

U.S. 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) **June 3, 2019**

Commission File No. **001-33718**

U.S. STEM CELL, INC.

(Name of small business issuer as specified in its charter)

Florida

State of Incorporation

65-0945967

IRS Employer Identification No.

13794 NW 4th Street, Suite 212, Sunrise, Florida 33325

(Address of principal executive offices)

(954) 835-1500

(Issuer's telephone number)

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 Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	USRM	OTC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities 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.

Unless otherwise indicated or the context otherwise requires, all references in this Form 8-K to “we,” “us,” “our,” “our company,” or the “Company” refer to U.S. Stem Cell, Inc. and its subsidiaries.

Item 8.01 Other Items

On May 9, 2018, the U.S. Department of Justice filed an injunctive action, specifically United States of America v. U.S. Stem Clinic, LLC, U.S. Stem Cell, Inc., Kristin C. Comella, and Theodore Gradel. The Complaint alleges, among other matters that the defendants manufacture “stromal vascular fraction” (SVF) products from patient adipose (fat) tissue, which the companies then market as stem cell-based treatments, and which U.S. Stem Cell Clinic, LLC administers to patients, without first obtaining what the government alleges are necessary FDA approvals.

The U.S. and the defendants filed cross motions for summary judgment, each asking for a ruling in its favor. On June 3, 2019, the Court entered an order granting Summary Judgment for the government and denying the defendants’ motion for summary judgment. The order focused on the defendants’ actions in providing and marketing SVF therapy. In an order dated June 4, 2019, the Court granted the defendants’ request to allow it the opportunity to work out the language of the form of injunction with the government, and if unsuccessful, to provide a status report to the Court by June 14, 2019, outlining areas of disagreement. The Court further ordered that the defendants (U.S. Stem Clinic, LLC, U.S. Stem Cell, Inc., Kristin C. Comella, and Theodore Gradel) ‘not sell, provide or otherwise engage in any SVF therapy or any other activities to be regulated by the FDA as explained in the Court’s Order on the Parties’ Motions for Summary Judgment.’”

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934 the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Registrant
Date: June 6, 2019

U.S. Stem Cell, Inc.

By: /s/ Michael Tomas
Michael Tomas
Chief Executive Officer