

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): **March 1, 2023**

Vistagen Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

NEVADA

(State or other jurisdiction of
incorporation)

000-54014

(Commission File Number)

20-5093315

(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 8.01 Other Events

On March 1, 2023, Vistagen Therapeutics, Inc. (the “Company”) issued a press release to announce that the U.S. Patent and Trademark Office has granted U.S. Patent No. 11,419,881 for treatment of migraine headache with PH80, the Company’s investigational pherine nasal spray designed with a potential rapid-onset mechanism of action. The newly issued patent will be in effect until at least 2040. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits Index**

Exhibit No.	Description
99.1	Press Release issued by Vistagen Therapeutics, Inc., dated March 1, 2023.
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: March 1, 2023

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



Vistagen Announces Issuance of U.S. Patent for PH80 Nasal Spray for Treatment of Migraine

PH80 patent portfolio now includes U.S. patents for treatment of both hot flashes and migraine

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Mar. 1, 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 announced that the U.S. Patent and Trademark Office (USPTO) has granted a U.S. patent for Vistagen's PH80 nasal spray for treatment of migraine. The newly issued patent will be in effect until at least 2040.

PH80 is an investigational pherine nasal spray designed with a potential rapid-onset mechanism of action that is fundamentally differentiated from all currently approved treatments for migraine. PH80 does not require systemic exposure to produce an effect, providing a significant potential therapeutic advantage over traditional pharmaceuticals targeted at the CNS. PH80 nasal spray initiates neural impulses in the olfactory bulb transmitted by pathways that rapidly affect brain function, including the amygdala and hypothalamus, which have been linked to the pathology of migraine.

Migraine affects about 40 million adults in the U.S. each year, and while approved treatments are available, many individuals could benefit from safer and more efficacious treatment options. PH80 has the potential to be a safe, fast-acting, easy to use nasal spray for the treatment of migraine.

Vistagen's recently completed acquisition of Pherin Pharmaceuticals resulted in the full ownership of intellectual property rights worldwide to five pherine drug candidates, including, the newly issued PH80 patent for the treatment of migraine (U.S. Patent 11,419,881), among others.

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. The Company is advancing therapeutics with the potential to be faster-acting, and with fewer side effects and safety concerns, than those that are currently available for treatment of anxiety and depression and other CNS disorders. Several of Vistagen's product candidates belong to a new class of drugs known as pherines, which are designed with a novel rapid-onset mechanism of action that activates chemosensory neurons in the nasal passages and can impact key neural circuits 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 and depression. 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 the scope of protection provided by the U.S. patents issued for any of the Company’s drug candidates, including PH80, PH94B, PH10 or any other pherine drug candidate, will be sufficient to deter competition; any of Vistagen’s drug candidates will successfully complete ongoing or future clinical trials, receive regulatory approval or be commercially successful; Vistagen’s ability to realize the anticipated benefits of the acquisition of Pherin, including the possibility that the expected benefits will not be realized or will not be realized within the expected time period; or unknown liabilities that may or may not be within Vistagen’s control. Certain of these risks are more fully discussed in the section entitled “Risk Factors” in the Company’s most recent Annual Report on Form 10-K for the fiscal year ended March 31, 2022 and in the Company’s most recent Quarterly Report on Form 10-Q for the quarter ended December 31, 2022, 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.

Investors

Mark Flather
Vice President, Investor Relations
(650) 577-3617
mflather@vistagen.com

Media

Nate Hitchings
SKDK
nhitchings@skdknick.com

Source: Vistagen