

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): September 14, 2023

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 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 (§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 September 14, 2023, Venus Concept Inc. (the “Company”) issued a press release relating to its receipt of 510(k) clearance from the U.S. Food and Drug Administration (the “FDA”) to market the Venus Versa Pro System, the Company’s new multi-application platform, for a variety of aesthetic and cosmetic procedures. A copy of the press release regarding the above-described FDA clearance is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release dated September 14, 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, 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: September 14, 2023

By: /s/ Domenic Della Penna

Domenic Della Penna
Chief Financial Officer

Venus Concept Receives 510(k) Clearance for the Venus Versa Pro System, Its New Multi-Application Platform

TORONTO, September 14, 2023 (GLOBE NEWSWIRE) -- Venus Concept Inc. ("Venus Concept" or the "Company") (NASDAQ: VERO), a global medical aesthetic technology leader, announced today that it has received a 510(k) clearance from the U.S. Food and Drug Administration ("FDA") to market its Venus Versa Pro System, the Company's new multi-application platform, for a variety of aesthetic and cosmetic procedures.

Venus Versa is a modular system based on a multi-application approach. It is customizable and upgradable and offers the most in-demand aesthetic treatments by supporting 10 optional applicators which utilize Venus Concept's (MP)², IPL and NanoFractional RF technologies. Designed as a modular platform, the Venus Versa can be configured to best suit any practice's needs with the ability to add additional applications as the practice grows or changes.

The all new Venus Versa Pro System expands on the already comprehensive Venus Versa platform by incorporating proprietary advances in NanoFractional RF technologies from our dedicated skin resurfacing system, Venus VivaMD, providing higher power and deeper skin penetration for optimal results.

"This important clearance is a direct outcome of the new strategic plan we implemented earlier this year," said Rajiv De Silva, Chief Executive Officer of Venus Concept. "Our new strategy has led us to prioritize the allocation of resources to our most promising growth opportunities and focus on continued innovation to accelerate our path to long-term, sustainable, profitability and growth. We anticipate that the Venus Versa Pro System will be an important contributor to revenue growth in 2024."

"The Venus Versa Pro System once again demonstrates our commitment to continue to build upon our robust R&D pipeline," said Hemanth Varghese, President & Chief Innovation and Business Officer of Venus Concept. "The advancements we are introducing in the Venus Versa Pro System, will provide superior, comprehensive technologies to support our existing and future customers, and address the growing demand for multi-modal solutions in aesthetics. Venus Versa has been one of the company's best-selling products over the last 5 years with thousands of installations worldwide. We are confident that its new generation Venus Versa Pro System, can surpass the success of Venus Versa, offering our existing customer base an attractive upgrade option, as well as offering new customers a new standard of care to address nearly all their patient's aesthetic concerns with one platform. We look forward to formally announcing our commercial launch in the coming weeks."

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 14 direct markets. Venus Concept's product portfolio consists of aesthetic device platforms, including Venus Versa, Venus Versa Pro, Venus Legacy, Venus Velocity, Venus Fiore, Venus Viva, Venus Glow, Venus Bliss, Venus BlissMAX, Venus Epileve, Venus Viva MD and AI.ME. Venus Concept's hair restoration systems include NeoGraft® and the ARTAS iX® Robotic Hair Restoration system. Venus Concept has been backed by leading healthcare industry growth equity investors including EW Healthcare Partners (formerly Essex Woodlands), HealthQuest Capital, Longitude Capital Management, Aperture Venture Partners, and Masters Special Situations.

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 and Section 21E of the Securities Exchange Act of 1934, as amended. 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; the contribution of the Venus Versa Pro System to our revenue; the efficacy of the Venus Versa Pro System; and the anticipated commercial launch date of the Venus Versa Pro System, 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 II Item 1A—“Risk Factors” in our Quarterly Reports on Form 10-Q and Part I Item 1A—“Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022. 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:

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