

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): August 5, 2020

IMAC Holdings, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38797
(Commission
File Number)

83-0784691
(IRS Employer
Identification No.)

1605 Westgate Circle, Brentwood, Tennessee
(Address of Principal Executive Offices)

37027
(Zip Code)

Registrant's Telephone Number, Including Area Code: (844) 266-4622

(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 (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, par value \$0.001 per share	IMAC	The NASDAQ Stock Market LLC
Warrants to Purchase Common Stock	IMACW	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 August 5, 2020, IMAC Holdings, Inc. (the “Company”) issued a press release announcing the approval by the United States Food and Drug Administration (the “FDA”) of the Company’s investigational new drug application, which IMAC submitted in May 2020, for the use of umbilical cord-derived allogenic mesenchymal stem cells for the treatment of bradykinesia, or the gradual loss and slowing down of spontaneous body movement, due to Parkinson’s disease. Pursuant to the FDA’s approval, the Company anticipates beginning a phase 1 clinical trial of its stem cell treatment within 30 days. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Cautionary Note Regarding Forward-Looking Statements

The information contained in this Current Report on Form 8-K and the exhibits attached hereto contain “forward-looking” statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements related to the benefits of the Transaction. The words “intend,” “may,” “should,” “would,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other comparable terminology are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. While the Company believes its plans, intentions and expectations reflected in those forward-looking statements are reasonable, these plans, intentions or expectations may not be achieved. The Company’s actual results, performance or achievements could differ materially from those contemplated, expressed or implied by the forward-looking statements. For information about the factors that could cause such differences, please refer to the Company’s filings with the U.S. Securities and Exchange Commission. Given these uncertainties, you should not place undue reliance on these forward-looking statements. The Company assumes no obligation to update any forward-looking statement.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Press Release, dated August 5, 2020.</u>

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.

August 6, 2020

IMAC HOLDINGS, INC.

By: /s/ Jeffrey S. Ervin

Name: Jeffrey S. Ervin

Title: Chief Executive Officer

IMAC Holdings Receives FDA Authorization to Initiate Clinical Study of Its Umbilical Cord-Derived Allogenic Mesenchymal Stem Cells for the Treatment of Bradykinesia Due to Parkinson's Disease

BRENTWOOD, Tenn., Aug. 05, 2020 (GLOBE NEWSWIRE) -- IMAC Holdings, Inc. (Nasdaq: IMAC) (the "Company" or "IMAC"), a provider of innovative medical advancements and care specializing in regenerative rehabilitation orthopedic treatments without the use of surgery or opioids, today announced the United States Food and Drug Administration (the "FDA") approved its investigational new drug application, which IMAC submitted in May 2020, for the use of umbilical cord-derived allogenic mesenchymal stem cells for the treatment of bradykinesia, or the gradual loss and slowing down of spontaneous body movement, due to Parkinson's disease.

The Company will now initiate enrollment of 15 patients for its Phase 1 trial to evaluate the safety and tolerability of the stem cell product acquired from technology developed by a major research university to treat patients with Bradykinesia due to Parkinson's utilizing intravenous administration of Wharton's jelly-derived mesenchymal stem cells. The Company believes that the causes of bradykinesia may be related to an inflammatory response in the body. The Company's new study is designed to confirm this belief and support the Company's long-term strategy for the use of regenerative medicine in combination with physical rehabilitation to reduce the effect of movement-restricting diseases.

"Our regenerative rehabilitation centers have long focused on the importance of finding and applying non-opioid, non-surgical solutions to physical ailments in orthopedics. In 2017, our neurosurgeon researched opportunities to apply stem cells to treating Parkinson's, and we put a team together to design a treatment for our neurological patients that simply could not achieve maximum benefit from physical therapy alone," commented Jeffrey Ervin, IMAC's Chief Executive Officer. "Having received approval to proceed with our study, IMAC is extremely optimistic regarding the potential of this stem cell technology. This has the potential to not only expand proprietary service options for neurological patients, but also advance the way physically debilitating inflammatory conditions are managed as a whole. We would like to thank the FDA for the collaborative process and the partners who helped us achieve this milestone, including patient advocate, Doug Oliver and his team at Regenerative Outcomes."

The Phase 1 trial will consist of three treatment protocols: five patients with bradykinesia due to Parkinson's will receive a low dose intravenous infusion of stem cells, five patients will receive a medium dose intravenous infusion of stem cells and five patients will receive a high dose intravenous infusion of stem cells. The Phase 1 trial will be conducted over 12 months to determine the incidence and extent of adverse events, although the Company will also investigate the efficacy of its stem cell treatment. More information on the clinical trial, including patient criteria, can be found on clinicaltrials.gov.

IMAC will enroll participants from its existing clinics in Illinois, Tennessee, Kentucky and Missouri in its Phase 1 trial. Prospective enrollees may email fdatrial@imacregeneration.com to be considered for the trial. IMAC's medical doctors and physical therapists have been trained to administer the treatment and manage the therapy for the clinical trial, which is anticipated to begin in 30 days.

About IMAC Holdings, Inc.

IMAC Holdings was created in March 2015 to expand on the footprint of the original IMAC Regeneration Center, which opened in Kentucky in August 2000. IMAC Regeneration Centers combine life science advancements with traditional medical care for movement restricting diseases and conditions. IMAC owns or manages 16 outpatient clinics that provide regenerative, orthopedic and minimally invasive procedures and therapies. It has partnered with several active and former professional athletes, opening six Ozzie Smith IMAC Regeneration Centers, two David Price IMAC Regeneration Centers, as well as Mike Ditka IMAC Regeneration Centers and a Tony Delk IMAC Regeneration Center. IMAC's outpatient medical clinics emphasize its focus around treating sports and orthopedic injuries and movement-restricting diseases without surgery or opioids. More information about IMAC Holdings, Inc. is available at www.imacregeneration.com.

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Safe Harbor Statement

This press release contains forward-looking statements. These forward-looking statements, and terms such as “anticipate,” “expect,” “believe,” “may,” “will,” “should” or other comparable terms, are based largely on IMAC’s expectations and are subject to a number of risks and uncertainties, certain of which are beyond IMAC’s control. Actual results could differ materially from these forward-looking statements as a result of, among other factors, risks and uncertainties associated with its ability to raise additional funding, its ability to maintain and grow its business, variability of operating results, its ability to maintain and enhance its brand, its development and introduction of new products and services, the successful integration of acquired companies, technologies and assets, marketing and other business development initiatives, competition in the industry, general government regulation, economic conditions, dependence on key personnel, the ability to attract, hire and retain personnel who possess the skills and experience necessary to meet customers’ requirements, and its ability to protect its intellectual property. IMAC encourages you to review other factors that may affect its future results in its registration statement and in its other filings with the Securities and Exchange Commission. In light of these risks and uncertainties, there can be no assurance that the forward-looking information contained in this press release will in fact occur.

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Source: IMAC Holdings, Inc.