

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): October 14, 2021

VENUS CONCEPT INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38238
(Commission
File Number)

06-1681204
(IRS Employer
Identification Number)

235 Yorkland Blvd, Suite 900
Toronto, Ontario M2J 4Y8
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (877) 848-8430

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, \$0.0001 par value per share	VERO	The Nasdaq Global Market

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

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 October 19, 2021, Venus Concept issued a press release relating to receipt of FDA 510(k) clearance to market and sell Venus Freedom, a new product intended for treatment of minor muscle aches and pain, relief of muscle spasm, and temporary improvement of local blood circulation. A copy of the press release is attached hereto and filed as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release dated October 19, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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

VENUS CONCEPT INC.

Date: October 19, 2021

By: /s/ Domenic Della Penna

Domenic Della Penna
Chief Financial Officer



Venus Concept Receives FDA 510(k) Clearance for the Venus Freedom™

TORONTO, October 19, 2021, (GLOBE NEWSWIRE) - Venus Concept Inc. (“Venus Concept” or the “Company”) (NASDAQ: VERO), a global medical aesthetic technology leader, today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (“FDA”) to market the Venus Freedom device in the United States.

Venus Freedom is a noninvasive, non-ablative device with three applicators for the delivery of non-thermal radiofrequency energy combined with massage and magnetic field pulses. It is intended for the treatment of minor muscle aches and pain, relief of muscle spasm, and temporary improvement of local blood circulation.

“Following the receipt of Health Canada authorization for our Venus Fiore Feminine Health System in July, we are very pleased to further expand our portfolio of technologies that can treat a broad range of common women’s health conditions with the FDA 510(k) clearance of Venus Freedom,” said Domenic Serafino, Chief Executive Officer and Director of Venus Concept Inc. “Venus Concept devoted nearly six years to developing this technology in order to create a comprehensive, safe and effective system that has the ability to treat a variety of different women’s wellness issues, addressing important medical needs and supported with significant clinical data. We look forward to commencing a limited launch of the Venus Freedom in the U.S. during the first quarter of 2022. We intend to sell the Venus Freedom using a unique utilization-focused business model which we believe will make the return on investment of this system very attractive for both Venus Concept and the OBGYN community.”

The receipt of FDA 510(k) clearance for Venus Freedom follows the recent receipt of Health Canada authorization to market the Venus Fiore Feminine Health System in July 2021. In Canada, Venus Fiore is intended for women who are post-menopausal, or have undergone surgically induced menopause, and is intended to treat the vaginal canal to improve symptoms of vaginal laxity and for increased sexual function, skin tightening/improvement in skin laxity of the Mons Pubis (MP) anatomy and the Labia Majora (LA) anatomy and to improve blood flow.

About Venus Concept

Venus Concept is an innovative global medical aesthetic technology leader with a broad product portfolio of minimally invasive and non-invasive medical aesthetic and hair restoration technologies and reach in over 60 countries and 19 direct markets. Venus Concept focuses its product sales strategy on a subscription-based business model in North America and in its well-established direct global markets. Venus Concept’s product portfolio consists of aesthetic device platforms, including Venus Versa, Venus Legacy, Venus Velocity, Venus Fiore, Venus Freedom, Venus Viva, Venus Freeze Plus, Venus Glow, Venus Bliss, Venus Epileve and Venus Viva MD. Venus Concept’s hair restoration systems include NeoGraft®, an automated hair restoration system that facilitates the harvesting of follicles during a FUE process and the ARTAS® and ARTAS iX® Robotic Hair Restoration systems, which harvest follicular units directly from the scalp and create recipient implant sites using proprietary algorithms. Venus Concept has been backed by leading healthcare industry growth equity investors including EW Healthcare Partners (formerly Essex Woodlands), HealthQuest Capital, Longitude Capital Management, and Aperture Venture Partners.



Cautionary Statement Regarding Forward-Looking Statements

This communication contains “forward-looking” statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “1933 Act”) and Section 21E of the Securities Exchange Act of 1934, as amended (the “1934 Act”). Any statements contained herein that are not of historical facts may be deemed to be forward-looking statements. In some cases, you can identify these statements by words such as “anticipates,” “believes,” “plans,” “expects,” “projects,” “future,” “intends,” “may,” “should,” “could,” “estimates,” “predicts,” “potential,” “continue,” “guidance,” and other similar expressions that are predictions of or indicate future events and future trends. These forward-looking statements include, but are not limited to, statements about our financial performance; the growth in demand for our systems and other products; and general economic conditions, including the global economic impact of COVID-19, and involve risks and uncertainties that may cause results to differ materially from those set forth in the statements. These forward-looking statements are based on current expectations, estimates, forecasts, and projections about our business and the industry in which the Company operates and management’s beliefs and assumptions and are not guarantees of future performance or developments and involve known and unknown risks, uncertainties, and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this communication may turn out to be inaccurate. Factors that could materially affect our business operations and financial performance and condition include, but are not limited to, those risks and uncertainties described under Part I Item 1A - “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, Part II Item 1 A - “Risk Factors” in our Form 10 Q for the quarter ended June 30, 2021 and in other documents the Company may file with the SEC. You are urged to consider these factors carefully in evaluating the forward-looking statements and are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are based on information available to us as of the date of this communication. Unless required by law, the Company does not intend to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise.

Investor Relations Contact:

Westwicke Partners on behalf of Venus Concept:

Mike Piccinino, CFA

VenusConceptIR@westwicke.com
