

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 11, 2024

InfuSystem Holdings, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-35020
(Commission File Number)

20-3341405
(I.R.S. Employer Identification Number)

3851 West Hamlin Road
Rochester Hills, Michigan 48309
(Address of principal executive offices) (Zip Code)

(248) 291-1210
(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 \$.0001 per share	INFU	NYSE American 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 7.01 - Regulation FD Disclosure

On September 11, 2024, InfuSystem Holdings, Inc. (the "Company"), and its joint venture partner Sanara MedTech Inc. ("Sanara"), issued a press release announcing the execution of an exclusive United States distribution agreement, and minority investment, with ChemoMouthpiece, LLC. The press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished in this Item 7.01 — "Regulation FD Disclosure" of this Current Report on Form 8-K and the press release attached hereto as Exhibit 99.1 shall not be deemed "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of such section, and shall not be deemed to be incorporated by reference into the filings of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

Item 9.01 - Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of InfuSystem Holdings, Inc. dated September 11, 2024
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.

INFUSYSTEM HOLDINGS, INC.

By: /s/ Barry Steele
Barry Steele
Chief Financial Officer

Dated: September 11, 2024



InfuSystem Holdings, Inc.
3851 W. Hamlin Road
Rochester Hills, MI 48309
248-291-1210

FOR IMMEDIATE RELEASE

CONTACT: Joe Dorame, Joe Diaz & Robert Blum
Lytham Partners, LLC
602-889-9700

InfuSystem and Sanara MedTech Inc. Announce Exclusive United States Distribution Agreement with ChemoMouthpiece, LLC

Rochester Hills, Michigan, September 11, 2024 - InfuSystem Holdings, Inc. (NYSE American: INFU) (“InfuSystem” or the “Company”), a leading national health care service provider, facilitating outpatient care for durable medical equipment manufacturers and health care providers, and its joint venture partner Sanara MedTech Inc. (“Sanara”), announced today the execution of an exclusive United States distribution agreement with ChemoMouthpiece, LLC (“ChemoMouthpiece”).

Richard DiIorio, InfuSystem’s CEO, stated, “Sanara and InfuSystem entered into our partnership in order to bring together our combined technical, operational and commercial strengths to deliver proprietary efficacious products to patients. We believe this exclusive agreement, which builds on our partnership, will allow us to do that by offering the Chemo Mouthpiece[®], an oral cryotherapy device, bringing potential relief to thousands of cancer patients suffering from oral mucositis.”

Ron Nixon, Sanara’s CEO, stated, “Oral mucositis is a debilitating condition impacting hundreds of thousands of oncology patients annually. ChemoMouthpiece has developed a clinically validated product with FDA 510(k) clearance that can bring relief to affected patients. The American Medical Association has recently issued the CPT code (effective July 2024) to be applied for potential reimbursement by physicians and payers for the use of an oral cavity device for cryotherapy procedure in conjunction with chemotherapy. The product aligns well with Sanara’s skincare strategy, which includes the licensed collagen peptides from Tufts University that focus on radiation dermatitis. We look forward to providing the Chemo Mouthpiece[®], an oral cryotherapy device, to oncology patients undergoing chemotherapy.”

Transaction Overview

- ChemoMouthpiece owns and manufactures a 510(k) cleared device that uses cryotherapy to reduce the incidence and severity of oral mucositis in patients undergoing stomatotoxic chemotherapy treatments.
 - SI Healthcare Technologies, LLC (f/k/a SI Wound Care, LLC) (“SI Technologies”), a 50/50 joint venture between Sanara and InfuSystem, will be the exclusive distributor of ChemoMouthpiece’s kits in the United States.
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- SI Technologies plans to market and distribute the product through InfuSystem to approximately 3,000 cancer centers through InfuSystem's existing Oncology sales team.
- SI Technologies will purchase the product kits from ChemoMouthpiece at a fixed price and pay a royalty on net revenues for the use of the product intellectual property.
- Sanara invested \$5 million for a 6.6% ownership position in ChemoMouthpiece.
- SI Technologies will have a purchase option that expires on January 31, 2029 to purchase the U.S. business of ChemoMouthpiece, including all U.S. intellectual property related to the product.

Oral Mucositis

Oral mucositis causes painful mouth ulcers, which are a common complication of chemotherapy and radiation. In the U.S., there are an estimated 500,000 - 1,000,000 patients who have oral mucositis annually and the estimated market size exceeds \$600 million. SI Technologies believes this product will show material cost reductions for oncology treatment centers, improve patient quality of life and allow for continued treatment of cancer therapy for patients. ChemoMouthpiece is planning to publish studies in the future reinforcing the efficacy of their product.

David Yoskowitz, ChemoMouthpiece's President and CEO stated, "We are pleased to have selected SI Technologies as our exclusive distribution partner in the United States. We believe that InfuSystem's experienced team of seasoned oncology professionals currently calling on approximately 3,000 U.S. cancer centers will accelerate the uptake of the Chemo Mouthpiece[®], bringing a much-needed option for patients that would otherwise suffer from the debilitating effects of oral mucositis." David added, "We understand that the executive team of SI Technologies has a long history of launching products into the oncology space, and coupled with Sanara's ownership position in ChemoMouthpiece, we are confident that they will execute the successful launch of the Chemo Mouthpiece[®] oral cryotherapy device."

Pickwick Capital Partners, LLC, served as the exclusive advisor to ChemoMouthpiece on this transaction.

About ChemoMouthpiece, LLC

ChemoMouthpiece, LLC is a privately held medical device company that develops and commercializes propriety oral cryotherapy products for cancer patients. The Chemo Mouthpiece[®] device was developed based on the personal experience of inventor, founder and CEO, David Yoskowitz, who when diagnosed with Hodgkin's Lymphoma, experienced oral mucositis firsthand. His treatment options included ice chips to mitigate and minimize the pain. Yet this caused nausea, was difficult to maintain in his mouth, and did not effectively cool the entire oral cavity which led him to search for a better option. The Chemo Mouthpiece[®] cools down the entire oral cavity, causing vasoconstriction, which in effect slows and reduces the flow of chemotherapy in the oral cavity, thus greatly reducing the risk of developing oral mucositis. The cryotherapy approach has been positively studied for decades and the Chemo Mouthpiece[®] has significant and improved advantages over conventional cryotherapy interventions. For more information on ChemoMouthpiece, LLC, please visit our website at www.chemomouthpiece.com.

About Sanara MedTech Inc.

Sanara MedTech Inc. is a medical technology company focused on developing and commercializing transformative technologies to improve clinical outcomes and reduce healthcare expenditures in the surgical, chronic wound and skincare markets. The Company markets, distributes and develops surgical, wound and skincare products for use by physicians and clinicians in hospitals, clinics and all post-acute care settings and offers wound care and dermatology virtual consultation services via telemedicine. Sanara's products are primarily sold in the North American advanced wound care and surgical tissue repair markets. Sanara markets and distributes CellerateRX® Surgical Activated Collagen, FORTIFY TRG® Tissue Repair Graft and FORTIFY FLOWABLE® Extracellular Matrix as well as a portfolio of advanced biologic products focusing on ACTIGEN™ Verified Inductive Bone Matrix, ALLOCYTE® Plus Advanced Viable Bone Matrix, BiFORM® Bioactive Moldable Matrix, TEXAGEN® Amniotic Membrane Allograft, and BIASURGE® Advanced Surgical Solution to the surgical market. In addition, the following products are sold in the wound care market: BIAKÖS® Antimicrobial Skin and Wound Cleanser, BIAKÖS® Antimicrobial Wound Gel, and BIAKÖS® Antimicrobial Skin and Wound Irrigation Solution. Sanara's pipeline also contains potentially transformative product candidates for mitigation of opportunistic pathogens and biofilm, wound re-epithelialization and closure, necrotic tissue debridement and cell compatible substrates. The Company believes it has the ability to drive its pipeline from concept to preclinical and clinical development while meeting quality and regulatory requirements. Sanara is constantly seeking long-term strategic partnerships with a focus on products that improve outcomes at a lower overall cost.

About InfuSystem Holdings, Inc.

InfuSystem Holdings, Inc. (NYSE American: INFU), is a leading national health care service provider, facilitating outpatient care for durable medical equipment manufacturers and health care providers. INFU services are provided under a two-platform model. The first platform is Patient Services, providing the last-mile solution for clinic-to-home healthcare where the continuing treatment involves complex durable medical equipment and services. The Patient Services segment is comprised of Oncology, Pain Management and Wound Therapy businesses. The second platform, Device Solutions, supports the Patient Services platform and leverages strong service orientation to win incremental business from its direct payer clients. The Device Solutions segment is comprised of direct payer rentals, pump and consumable sales, and biomedical services and repair. Headquartered in Rochester Hills, Michigan, the Company delivers local, field-based customer support and also operates Centers of Excellence in Michigan, Kansas, California, Massachusetts, Texas and Ontario, Canada.

Forward-Looking Statements

Certain statements contained in this press release are 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, such as statements relating to future actions, business plans, strategic partnerships, growth initiatives, objectives and prospects, future operating or financial performance, guidance and expected new business relationships and the terms thereof (including estimated potential revenue under new or existing contracts). The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "should," "plan," "goal," "expect," "strategy," "future," "likely," variations of such words, and other similar expressions, as they relate to the Company, are intended to identify forward-looking statements. Forward-looking statements are subject to factors, risks and uncertainties that could cause actual results to differ materially, including, but not limited to, our ability to successfully execute on our

growth initiatives and strategic partnerships, our ability to enter into definitive agreements for new business relationships on expected terms or at all, our ability to generate estimated potential revenue amounts under new or existing contracts, our dependence on estimates of collectible revenue, potential litigation, changes in third-party reimbursement processes, changes in law, global financial conditions and recessionary risks, rising inflation and interest rates, supply chain disruptions, systemic pressures in the banking sector, including disruptions to credit markets, the Company's ability to remediate its previously disclosed material weakness in internal control over financial reporting, contributions from acquired businesses or new business lines, products or services and other risk factors disclosed in the Company's most recent annual report on Form 10-K and, to the extent applicable, quarterly reports on Form 10-Q. Our strategic partnerships are subject to similar factors, risks and uncertainties. All forward-looking statements made in this press release speak only as of the date hereof. We do not undertake any obligation to update any forward-looking statements to reflect future events or circumstances, except as required by law.

Additional information about InfuSystem Holdings, Inc. is available at www.infusystem.com.

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