giants lineup. We've got a lot of pinch hitters. So, happy to talk to you. I didn't catch your name. Sorry about that.

As to PAL-1, it's still too early. There's so much that we need to assess associated with that study. With the fact that we have the PALISADE-2 study in an interim analysis mode, we're just going to need more time to try to figure it out. There are obviously a lot of things that you can speculate about, but it would just be speculation: CMC-related, methodology-related, COVID-related, etc.

There's a lot of potential variables that could have brought noise into the study, especially a study that we had to scale up to 20 sites during the pandemic. So there'll be more on that later. We'll certainly expect to give more details at a future date, once we've been able to go through everything that is available, as the data continue to come through.

As to the interim analysis, again, it's an independent biostatistician interim analysis, so we don't get anything on that until the data are gathered by that statistician and then the interim analysis is generated. Sometime within the next—hopefully, in about a month or so, we'll see something — maybe in a little bit more than a month - we'll see some of the data from that interim analysis, and that'll give us some guidance, and some additional guidance to provide to the FDA when we get in front of them, hopefully before the end of the year—that's the goal—to discuss the path forward, which in large part will depend on what we learn about PALISADE-1 between now and that meeting, what we learn from the interim analysis between now and that meeting, and what we learn further from the open-label safety study between now and that meeting. There's been a lot of doses administered in that open-label safety study, over 25,000 doses, so we have a robust body of work.

There's been a lot that's been generated since the last time that we met with FDA in the middle of 2020 to settle on the design for PALISADE-1 and PALISADE-2, which was using the SUDS as the primary endpoint. We're going back into that discussion, obviously, with the mindset of seeing what we've seen or will see related to the PALISADE studies, but at the same time we're not going for an endpoint that is without precedent, right? The three approved drugs, they're all antidepressants, for social anxiety disorder were all approved on the basis of that gold-standard LSAS as the primary endpoint, which is why we've been focusing a lot on it.

Remember, as most of you will, that we had the two different studies in Phase 2, one that was real world-based with the LSAS as one of the endpoints, and then the other was the single-use assessment like PALISADE-1 and PALISADE-2 in a clinical environment. There will be a lot to talk about with the FDA, and what we do know is we're confident in the ability of the drug to make a difference in the lives of people, and that's what we've got to do now - we've got to find a study design that fits the unique pharmacology of the drug and what we're seeing in the studies that now involve multiple assessments over longer periods of time. That's how we see the drug being used in the real world.

Vijay Subramanian

Got it. Got it. Thank you. Yes, thank you for the details.

I understand that there is still a lot going on with PALISADE-1 and you're still figuring that out, but just wondering if you can share how the drug in placebo arms performed relative to Phase 2 at the primary endpoint? Was there a higher placebo response versus the Phase 2, for example?

Shawn Singh

Yes, we'll get to that later. We're not ready to put it out right now in the context of the interim analysis, and we need to see more data. But we'll put more details out on that at a future date. It didn't hit the primary endpoint, so it's as simple as that at this point.

Vijay Subramanian

Got it. Got it. Thank you.

Operator

Our next question comes from Brian Skorney from Baird. Please state your question.

Brian Skorney

Hey. Good afternoon, guys. Thanks for taking my question.

On the open-label extension and what you said about the 20-point reduction, just a couple of questions there. At what point is the 20-point reduction from? I think there was a couple of different time points. Is it going into the challenge itself? Is it some average baseline leading up to the challenge? Just trying to get a feel for when you say a 20-point reduction, that it's not at a peak anxiety portion of the study.

I assume, since it's open-label, everyone knows that they're going on treatment, so there's some placebo effect here. I guess, have you looked back historically at initiation, something that a patient's been told was an active treatment, what sort of placebo effect you could have in a three-month period?

Shawn Singh

Yes, Brian, those are good points. All solid. No question about it.

Remember, this study design is different than the PALISADE-1 study. This is, again, more like what we saw in the Phase 2 study where people took the drug and had it at home and had the ability to take it up to four times a day when needed over a two-week period.

Here, what happens, it's the same thing. People are assessed over multiple months;, they're assessed at baseline on LSAS at the visit when they're dispensed drug for the first time. The subsequent 20-point increase at one month was about 40%, at two months, a little bit over 40%, and at three months, a bit over 50% of that cohort saw reduced anxiety on the LSAS. Each month, it's compared against the baseline for that particular subject.

A 20-point drop anywhere on that Liebowitz Social Anxiety Scale, which for many of you, if you don't know, a scale that Dr. Liebowitz established, provides a score across 24 different questions, both as to fear or anxiety and also as to avoidance, so it's a combined score. But a 20-point reduction really on any point of the scale from where the subject was at baseline is a very significant change in that person's ability to manage their SAD. Let's say someone was a severe SAD subject and they dropped 20 points, on that scale, they would drop down to somewhere in the moderate social anxiety zone on the scale. We think 20 points is a big deal.

In some cases, it's been a little bit more than that, but what we saw is that basically for every two patients in that cohort who were treated with PH94B for three months, one of them would show a 20-point or greater reduction in SAD severity as measured on the LSAS. Even at the one-month point, it was basically one for every three or so patients that were treated with PH94B. Again, they're doing this at home, on their own, as provoked, as needed, because it's an acute as-needed dynamic that we want to assess with this drug - how people, when they are about to embrace what typically is an anxiety-provoking situation for them, social or performance, whatever it is, use the drug acutely, but whether the acute use over time builds confidence and success. Building on success, that's what we see underlying the continued improvement, and you use the LSAS to look back over the prior week, which is why it's more of a chronic clinical assessment tool.

These are the signals and, of course, there is something to be said about placebo. Typically, people aren't going to hang around in a long-term safety study. Placebo, at some point, doesn't work, but we're taking that into consideration. Again, it's just a signal, and it's going to be guiding us as to how we would design a go-forward Phase 3 study that can build on the composite framing of all the work that's been done so far.

Brian Skorney

Great. Thanks, Shawn.

Operator

At this time, we have no more questions.

Mark Flather

Thank you, Erica.

If you have any additional questions, please do not hesitate to get in touch with us by emailing ir@vistagen.com or contacting the individuals listed in our press release issued today. We also encourage you to sign up on our website to stay connected with the latest news from VistaGen.

Thank you for tuning in, and we appreciate everyone's attention and support. We look forward to keeping you current on our continuing progress. This concludes our call. Have a great day. You may all disconnect now.