

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): April 25, 2022

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 April 25, 2022, Venus Concept Inc. (the “Company”) announced that the first patient has been treated in a U.S. Investigational Device Exemption (IDE) clinical study evaluating the safety and efficacy of the Company’s Aime robotic technology for the treatment of moderate to severe facial wrinkles. A copy of the press release 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 April 25, 2022.
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: April 25, 2022

By: /s/ Domenic Della Penna
Domenic Della Penna
Chief Financial Officer



Venus Concept Announces First Patient Treatment in Study Evaluating the Safety and Efficacy of Aime™ Next Generation Robotic Technology for the Treatment of Moderate to Severe Facial Wrinkles

TORONTO, April 25, 2022 (GLOBE NEWSWIRE) – Venus Concept Inc. (“Venus Concept” or the “Company”) (NASDAQ: VERO), a global medical aesthetic technology leader, today announced that the first patient has been treated in a U.S. Investigational Device Exemption (IDE) clinical study evaluating the safety and efficacy of the Company’s Aime™ next generation robotic technology for the treatment of moderate to severe facial wrinkles. Aime is a robotic platform designed to provide micro-coring for medical aesthetic applications.

“The introduction of robotics is one of the most exciting breakthroughs in aesthetic medicine,” said principal investigator Steven Dayan, M.D. “While robotic technologies have impacted nearly all fields of medicine and industry, they have been slow to take a hold in aesthetics given the need to be precise, patient and provider friendly, and affordable, while also delivering a reliable aesthetic improvement. However, recent advancements in technology and thinking are leading to newer designs and treatments.”

Dr. Dayan continued: “We are pleased to have successfully completed the initial patient treatment with the Aime robotic platform for this important clinical study. Aime represents an innovative approach to aesthetic procedures, with the potential to provide clinicians with consistent, predictable treatment delivery and enhanced visualization. Aime could very well differentiate adopting clinicians as the use of robotic technology emerges in aesthetic procedures.”

The study is a prospective, multicenter clinical study evaluating the safety and efficacy of mechanical coring to improve the appearance of wrinkles of the face. It will be conducted at four investigational centers in the U.S. and consist of up to 70 subjects between 22 and 75 years of age. The study will evaluate the progress of subjects after two treatments on the cheeks, delivered 30 days apart. The primary endpoint will be the proportion of correctly identified photograph sets from baseline and Day 120 as assessed by at least 3 independent blinded evaluators.

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 18 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 Viva, Venus Glow, Venus Bliss, Venus BlissMAX, 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, Aperture Venture Partners, and Masters Special Situations.

Cautionary Statement Regarding Forward-Looking Statements

This communication contains 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 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 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, 2021. 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:

ICR Westwicke on behalf of Venus Concept:

Mike Piccinino, CFA

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