
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) September 24, 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 1.01. Entry Into A Material Definitive Agreement

See Item 2.01.

Item 2.01 – Acquisition Or Disposition Of Assets.

On March 3, 2017, the Company entered into an asset sale and lease agreement (sale/leaseback transaction, the “Asset Sale and Lease Agreement”) with General American Capital Partners (“GACP”), whereby the Company sold certain lab, medical and other equipment relating to the cell banking business for \$400,000 and leased back the sold equipment over a three year term. In addition, the Company also entered into an asset purchase agreement of intellectual property with GACP whereby the Company agreed to sell all of the Company’s worldwide rights, title or interest in certain intellectual and other property (as defined) associated with the cell banking business and the Company entered into a customer purchase agreement with GACP, whereby the Company agreed to sell, the first 5,000 customers of the cell banking business[after the effective date of the Asset Sale and Lease Agreement with rights to purchase additional customers.

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. On June 3, 2019, the Court entered an order granting Summary Judgment for the government. The Court further ordered that the defendants (including the Company) ‘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.” (the “Court Order”).

As a consequence of the Court Order, the Company resolved to divest itself of certain equipment and other assets (the “Equipment Assets”) used in connection with the Company’s human tissue banking business, but consistent however with the requirements of the Court Order, and to adjust the business plan and operations to accommodate this potential divestiture. To facilitate the above, the Company entered into the following agreements, which are not yet effective, as discussed below:

- Termination and Release Agreement by and between GACP, the Company, and Michael Tomas and Kristin Comella dated September 24, 2019 (terminating the Non-Competition and Non-Solicitation Agreement between U.S. Stem Cell, Inc. and GACP Stem Cell Bank LLC., dated March 3, 2017).
- Letter Agreement on Stem Cell Processing and Storage by and between the Company and American Cell Technology, LLC, dated September 24, 2019.

The foregoing agreements are qualified in their entirety by reference to such documents, which are attached as Exhibits hereto.

The FDA must be provided with fifteen days’ prior notice of the contemplated transactions, pursuant to the Court Order. Such notice has been sent.

Along with diversifying the portfolio of products distributed by the Company, including equipment and biologics, it is the intention of the Company to both continue to adhere to the Court Order as well as re-establish its good standing with the Agency (FDA). These points are not mutually exclusive nor negotiable and we believe that there are still business and patient goodness opportunities while still abiding by all legal requirements. As a result, the Company shall be continuing with the development of US Stem Cell Training, Inc., an operating division of our company, that is a content developer of regenerative medicine/cell therapy informational and training materials for physicians and patients and complies with both requirements--as well as Vet biologics, an operating division of our company, that is a veterinary regenerative medicine company committed to providing veterinarians with the ability to deliver the highest quality regenerative medicine therapies to dogs, cats and horses. In addition, our company is transitioning the current clinics to a more diversified regenerative medicine platform, while complying with recent court rulings. While not providing legal advice, the company may also engage in managing third-party clinics to ensure they too abide by recent regulatory requirements

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	Description
10.1	<u>Termination and Release Agreement by and between General American Capital Partners, U.S. Stem Cell, Inc., and Michael Tomas and Kristin Comella dated September 24, 2019.</u>
10.2	<u>Letter Agreement on Stem Cell Processing and Storage by and between the Company and American Cell Technology, LLC, dated September 24, 2019.</u>

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

U.S. Stem Cell, Inc.

Date: September 27, 2019

By: /s/ Michael Tomas _____

Michael Tomas

Chief Executive Officer

TERMINATION AND RELEASE AGREEMENT

This Termination and Release Agreement ("Agreement") is made and entered into by and among GACP Stem Cell Bank LLC, a Florida limited liability company ("Company"), U.S. Stem Cell, Inc., a Florida corporation ("US Stem Cell"), and Michael Tomas and Kristin Comella ("Key Persons" and collectively, with US Stem Cell, and the Company, the "Parties"), dated as of the last signature date.

WITNESSETH:

WHEREAS, on March 3, 2017 (the "Closing Date"), Company and US Stem Cell entered into an Asset Sale and Lease Agreement, as subsequently amended on May 9, 2018 (the "ASLA"), a copy of which is attached hereto as **Exhibit A**, pursuant to which Company purchased from US Stem Cell certain equipment and other assets (the "Equipment Assets") used in connection with US Stem Cell's human tissue banking business (the "Human Banking Business"), but excluding any stem cells deposited by clients with US Stem Cell in US Stem Cell's operation of the Human Banking Business ("Deposits"); and

WHEREAS, Company did not take possession of or otherwise exercise control over the Equipment Assets on or since the Closing Date, but rather pursuant to the ASLA, leased the Equipment Assets back to US Stem Cell for US Stem Cell's use in operating its Human Banking Business; and

WHEREAS, on the Closing Date, Company and US Stem Cell also entered into the following documents, setting forth the rights of Company and US Stem Cell upon expiration or termination of the ASLA (the "Termination Date"):

- Customer Purchase Agreement by and between Company and US Stem Cell (the "CPA"), a copy of which is attached hereto as **Exhibit B**;
- Asset Purchase Agreement by and between Company and US Stem Cell, as amended on June 18, 2018 (collectively, the "APA"), a copy of which is attached hereto as **Exhibit C**;
- Non-Competition and Non-Solicitation Agreement by and among, Company, US Stem Cell, Michael Tomas and Kristin Comella, a copy of which is attached hereto as **Exhibit D** (the "Non-Comp," and together with the CPA and the APA, the "End of Lease Documents"); and

WHEREAS, Company intends to sell the Equipment Assets to American Cell Technology, LLC, a Florida limited liability company ("ACT"), pursuant to and in accordance with the terms of that certain Asset Purchase and Sale Agreement by and between Company and ACT (the "APSA"); and

WHEREAS, Company and US Stem Cell wish to terminate the ASLA and the End of Lease Documents; and

NOW, THEREFORE, in consideration of the premises, mutual covenants and promises hereinafter set forth, and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. **Recitals.** The foregoing recitals are true and correct and incorporated herein by reference.

2. **Termination of Agreements.** The Parties hereby terminate the ASLA, the CPA, the APA, and the Non-Comp (the "Termination"), other than the provisions effectuating the sale and transfer of the Equipment Assets (as defined in the ASLA) by US Stem Cell to Company. Notwithstanding the foregoing, US Stem Cell's obligation to indemnify Company, its Affiliates and Representatives (as defined in the ASLA) for any losses incurred by Company, or its Affiliates and Representatives, relating to or arising from US Stem Cell's operation of the Human Banking Business shall survive the consummation of the Termination. Upon consummation of the Termination, the Parties shall be released from, and shall not have any further liability under the ASLA, the CPA, the APA, or the Non-Comp and shall not be responsible for the performance of the obligations set forth in the ASLA, the CPA, the APA, or the Non-Comp, other than US Stem Cell's obligation to indemnify Company for losses arising from US Stem Cell's operation of the Human Banking Business. The Parties waive, including but not limited to the provisions of Paragraph 2 of the Non-Comp Agreement, all requirements for notice and termination.

3. **Effective Date.** The Termination and the transactions contemplated hereby shall be effective and consummated on the effective date of the APSA, provided the conditions set forth in **Section 6** of this Agreement are satisfied in full (the "Effective Date").

4. **Mutual General Release between Company and US Stem Cell.** Company, for itself and all affiliates or entities that it owns or controls in whole or in part ("Company Parties") and US Stem Cell, for itself and all affiliates or entities that it owns or controls in whole or in part ("USSC Parties"), hereby remise, release, acquit, satisfy and forever discharge each other (including each other's past and present parent, subsidiary, affiliate or predecessor entities, and any and all of his, her, its and/or their respective past and present directors, managers, officers, employees, attorneys, accountants, and agents, and their respective heirs, personal representatives and successors and assigns, all of the foregoing hereinafter collectively referred to as the "Releasees"), of and from any and all manner of claims, actions, causes of action, suits, debts, sums of money, accounts, reckonings, contracts, controversies, agreements, promises, damages, and demands whatsoever, in law or in equity, which either of them had or now have, or which a successor or assign of either of them hereafter can, shall or may have, against any of the Releasees for, upon, or by reason of any matter, cause or thing whatsoever, from the beginning of the world to the date of this Agreement, whether known or unknown, direct or indirect, vested or contingent ("Release"). Without limiting the generality of the foregoing, this Release includes but is not limited to the release of any and all claims, rights, and causes of action, of any type or kind whatsoever, which were or could have been raised or asserted by either Party against the other Party related to their business dealings, agreements, and operations of stem cell clinics prior to the Effective Date. Notwithstanding the foregoing, this Release does not constitute a release, abandonment, transfer or relinquishment of, and expressly excludes: (a) US Stem Cell Parties' obligation to indemnify, hold harmless and defend the Company Parties from and against any and all claims, demands, costs, expenses, liabilities, causes of action and damages of every kind and character (including attorneys' fees) that may be asserted by any third party in any way related or incident to, arising out of, or in connection with US Stem Cell's operation of the Human Banking Business; or (b) the terms and conditions of this Agreement, including any and all obligations of the Parties set forth in this Agreement.

5. **Order of Permanent Injunction.** The Parties acknowledge that US Stem Cell is a defendant, together with certain other parties, in an action by the Food and Drug Administration (“FDA”) against US Stem Cell and other parties, in a case styled UNITED STATES OF AMERICA v. US STEM CELL CLINIC, LLC, A FLORIDA LIMITED LIABILITY COMPANY; US STEM CELL, INC., A FLORIDA PROFIT CORPORATION; AND INDIVIDUAL KRISTIN C. COMELLA (collectively, “Defendants”), United States District Court, Southern District of Florida, Case No.:18-cv-61047-UU, pursuant to which an Order of Permanent Injunction and subsequent orders (collectively, the “Order”) have been issued against the Defendants, which in general, restrain and enjoin the Human Banking Business and others from performing any act with respect to the SVF Product; which require Defendants to place a label on certain articles or place a sign where SVF Product is stored stating that the articles must not be used, moved, altered, or tampered with in any manner pursuant to Order; and Defendants have in fact placed such a sign on the tissue bank freezers US Stem Cell hereby represents and warrants that it has, to the best of its ability, complied in all material respects, and after the Execution Date and the Effective Date shall continue, to the best of its ability, to comply in all material respects with the terms of the Order, until the Order has been reversed or otherwise overturned by operation of law. Company hereby represents and warrants that it has received and reviewed the Order. US Stem Cell agrees to, and shall, indemnify and hold harmless Company against and in respect of any and all damages, losses, deficiencies, liabilities, obligations, commitments, costs or expenses (including the fees and expenses of counsel or experts) arising out of or resulting from US Stem Cell’s failure to comply, to the best of its ability, in all material respects with the Order or with any other regulatory obligation to which it is or will become subject, whether related to the Order or otherwise. Company hereby represents and warrants that it will, to the best of its ability, comply in all material respects, with the terms of the Order, until the earlier of the Effective Date or the date on which the Order has been reversed or otherwise overturned by operation of law. Company shall also require, as a condition precedent of the APSA, that ACT represent and warrant that it will, to the best of its ability, comply in all material respects, after the Effective Date, with the terms of the Order, until the Order has been reversed or otherwise overturned by operation of law. Company agrees to, and shall, indemnify and hold harmless US Stem Cell against and in respect of any and all damages, losses, deficiencies, liabilities, obligations, commitments, costs or expenses (including the fees and expenses of counsel or experts) arising out of or resulting from Company’s failure to comply, to the best of its ability, in all material respects with the Order.

6. **Third-Party Consents.** Company and US Stem Cell represent to each other that, prior to the Effective Date, all governmental or third-party consents, notifications, orders, etc., that are required in order to effectuate this transaction shall have been obtained, and copies of such consents, notifications, orders, etc., shall have been provided to each other as appropriate, including the required notification by U.S. Stem Cell to the FDA of this Agreement and the transaction contemplated hereunder, and any court approval required, if any, to approve this Agreement and the transaction contemplated hereunder. In the event the foregoing conditions are not satisfied on or before February 1, 2020, then this Agreement shall terminate, and the Parties shall have no further obligation to each other hereunder.

7. **Representations and Warranties of the Parties.** Each Party represents and warrants to the other Party that:

(a) it has all the requisite power and authority to enter into, deliver and perform this Agreement;

(b) the execution, delivery of and performance of this Agreement by such Party has been duly authorized by all necessary actions on the part of such Party and no further action is required by such Party;

(c) except as specifically provided for in this Agreement, no consent, approval, order, designation, declaration, qualification or filing with or notification to any governmental agency or regulatory authority is necessary or required by law to be made by it as a prerequisite to the execution, delivery and performance of this Agreement; and

(d) this Agreement has been duly executed by such Party and, when delivered in accordance with the terms hereof, will constitute the valid and binding obligation of such Party enforceable against such Party in accordance with its terms.

The Parties shall deliver resolutions of each of their governing boards authorizing the Termination and the transactions contemplated hereby.

8. Further Assurances. The Parties' shall, at any time and from time to time, upon the request of the other Party, execute, acknowledge and deliver all such further deeds, assignments, transfers, conveyances, powers of attorney and assurances, and take all such further actions, as shall be reasonably necessary to give effect to the transactions hereby consummated.

9. Counterparts. This Agreement may be executed in counterparts, including by facsimile, PDF or other electronic transmission, which when taken together shall constitute a single document.

10. Binding Effect; Amendment. This Agreement shall be binding upon and shall inure to the benefit of Seller and Company and their respective successors and assigns. This Agreement may only be amended by a writing signed by the Parties.

11. Governing Law; Venue. This Agreement shall be governed by and construed in accordance with the internal laws of the state of Florida without reference to conflict of law principles. Exclusive venue for any action brought by a Party to interpret, enforce or otherwise arising under this Agreement shall be a federal or state court of competent subject matter jurisdiction in Miami-Dade County, Florida.

12. Attorney's Fees. The prevailing Party in any litigation arising out of or related to this Agreement shall be entitled to recover its reasonable attorney's fees from the non-prevailing Party.

13. Waiver of Jury Trial. TO THE FULLEST EXTENT LEGALLY PERMISSIBLE, THE PARTIES HERETO WAIVE TRIAL BY JURY IN RESPECT OF ANY CLAIM, DISPUTE OR ACTION ARISING OUT OF, OR RELATED TO, THIS AGREEMENT. THIS PROVISION IS A MATERIAL INDUCEMENT FOR THE PARTIES HERETO ENTERING INTO THIS AGREEMENT.

14. **Enforceability.** The provisions of this Agreement shall be applied and interpreted in a manner consistent with each other so as to carry out the purposes and intent of the Parties, but, if for any reason any provision of this Agreement is held to be illegal, invalid, or unenforceable under present or future laws effective during the term hereof, such provision shall be fully severable, provided that the fundamental purposes and intent of the Parties is not thereby defeated; in the event of any such severance, this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, and the remaining provisions shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance therefrom.

15. **Binding Agreement.** The Parties hereto warrant that they have carefully read this Agreement, which they intend to be legally bound by the same, that they have entered into this Agreement freely and voluntarily, and that they have the full right, power, authority and capacity to enter into and execute the same. The Parties hereto further warrant that this Agreement is entered into with no Party relying upon any statement or representation made by any other Party not embodied in this Agreement.

16. **Waiver.** Any waiver, alteration, or modification of any of the provisions of this Agreement shall be valid only if made in writing and signed by the Parties hereto. Each Party hereto may waive any of its rights hereunder without effecting a waiver with respect to any subsequent occurrence. No waiver of any provision hereof shall operate as a waiver of such provision or any provision on a future occasion.

17. **Headings.** The headings used herein are for convenience only and shall not be used to aid in the interpretation of any provision of the Agreement.

18. **Successors.** This Agreement is intended to bind and inure to the benefit of, and be enforceable by the Parties and their respective heirs, legal representatives, successors, and assigns.

[SIGNATURES ON FOLLOWING PAGE]

IN WITNESS WHEREOF, the Parties have executed this agreement as of the date set forth below.

U.S. Stem Cell, Inc.

GACP Stem Cell Bank LLC

By: /s/ Michael Tomas

/s/ David Neithardt

Title: Chief Executive Officer

Name: David Neithardt

Title: Authorized Signatory

Date: September 24, 2019

Date: 09/20/19

/s/ Michael Tomas

/s/ K Comella

Name: Michael Tomas

Name: Kristin Comella

Date: September 24, 2019

Date: 09/24/19

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Termination and Release Agreement
by and between
GACP Stem Cell Bank LLC, U.S. Stem Cell, Inc., Michael Tomas and Kristin Comella



U.S. Stem Cell, Inc. assigns all of its rights, and delegates all of its responsibilities (excluding any liability resulting from U.S. Stem Cell, Inc.'s own conduct) to American Cell Technology LLC ("ACT") under all Stem Cell Processing and Storage Agreements and similar agreements ("Agreements") related to human tissue banking, on the following terms and conditions:

1. This assignment shall not be effective unless related agreements among the parties and GACP are executed.
2. This assignment is subject to that Permanent Injunction and other orders "(Order)" referenced and defined in the parties' related agreements.
3. This assignment shall not be effective and consummated until the conclusion of the required 15 day notice provision to the FDA under the Order, and if the FDA objects or requires additional information, until those objections and requests are resolved.
4. All payments received by US Stem Cell, Inc. under the Agreements until the effective date of this assignment shall remain the property of US Stem Cell, Inc.

/s/ Michael Tomas
Signature of USSC

/s/ Sean Berman
Sean Berman, Manager Sept 24, 2019
Signature of ACT