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): June 29, 2021

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 2.02 Results of Operations and Financial Condition.

On June 29, 2021, VistaGen Therapeutics, Inc. (the "*Company*") issued a press release to announce the Company's financial results for its fiscal year ended March 31, 2021 and to provide a corporate update. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

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	Press Release issued by VistaGen Therapeutics, Inc., dated June 29, 2021

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: June 29, 2021

By: */s/ Shawn K. Singh*

Shawn K. Singh, J.D.
Chief Executive Officer

Exhibit 99.1

VistaGen Therapeutics Reports Fiscal Year 2021 Financial Results and Provides Corporate Update

PALISADE-1 Phase 3 trial underway to evaluate PH94B for rapid-onset acute treatment of anxiety in adults with social anxiety disorder (SAD)

Management to host corporate update conference call and audio webcast today at 2:00 p.m. PT

SOUTH SAN FRANCISCO, Calif., June 29, 2021 – VistaGen Therapeutics, Inc. (NASDAQ: VTGN), a biopharmaceutical company committed to developing and commercializing a new generation of medicines with the potential to go beyond the current standard of care for anxiety, depression and other central nervous system (CNS) disorders, today provided a corporate update and reported financial results for its fiscal year ended March 31, 2021.

“Our fiscal year 2021 was transformative, involving several drug development, financial and regulatory milestones that fortified the foundation for our very strong start this fiscal year. Notably, we achieved an important consensus with the U.S. Food and Drug Administration regarding our PALISADE Phase 3 program for PH94B in social anxiety disorder. Building on that positive meeting, we completed a PH94B collaboration in ex-U.S. markets, strengthened our balance sheet with substantial investment from numerous long-biased, healthcare-focused institutional investors, and advanced several development programs across our CNS pipeline, most notably preparations for PALISADE-1, our U.S. multi-center Phase 3 clinical study of PH94B as a potential rapid-onset, acute treatment of anxiety in adults with social anxiety disorder. If successful, PALISADE-1 is designed to be among the studies necessary to support a potential PH94B New Drug Application to the U.S. Food and Drug Administration in 2023. We recently initiated PALISADE-1, moving us closer to our goal of going beyond the current treatment paradigm for social anxiety disorder, not only displacing antidepressants, benzodiazepines and beta blockers, but also reaching those in need of support who find those therapies to be undesirable or inadequate. We anticipate topline data from PALISADE-1 in mid-2022. Later this year, we expect to launch PALISADE-2, a second U.S. multi-center Phase 3 clinical study of PH94B designed to be substantially similar to PALISADE-1 and equally supportive of our U.S. New Drug Application goal.”

Singh added, “During the current fiscal year, we also expect to prepare for and initiate several exploratory Phase 2A clinical trials of PH94B in additional anxiety disorders, advance preparations necessary to initiate a U.S. multi-center Phase 2B clinical trial of PH10 as a potential rapid-onset, stand-alone treatment for major depressive disorder, and initiate a Phase 1B clinical trial of AV-101 with probenecid, which, if successful, has the potential to support exploratory Phase 2A development of the combination in several CNS disorders.”

“To develop and commercialize game-changing treatments, you need great people. During the past year, we have strengthened our team by adding several key personnel with deep CNS drug development and commercial experience to drive our programs through important late-stage development milestones and appropriately-timed pre-commercial and commercial launch operations. We look forward to initiating several more clinical trials this fiscal year and remain focused on pursuing our mission to improve mental health and well-being for individuals in the U.S. and abroad,” concluded Singh.

Corporate Highlights

- Reached consensus with U.S. Food and Drug Administration (FDA) on key aspects of the design of Phase 3 clinical trials of PH94B for acute treatment of anxiety in adults with SAD after a positive meeting. The Phase 3 clinical studies of PH94B in the Company's PALISADE Phase 3 program will substantially mirror the public speaking challenge in the statistically significant Phase 2 study of PH94B, providing significant time and cost-efficiency for the program.

- Entered into a strategic licensing and collaboration agreement with EverInsight Therapeutics, Inc. (now AffaMed Therapeutics, Inc.) for clinical development and commercialization of PH94B in Greater China, South Korea and Southeast Asia (Territory), pursuant to which VistaGen received a non-dilutive upfront payment of $5 million. VistaGen is eligible to receive additional development and commercial milestone payments of up to $172 million and tiered royalties on sales of PH94B in the Territory, if Phase 3 development efforts there are successful.

- Reported positive preclinical data differentiating the mechanism of action (MOA) of PH94B and PH10 from risk-ridden benzodiazepines, demonstrating that the MOA of PH94B and PH10 does not involve direct activation of GABA-A receptors, in distinct contrast to the MOA of benzodiazepines, which act as direct positive modulators of GABA-A receptors.

- Reported positive preclinical data demonstrating the potential of the combination of AV-101 and probenecid to substantially increase the brain concentration of AV-101's active metabolite, 7-Cl-KYN, a potent and selective full antagonist of the NMDA receptor glycine co-agonist site, thereby reducing, rather than blocking, NMDA receptor signaling.

- Raised $127.5 million gross proceeds from partnering and corporate finance transactions, including a $100 million underwritten public offering led by Jefferies Group LLC and William Blair & Company involving significant participation from key healthcare-focused institutional investors, such as Acuta Capital, New Enterprise Associates, OrbiMed and Venrock Healthcare Capital Partners.

- Appointed key senior leadership to execute corporate initiatives through commercialization.

CNS Pipeline Updates

PH94B

PH94B is a synthetic investigational neurosteroid developed from proprietary compounds called pherines. With its novel MOA, PH94B is an odorless nasal spray administered at microgram-level doses to achieve rapid-onset anti-anxiety, or anxiolytic, effects. The novel pharmacological MOA of PH94B is fundamentally differentiated from that of all FDA-approved anti-anxiety drugs, including all antidepressants approved by the FDA for treatment of SAD, as well as all benzodiazepines and beta blockers prescribed on an off-label basis. PH94B engages peripheral chemosensory receptors in nasal passages that trigger a subset of neurons in the main olfactory bulbs (OB) at the base of the brain. The OB neurons then stimulate inhibitory GABAergic neurons in the limbic amygdala, decreasing the activity of the sympathetic nervous system, and facilitating fear extinction activity of the limbic-hypothalamic system, the main fear and anxiety center in the brain, as well as in other parts of the brain. Importantly, PH94B does not require systemic uptake and distribution to produce its rapid-onset anti-anxiety effects.

VistaGen recently initiated its PALISADE Phase 3 program with PALISADE-1, a U.S., multi-center, randomized, double-blind, placebo-controlled Phase 3 clinical study to evaluate the efficacy and safety of PH94B for the acute treatment of anxiety in adults with SAD. The Company expects to initiate PALISADE-2, the second U.S. Phase 3 study in its PALISADE Phase 3 program, in the second half of 2021. If successful, these clinical studies are designed to be among the studies necessary to support a potential U.S. New Drug Application (NDA) to the FDA. PH94B has been granted Fast Track designation status by the FDA for development as an acute treatment of anxiety in adults with SAD.

In addition to SAD, the Company is also preparing for exploratory Phase 2A clinical studies of PH94B in adults experiencing other anxiety disorders, including adjustment disorder with anxiety, postpartum anxiety, post-traumatic stress disorder, and pre-procedural anxiety.

PH10

PH10 is a synthetic investigational neurosteroid, which also was developed from proprietary compounds called pherines. Its novel, rapid-onset MOA is fundamentally differentiated from the MOA of all current treatments for major depressive disorder (MDD) and other depression disorders. PH10 is self-administered at microgram-level doses as an odorless nasal spray. PH10 activates nasal chemosensory cells in the nasal passages, connected to neural circuits in the brain that produce antidepressant effects. Specifically, PH10 engages peripheral chemosensory receptors in the nasal passages that trigger a subset of neurons in the main OB that stimulate neurons in the limbic amygdala. This is turn increases activity of the limbic-hypothalamic sympathetic nervous system and increases the release of catecholamines. Importantly, unlike all currently approved oral antidepressants, PH10 does not require systemic uptake and distribution to produce rapid-onset of antidepressant effects. In all clinical studies to date, PH10 has not caused psychological side effects (such as dissociation and hallucinations) or safety concerns that may be associated with rapid-onset ketamine-based therapy, including intravenous ketamine or intranasal ketamine.

Exploratory Phase 2A clinical development of PH10 for MDD has been completed. VistaGen is now preparing for Phase 2B clinical development of PH10. The Company expects to initiate a U.S. multi-center, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of PH10 as a potential stand-alone treatment for MDD in mid-2022. PH10 also has potential as a novel treatment for treatment-resistant depression, postpartum depression and suicidal ideation.

AV-101

AV-101 is an oral prodrug of 7-chloro-kynurenic acid (7-Cl-KYNA) and targets the N-methyl-D-aspartate receptor (NMDAR), an ionotropic glutamate receptor in the brain. Abnormal NMDAR function is associated with numerous CNS diseases and disorders. AV-101 is a potent and selective full antagonist of the glycine co-agonist site of the NMDAR that inhibits the function of the NMDAR. However, unlike ketamine and many other NMDAR antagonists, 7-Cl-KYNA is not an ion channel blocker. At doses administered in all studies to date, AV-101 has been observed to be orally bioavailable, well tolerated and has not exhibited dissociative or hallucinogenic psychological side effects or safety concerns. In light of these findings and data from preclinical studies, the Company believes that AV-101, in combination with FDA-approved probenecid, has potential to become a new oral treatment alternative for MDD and certain neurological indications involving the NMDAR.

VistaGen is currently preparing for a Phase 1B clinical study to evaluate AV-101 in combination with probenecid. The Company expects to initiate the study in the second half of 2021. The FDA has granted Fast Track designation for development of AV-101 as a potential adjunctive treatment for MDD and as a non-opioid treatment for neuropathic pain. AV-101 also has the potential to be developed as a treatment for levodopa-induced dyskinesia, suicidal ideation, and epilepsy.

Key senior leadership additions

VistaGen strengthened its leadership by adding key personnel with extensive CNS drug development and commercial experience to drive its clinical and commercial programs through important late-stage clinical development milestones and potential commercial launch and beyond. The Company recently added key team members in multiple areas such as clinical operations, research and development, CMC, regulatory affairs and commercial operations. Notably, the addition of Ann Cunningham as the Company’s Chief Commercial Officer has advanced pre-commercial planning for PH94B in SAD, as well as for a broad range of other anxiety and depression markets. The Company also added pharmaceutical industry veteran Dr. Joanne Curley to its Board of Directors. Dr. Curley has deep experience in pharmaceutical product development, operations, and commercialization.

Fiscal Year 2021 Financial Results

Revenue: The Company recognized $1.1 million in sublicense revenue from its $5 million non-dilutive upfront payment pursuant to its PH94B development and commercialization agreement with EverInsight Therapeutics (now AffaMed Therapeutics) during the year ended March 31, 2021, compared to none in the year ended March 31, 2020.

Research and development (R&D) expense: Research and development expense decreased from $13.4 million to $12.5 million for the years ended March 31, 2020 and 2021, respectively. The decrease is primarily due to the completion of a Phase 2 clinical study of AV-101 in MDD in Fiscal 2020, offset by increased development expenses for PH94B and PH10 in Fiscal 2021.

General and administrative (G&A) expense: General and administrative expense decreased to approximately $6.5 million from approximately $7.4 million for the years ended March 31, 2021 and 2020, respectively. Cash compensation expense for the year ended March 31, 2021 increased by approximately $0.7 million, including the impact of new employees, and was offset by a decrease of approximately $1.0 million in noncash stock-based compensation for the year ended March 31, 2021 compared to those expenses in the year ended March 31, 2020. Further, in the year ended March 31, 2020, the Company modified certain outstanding warrants and recognized non-cash warrant modification expense of approximately $0.8 million.

Net loss: Net loss for the fiscal years ended March 31, 2021 and 2020 was approximately $17.9 million and $20.8 million, respectively.

Cash Position: At March 31, 2021, the Company had cash and cash equivalents of approximately $103.1 million.

As of June 29, 2021, the Company had 191,382,350 shares of common stock outstanding.

Conference Call

VistaGen will host a conference call and live audio webcast this afternoon at 2:00 p.m. Pacific Time to provide a corporate update and discuss its financial results for its fiscal year ended March 31, 2021.

U.S. Dial-in (Toll Free): 1-877-407-9716
International Dial-in Number (Toll): 1-201-493-6779
Conference ID: 13720908
Webcast Link: **http://public.viavid.com/index.php?id=145419**

A telephone playback of the conference call will be available after approximately 5:00 p.m. Pacific Time on June 29, 2020. To listen to the replay, call toll free 1-844-512-2921 within the United States or 1-412-317-6671 when calling internationally (toll). Please use the replay PIN number 13720908.

About VistaGen
VistaGen Therapeutics is a biopharmaceutical company committed to developing and commercializing innovative medicines with the potential to go beyond the current standard of care for anxiety, depression, and other CNS disorders. Each of VistaGen's drug candidates has a differentiated potential mechanism of action, has been well-tolerated in all clinical studies to date and has therapeutic potential in multiple CNS indications. For more information, please visit www.VistaGen.com and connect with VistaGen on Twitter, LinkedIn, and Facebook.

Forward Looking Statements

This press release contains certain forward-looking statements within the meaning of the federal securities laws. These forward-looking statements involve known and unknown risks that are difficult to predict and include all matters that are not historical facts. In some cases, you can identify forward-looking statements by the use of words such as “may,” “could,” “expect,” “project,” “outlook,” “strategy,” “intend,” “plan,” “seek,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “strive,” “goal,” “continue,” “likely,” “will,” “would” and variations of these terms and similar expressions, or the negative of these terms or similar expressions. Such forward-looking statements are necessarily based upon estimates and assumptions that, while considered reasonable by us and our management, are inherently uncertain. Our actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include, without limitation, risks and uncertainties relating to delays in launching and/or conducting our planned clinical trials, including delays due to the impact of the COVID-19 pandemic; fluctuating costs of materials and other resources required to conduct our planned clinical and non-clinical trials; market conditions; the impact of general economic, industry or political conditions in the United States or internationally; adverse healthcare reforms and changes of laws and regulations; manufacturing and marketing risks, which may include, but are not limited to, unavailability of or delays in delivery of raw materials for manufacture of our CNS drug candidates and difficulty in initiating or conducting clinical trials; inadequate and/or untimely supply of one or more of our CNS drug candidates to meet demand; entry of competitive products; and other technical and unexpected hurdles in the development, manufacture and commercialization of our CNS drug candidates; and the risks more fully discussed in the section entitled "Risk Factors" in our most recent Annual Report on Form 10-K for the fiscal year ended March 31, 2021, filed earlier today, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the U.S. Securities and Exchange Commission (SEC). Our SEC filings are available on the SEC’s website at www.sec.gov. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press release and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements, other than as may be required by law. If we do update one or more forward-looking statements, no inference should be made that we will make additional updates with respect to those or other forward-looking statements.

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VISTAGEN THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(Amounts in dollars, except share amounts)

	March 31, 2021	March 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 103,108,300	$ 1,355,100
Receivable from collaboration partner	40,600	-
Prepaid expenses and other current assets	835,100	225,100
Deferred contract acquisition costs - current portion	133,500	-
Total current assets	104,117,500	1,580,200
Property and equipment, net	367,400	209,600
Right of use asset - operating lease	3,219,600	3,579,600
Deferred offering costs	294,900	355,100
Deferred contract acquisition costs - non-current portion	234,100	-
Security deposits and other assets	47,800	47,800
Total assets	$ 108,281,300	$ 5,772,300
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 838,300	$ 1,836,600
Accrued expenses	1,562,700	561,500
Current notes payable	-	56,500
Deferred revenue - current portion	1,420,200	-
Operating lease obligation - current portion	364,800	313,400
Financing lease obligation - current portion	3,000	3,300
Total current liabilities	4,189,000	2,771,300
Non-current liabilities:		
Accrued dividends on Series B Preferred Stock	6,272,700	5,011,800
Deferred revenue - non-current portion	2,490,300	-
Operating lease obligation - non-current portion	3,350,800	3,715,600
Financing lease obligation - non-current portion	-	3,000
Total non-current liabilities	12,113,800	8,730,400
Total liabilities	16,302,800	11,501,700
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2021 and 2020:		
Series A Preferred, 500,000 shares authorized, issued and outstanding at March 31, 2021 and 2020	500	500
Series B Preferred; 4,000,000 shares authorized at March 31, 2021 and 2020; 1,131,669 shares and 1,160,240 shares issued and outstanding at March 31, 2021 and 2020, respectively	1,100	1,200
Series C Preferred; 3,000,000 shares authorized at March 31, 2021 and 2020; 2,318,012 shares issued and outstanding at March 31, 2021 and 2020	2,300	2,300
Series D Preferred; 2,000,000 shares and no shares authorized at March 31, 2021 and 2020, respectively; 402,149 shares and no shares issued and outstanding at March 31, 2021 and March 31, 2020, respectively	400	-
Common stock, $0.001 par value; 325,000,000 shares and 175,000,000 shares authorized at March 31, 2021 and 2020, respectively; 180,751,234 and 49,348,707 shares issued at March 31, 2021 and 2020, respectively	180,800	49,300
Additional paid-in capital	315,603,100	200,092,800
Treasury stock, at cost, 135,665 shares of common stock held at March 31, 2021 and 2020	(3,968,100)	(3,968,100)
Accumulated deficit	(219,841,600)	(201,907,400)
Total stockholders' equity (deficit)	91,978,500	(5,729,400)
Total liabilities and stockholders' equity (deficit)	$ 108,281,300	$ 5,772,300

VISTAGEN THERAPEUTICS

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Amounts in Dollars, except share amounts)

	Fiscal Years Ended March 31,	
	2021	**2020**
Sublicense revenue	$ 1,089,500	$ -
Total revenues	1,089,500	-
Operating expenses:		
Research and development	12,476,400	13,374,200
General and administrative	6,546,900	7,427,300
Total operating expenses	19,023,300	20,801,500
Loss from operations	(17,933,800)	(20,801,500)
Other income and expenses, net:		
Interest income, net	1,600	30,100
Other income	600	-
Loss before income taxes	(17,931,600)	(20,771,400)
Income taxes	(2,600)	(2,600)
Net loss and comprehensive loss	$ (17,934,200)	$ (20,774,000)
Accrued dividends on Series B Preferred stock	(1,385,600)	(1,263,600)
Beneficial conversion feature on Series D Preferred stock	(23,000,000)	-
Net loss attributable to common stockholders	$ (42,319,800)	$ (22,037,600)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.49)	$ (0.50)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	86,133,644	43,869,523