# 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): February 9, 2023**

# SEASTAR MEDICAL HOLDING CORPORATION
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-39927** | **85-3681132** |
|---|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(Commission File Number)** | **(I.R.S. Employer Identification No.)** |

| | |
|---|---|
| **3513 Brighton Blvd., Suite 410**<br>**Denver, CO**<br>**(Address of principal executive offices)** | **80216**<br>**(Zip Code)** |

**Registrant's telephone number, including area code: (813) 222-8996**

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 (*see* General Instruction A.2, below):

☐ 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 Exchange Act:

| **Title of each class** | **Trading Symbol(s)** | **Name of each exchange on which registered** |
|---|---|---|
| Common Stock, $0.0001 par value | ICU | The Nasdaq Stock Market LLC |
| Warrants, each whole warrant exercisable for one share of Common Stock for $11.50 per share | ICUCW | The Nasdaq Stock Market LLC |

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 February 9, 2023, SeaStar Medical Holding Corporation (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (FDA) approved the Company's investigational device exemption (IDE) application to conduct a pivotal study evaluating the effectiveness of its Selective Cytopheretic Device (SCD) in reducing hyperinflammation in adults with acute kidney injury (AKI) requiring continuous kidney replacement therapy (CKRT).

A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form8-K and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release, dated February 9, 2023 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**SIGNATURE**

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 hereunto duly authorized.

**SEASTAR MEDICAL HOLDING CORPORATION**

Date: February 9, 2023

By: /s/ Eric Schlorff
Name: Eric Schlorff
Title: Chief Executive Officer

**DRAFT 3+LHA clean + AL Comments**
**FEBRUARY 8, 2023**

**SeaStar Medical Receives FDA Approval to Begin Study with Selective Cytopheretic Device to Reduce Hyperinflammation in Adults with Acute Kidney Injury**

*Patient enrollment in pivotal clinical study expected to begin in March*

**DENVER, Feb. 9, 2023 –** SeaStar Medical (Nasdaq: ICU), a medical device company developing proprietary solutions to reduce the consequences of hyperinflammation on vital organs, announces today that the U.S. Food and Drug Administration (FDA) approved the Company's investigational device exemption (IDE) application to conduct a pivotal study evaluating the effectiveness of its Selective Cytopheretic Device (SCD) in reducing hyperinflammation in adults with acute kidney injury (AKI) requiring continuous kidney replacement therapy (CKRT).

The Company plans to begin enrollment in this 200-patient randomized, controlled trial in March 2023. We currently expect to generate interim study results during the fourth quarter of 2023 and topline study results and submission of a Pre-market Approval (PMA) application in the second half of 2024. The study's primary endpoint is a composite of 90-day mortality and dialysis dependency of patients treated with SCD in addition to CKRT standard of care, compared with the control group receiving CKRT standard of care.

"We are excited about the potential of SCD to treat life-threatening hyperinflammation in severely ill patients with AKI requiring CKRT. With approval to begin the pivotal study, we are one step closer to bringing this potentially lifesaving therapy to nephrology and critical care professionals and the adult patients they treat," said Kevin Chung, MD, Chief Medical Officer of SeaStar Medical. "We are eager to enroll participants quickly as we continue our rigorous evaluation of the SCD's safety and effectiveness. We believe the SCD has the potential to change the way we treat patients who need CKRT in the ICU while saving lives along the way."

The Company's innovative SCD is a patented cell-directed extracorporeal therapy that selectively targets the most highly activated pro-inflammatory neutrophils and monocytes to stop the cytokine storm that can cause organ failure and death. SCD therapy is currently delivered through continuous CKRT to target and neutralize pro-inflammatory neutrophils and monocytes, allowing the body to return to homeostasis. The SCD received FDA **Breakthrough Device Designation** in May 2022.

Approximately six million cases of adult AKI are diagnosed annually in the U.S, of which 200,000 require CKRT. The SCD has previously demonstrated success in critically ill adults with AKI requiring CKRT, a condition with a high mortality rate. In the Company's **SCD 005 pilot study** evaluating the safety and feasibility of the SCD in COVID-19 patients with AKI and/or acute respiratory distress syndrome (ARDS), patients experienced reductions in activated neutrophils and monocytes, which led to reduction in proinflammatory cytokines and improved clinical outcomes. Based on the per-protocol minimum of four days of therapy, mortality of treated patients was significantly lower (41%) than the control population treated under standard of care (81%). All patients in the study received CKRT as the SCD delivery vehicle.

**About SeaStar Medical, Inc.**

SeaStar Medical is a medical technology company focusing on redefining how extracorporeal therapies may reduce the consequences of excessive inflammation on vital organs. SeaStar Medical's novel technologies rely on science and innovation to provide life-saving solutions to critically ill patients. The Company is developing and commercializing extracorporeal therapies that target the effector cells that drive systemic inflammation, causing direct tissue damage and secreting a range of pro-inflammatory cytokines that initiate and propagate imbalanced immune responses. For more information visit **www.seastarmedical.com** or visit us on **LinkedIn** or **Twitter**.

**SeaStar Medical Forward-Looking Statements**

This press release contains certain forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1955. These forward-looking statements include, without limitation, SeaStar Medical's expectations with respect to the timing of regulatory approval of its products, the expected timing on enrollment, generation of study results, submission of PMA and other corporate milestones, the ability of SCD to treat patients with AKI, and the potential benefits of SCD to treat other diseases. Words such as "believe," "project," "expect," "anticipate," "estimate," "intend," "strategy," "future," "opportunity," "plan," "may," "should," "will," "would," "will be," "will continue," "will likely result," and similar expressions are intended to identify such forward-looking statements. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to significant risks and uncertainties that could cause the actual results to differ materially from the expected results. Most of these factors are outside SeaStar Medical's control and are difficult to predict. Factors that may cause actual future events to differ materially from the expected results, include, but are not limited to: (i) the inability to recognize the anticipated benefits of the business combination with LMAO, which may be affected by, among other things, competition and the ability of the post-combination company to grow and manage growth profitability and retain its key employees, (ii) costs related to the business combination, (iii) the outcome of any legal proceedings that may be instituted against SeaStar Medical following the business combination, (iv) the ability to maintain the listing of its securities on NASDAQ, (v) the ability to implement business plans, forecasts, and other expectations after the completion of the business combination, and identify and realize additional opportunities, (vi) the risk of downturns and the possibility of rapid change in the highly competitive industry in which SeaStar Medical operates, (vii) the risk that SeaStar Medical and its current and future collaborators are unable to successfully develop and commercialize its products or services, or experience significant delays in doing so, including failure to achieve approval of its products by applicable federal and state regulators, (viii) the risk that SeaStar Medical may never achieve or sustain profitability; (ix) the risk that SeaStar Medical may need to raise additional capital to execute its business plan, which may not be available on acceptable terms or at all; (x) the risk that third-parties suppliers and manufacturers are not able to fully and timely meet their obligations, (xi) the risk of product liability or regulatory lawsuits or proceedings relating to SeaStar Medical's products and services, (xii) the risk that SeaStar Medical is unable to secure or protect its intellectual property, and (xiii) other risks and uncertainties indicated from time to time in SeaStar Medical's registration statement on Form S-4, as amended (File No. 333-264993), including those under the "Risk Factors" section therein and in SeaStar Medical's other filings with the SEC. The foregoing list of factors is not exhaustive. Forward-looking statements speak only as of the date they are made. Readers are cautioned not to put undue reliance on forward-looking statements, and SeaStar Medical assume no obligation and do not intend to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise.

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