Vistagen Provides Corporate Update and Reports Fiscal Year 2023 Financial Results

June 28, 2023

Positive results in Phase 3 open label study of fasedienol (PH94B) in social anxiety disorder (SAD)

Positive U.S. Food and Drug Administration (FDA) feedback on the use of the Liebowitz Social Anxiety Scale (LSAS) as the primary efficacy endpoint in future Phase 3 studies of fasedienol in SAD

Successful itruvone (PH10) U.S. Phase 1 study supports previous successful Phase 1 studies and a positive Phase 2A study in major depressive disorder (MDD) conducted outside the U.S. and facilitates next-step U.S. Phase 2B development in MDD

Clinical-stage pipeline expanded to six differentiated product candidates targeting multiple large CNS markets

Pursuing multiple global and regional strategic development and commercialization partnerships to accelerate clinical and regulatory milestones across the CNS pipeline

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 28, 2023-- Vistagen (Nasdaq: VTGN), a late clinical-stage biopharmaceutical company aiming to transform the treatment landscape for individuals living with anxiety, depression and other central nervous system (CNS) disorders, today provided a corporate update and reported financial results for its fiscal year 2023 ended March 31, 2023.

“We continue to make significant progress across our CNS pipeline, which now includes six innovative clinical-stage product candidates, each with a differentiated mechanism of action, a favorable safety profile and substantial potential to improve millions of lives affected by anxiety, depression, hot flashes due to menopause and several other large market CNS disorders without therapeutic options that adequately satisfy patient needs,” said Shawn Singh, Chief Executive Officer of Vistagen. “Our deep understanding of the science and therapeutic potential underlying each of our product candidates provides a firm foundation for our confidence in our future. Given the collective body of positive safety and efficacy studies supporting our clinical-stage pipeline, now is the opportune time to amplify our efforts with multiple global and regional strategic development and commercialization partnerships across our portfolio to accelerate achieving key clinical and regulatory milestones within each program.”

Corporate Update

Positive results from PALISADE Phase 3 open label study amplify placebo-controlled Phase 2 studies of fasedienol (PH94B) in SAD and inform next steps in Phase 3 development to address a large and growing global unmet need.

Earlier this year, the Company reported that long-term administration of 3.2 µg of fasedienol, taken as-needed up to four times per day in a real-world setting, was well-tolerated with no new safety findings or trends identified, regardless of the number of doses administered by each subject. Overall, patients self-administered over 30,000 doses of fasedienol during the study with a mean duration of 4 months and a maximum study duration of over 10 months. Additionally, exploratory efficacy results from the study demonstrated clinically meaningful reductions in fear, anxiety and avoidance of anxiety-provoking social and performance situations in daily life, as measured by the Liebowitz Social Anxiety Scale (LSAS). We believe the continued improvement in LSAS scores observed in the study indicates the therapeutic potential of multiple, patient-tailored as-needed administrations of fasedienol over time to help patients build confidence and resilience, enabling them to engage in anxiety-provoking social and performance situations in their daily lives more frequently and with less fear and anxiety.

Positive FDA feedback on the path forward for development of fasedienol for SAD – FEARLESS Phase 3 program to center on the three prior FDA approvals in SAD using the LSAS as the primary efficacy endpoint.

In the first quarter of calendar 2023, the Company met with the FDA to discuss the next steps in its FEARLESS Phase 3 development plan for fasedienol in SAD, including conducting a potential New Drug Application (NDA)-enabling Phase 3 study of fasedienol in a real-world setting using the LSAS as the primary efficacy outcome measure in a manner similar to the registration studies for the three FDA-approved treatments for SAD. Support for an LSAS-based study design is demonstrated in the Company’s prior placebo-controlled Phase 2 study of fasedienol in SAD, in which the amount of separation between fasedienol and placebo as measured by the LSAS at the end of the first 2 weeks was comparable to what was observed after 12 weeks in the registration trials for the antidepressants currently approved by the FDA for treatment of SAD. Using the LSAS as the primary efficacy endpoint, all prior registration studies for these approved medications were positive.

Positive feedback from the FDA confirmed the acceptable use by the Company of the LSAS as a primary efficacy endpoint in its Phase 3 study of fasedienol for the treatment of SAD. Previously, the FDA granted Fast Track designation for the development of fasedienol for the treatment of SAD. Accordingly, the Company is now positioned to finalize key components of its NDA-enabling FEARLESS Phase 3 development program for fasedienol in SAD.

In contrast to the Company’s PALISADE Phase 3 single administration public speaking challenge studies in SAD conducted during the acute stage of the COVID-19 pandemic, the Company’s FEARLESS program in SAD will align with the LSAS-based study design supporting the precedent-setting NDA-enabling programs for the three antidepressants currently approved for treatment of SAD. The Company’s FEARLESS Phase 3 studies will be designed to assess multiple administrations of fasedienol, on a patient-tailored, as-needed basis in their daily lives, up to six times per day, in a real-world outpatient setting over a multiple-week period, with the clinician-administered LSAS as the primary efficacy endpoint. Dr. Michael R. Liebowitz, a Columbia University psychiatrist, former director and founder of the Anxiety Disorders Clinic at the New York State Psychiatric Institute and current Managing Director of The Medical Research Network LLC in New York City, is the creator of the LSAS. Dr. Liebowitz is a renowned authority on SAD and will serve as the Principal Investigator for the Company’s FEARLESS Phase 3 program in SAD.

Successful itruvone (PH10) U.S. Phase 1 clinical trial supports previous successful Phase 1 and Phase 2 studies conducted outside the U.S. and enables U.S. Phase 2B development in MDD.

Recently, the Company reported favorable safety and tolerability data from its U.S. Phase 1 clinical trial of itruvone, its innovative stand-alone, rapid-onset Phase 2 product candidate for the treatment of MDD. Itruvone nasal spray was well-tolerated and consistently continued to demonstrate a favorable safety profile. Results from this study build on previous successful Phase 1 studies and a positive placebo-controlled Phase 2A study of itruvone in MDD conducted outside the U.S. The successful U.S. Phase 1 study is expected to facilitate next step Phase 2B clinical development of itruvone in the U.S. During the past year, the FDA granted Fast Track designation for the development of itruvone for the treatment of MDD.

Positive results reported from Phase 2A study of PH80 in women diagnosed with vasomotor symptoms (hot flashes) due to menopause.

The Company recently reported that PH80 nasal spray demonstrated statistically significant efficacy versus placebo in a previously unreported exploratory placebo-controlled Phase 2A study for the acute treatment of vasomotor symptoms (hot flashes) due to menopause. PH80 induced a statistically significant reduction in the daily number of menopausal hot flashes compared to placebo at the end of the first week of treatment ($p<.001$), and the improvement was maintained through each treatment week until the end of the four-week treatment period. PH80 treatment also significantly reduced the severity, disruption in function and sweating related to hot flashes during the treatment period as compared with placebo. PH80 was well-tolerated with no serious adverse events, and the adverse event profiles were comparable between PH80 and placebo.

New U.S. and European patents expand PH80 intellectual property portfolio to include treatment of migraine.

PH80 is designed to initiate neural impulses in the olfactory bulb transmitted by pathways that rapidly affect the function of multiple structures in the brain, including the amygdala and hypothalamus, which have been linked to the pathology of migraine. Due to its innovative mechanism of action, the Company believes PH80 also has therapeutic potential to relieve premonitory and aura symptoms of migraines. Earlier this year, the U.S. Patent and Trademark Office granted a U.S. patent for PH80 nasal spray for treatment of migraine and the European Patent Office (EPO) issued an intention to grant a patent for the treatment of migraine by intranasal administration of PH80, thereby expanding the intellectual property portfolio of PH80 as the Company prepares for potential future development.

AV-101 receives additional European patent bolstering intellectual property portfolio.

Based on observations and findings from preclinical and clinical studies, the Company believes that AV-101 has the potential to become a new oral treatment alternative for multiple CNS indications involving the NMDAR (N-methyl-D-aspartate receptor). The Company is currently pursuing partnering and non-dilutive grant opportunities for Phase 2A clinical development of AV-101 as a treatment for one or more neurological disorders involving the NMDAR. Recently, the Company strengthened its AV-101 intellectual property portfolio after receiving a new patent granted by the EPO related to the synthesis of AV-101 and certain chemical intermediaries, which yields AV-101 in commercial quantities and has the scalability for commercial manufacture. The expanded intellectual property portfolio significantly enhances the attractiveness of AV-101 as a valuable asset for potential strategic development and commercialization partnerships.

The Company is pursuing multiple strategic global and regional development and commercialization partnerships to accelerate the achievement of a series of late-stage clinical and regulatory milestones across its CNS pipeline.

The Company now has six clinical-stage CNS product candidates. Given the depth of positive clinical studies assessing efficacy and safety of its CNS pipeline, the Company is pursuing multiple strategic development and commercialization partnerships, both global and regional, to efficiently unlock the full value of its product candidate portfolio. The Company believes global and regional partnerships designed to amplify its internal activities can accelerate key development timelines and regulatory milestones for each of its product candidates, enhancing the Company's ongoing efforts to deliver differentiated treatment options with improved efficacy and favorable safety profiles to millions of individuals suffering from anxiety, depression and other CNS disorders worldwide.

Fiscal Year 2023 Financial Results

***Research and development (R&D) expense*:** Research and development expense increased by approximately $9.0 million, from $35.4 million to $44.4 million for the fiscal years ended March 31, 2022 and 2023, respectively. The increase in R&D expense is primarily due to fasedienol development in SAD and adjustment disorder with anxiety, as well as nonclinical development and outsourced manufacturing and regulatory activities for fasedienol and itruvone.

***General and administrative (G&A) expense*:** General and administrative expense increased by approximately $1.2 million from $13.5 million to $14.7 million for the fiscal years ended March 31, 2022 and 2023, respectively.

***Net loss*:** Net loss attributable to common stockholders for the fiscal years ended March 31, 2022 and 2023 was approximately $48.7 million and $59.2 million, respectively.

***Cash position*:** At March 31, 2023, the Company had cash and cash equivalents of approximately $16.6 million.

As of June 27, 2023, the Company had 7,872,479 shares of common stock outstanding, which reflects the impact of the recent 1-for-30 reverse stock split, which enabled the Company to regain full compliance with the continued listing standards of the Nasdaq Capital Market.

Conference Call

Vistagen will host a conference call and live audio webcast this afternoon at 4:30 p.m. Eastern Time to provide a corporate update for its fiscal year 2023 ended March 31, 2023.

U.S. Dial-in (Toll-Free): 1-877-407-9716
International Dial-in Number (Toll): 1-201-493-6779
Conference ID: 13739679
Webcast Link: https://viavid.webcasts.com/starthere.jsp?ei=1622868&tp_key=e466ec0ec7

A live audio webcast of the conference call will also be available via the link provided above. Participants should access this webcast site 10 minutes

before the start of the call. In addition, a telephone playback of the call will be available after approximately 8:00 p.m. Eastern Time on Wednesday, June 28, 2023. 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 13739679.

About Vistagen

Vistagen (Nasdaq: VTGN) is a late clinical-stage biopharmaceutical company aiming to transform the treatment landscape for individuals living with anxiety, depression and other CNS disorders. Vistagen is advancing therapeutics with the potential to be faster-acting, and with fewer side effects and safety concerns, than those currently available for treatment of anxiety, depression and multiple CNS disorders. Vistagen's pipeline includes six clinical-stage product candidates, including fasedienol (PH94B), itruvone (PH10), PH15, PH80, and PH284, each an investigational agent belonging to a new class of drugs known as pherines, as well as AV-101, which is an oral antagonist of the N-methyl-D-aspartate receptor (NMDAR). Pherines, which are administered as low-dose nasal sprays, are designed with a novel rapid-onset mechanism of action that activates chemosensory neurons in the nasal cavity and can beneficially impact key neural circuits in the brain without systemic uptake or direct activity on CNS neurons in the brain. Vistagen is passionate about transforming mental health care and redefining what is possible in the treatment of anxiety, depression and several other CNS disorders. Connect at www.Vistagen.com.

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 Vistagen and its management, are inherently uncertain. As with all pharmaceutical products, there are substantial risks and uncertainties in the process of development and commercialization and actual results or developments may differ materially from those projected or implied in these forward-looking statements. Among other things, there can be no guarantee that any of the Company's drug candidates will successfully complete ongoing or, if initiated, future clinical trials, receive regulatory approval or be commercially successful, or that the Company will be able to successfully replicate the result of past studies of its product candidates, including fasedienol, itruvone, AV-101 and/or PH80. Other factors that may cause such a difference include, without limitation, risks and uncertainties relating to the Company's ability to secure adequate financing for its operations, including financing or collaborative support for continued clinical development of the Company's product candidates; risks and uncertainties related to the Company's ability to secure successful strategic global and/or regional development and commercialization partnerships; other risks and uncertainties related to delays in launching, conducting and/or completing ongoing and planned clinical trials; the scope and enforceability of the Company's patents, including patents related to the Company's pherine drug candidates and AV-101; fluctuating costs of materials and other resources and services required to conduct the Company's ongoing and/or planned clinical and non-clinical trials; market conditions; the impact of general economic, industry or political conditions in the United States or internationally; and other technical and unexpected hurdles in the development, manufacture and commercialization of the Company's product candidates. These risks are more fully discussed in the section entitled "Risk Factors" in the Company's recently filed Annual Report on Form 10-K for the fiscal year ended March 31, 2023, 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). The Company's 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 the Company's views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements other than as may be required by law. If the Company does update one or more forward-looking statements, no inference should be made that the Company will make additional updates with respect to those or other forward-looking statements.

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

	March 31, 2023	March 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,637,600	$ 68,135,300
Prepaid expenses and other current assets	802,700	2,745,800
Deferred contract acquisition costs - current portion	67,100	116,900
Total current assets	17,507,400	70,998,000
Property and equipment, net	507,300	414,300
Right-of-use asset - operating lease	2,260,300	2,662,000

Deferred offering costs	495,700	321,800
Deferred contract acquisition costs - non-current portion	217,600	146,400
Security deposits	100,900	100,900
Total assets	$ 21,089,200	$ 74,643,400
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,473,100	$ 2,758,600
Accrued expenses	787,400	1,329,200
Note payable	105,300	-
Deferred revenue - current portion	714,300	1,244,000
Operating lease obligation - current portion	485,600	433,300
Financing lease obligation - current portion	1,700	-
Total current liabilities	4,567,400	5,765,100
Non-current liabilities:		
Deferred revenue - non-current portion	2,314,600	1,557,600
Operating lease obligation - non-current portion	2,119,800	2,605,400
Financing lease obligation - non-current portion	7,400	-
Total non-current liabilities	4,441,800	4,163,000
Total liabilities	9,009,200	9,928,100
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2023 and March 31, 2022: no shares outstanding at March 31, 2023 and March 31, 2022	-	-
Common stock, $0.001 par value; 325,000,000 shares authorized at March 31, 2023 and March 31, 2022; 7,315,404 and 6,889,221 shares issued at March 31, 2023 and March 31, 2022, respectively	7,300	6,900
Additional paid-in capital	342,892,500	336,280,500
Treasury stock, at cost, 4,522 shares of common stock held at March 31, 2023 and March 31, 2022	(3,968,100)	(3,968,100)
Accumulated deficit	(326,851,700)	(267,604,000)
Total stockholders' equity	12,080,000	64,715,300
Total liabilities and stockholders' equity	$ 21,089,200	$ 74,643,400

References to common shares and per share amounts have been retroactively restated to reflect the Company's 1-for-30 reverse stock split of its common stock effective on June 6, 2023.

VISTAGEN THERAPEUTICS
CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS
(Amounts in Dollars, except share amounts)

	Fiscal Years Ended March 31,	
	2023	**2022**
Revenues:		
Sublicense revenue	$ (227,300)	$ 1,108,900
Total revenues	(227,300)	1,108,900
Operating expenses:		
Research and development	44,377,100	35,407,800
General and administrative	14,663,600	13,480,000
Total operating expenses	59,040,700	48,887,800
Loss from operations	(59,268,000)	(47,778,900)
Other income, net:		
Interest income, net	26,200	19,900
Loss before income taxes	(59,241,800)	(47,759,000)
Income taxes	(5,900)	(3,400)
Net loss and comprehensive loss	(59,247,700)	(47,762,400)
Accrued dividend on Series B Preferred stock	-	(945,100)
Net loss attributable to common stockholders	$ (59,247,700)	$ (48,707,500)
Basic and diluted net loss attributable to common stockholders per common share	$ (8.51)	$ (7.38)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	6,958,749	6,599,287

References to common shares and per share amounts have been retroactively restated to reflect the Company's 1-for-30 reverse stock split of its common stock effective on June 6, 2023.

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Investors:
Mark McPartland
Senior Vice President, Investor Relations
(650) 577-3606
markmcp@vistagen.com

Media:
Nate Hitchings
SKDK
nhitchings@skdknick.com

Source: Vistagen