# 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): April 28, 2020

# INTERNATIONAL STEM CELL CORPORATION

(Exact name of registrant as specified in its charter)

| Delaware | 000-51891 | 20-4494098 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification Number) |

5950 Priestly Drive, Carlsbad, California 92008
(Address of principal executive offices, including zip code)

(760) 940-6383
(Registrant's telephone number, including area code)

(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 CAR 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 |
|---|---|---|
| None | N/A | N/A |

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 Information**

As a result of the outbreak of, and local, state and federal governmental responses to, the COVID-19 coronavirus pandemic, International Stem Cell Corporation (the "Company") is furnishing this Current Report on Form 8-K to obtain an extension to file the Part III portion of its Annual Report on Form 10-K for the year ended December 31, 2019 (the "Part III Portion"), originally due on April 29, 2020. Specifically, the Company is relying on an order issued by the Securities and Exchange Commission (the "SEC") on March 25, 2020 (which extended and superseded a prior order issued on March 4, 2020), pursuant to Section 36 of the Securities Exchange Act of 1934, as amended (Release No. 34-88465)(the "Order"), regarding potential exemptions granted to public companies with respect to specified filing requirements, subject to the conditions contained in the Order. The Order allows a registrant up to an additional 45 days after the original due date of certain reports required to be filed with the SEC if the registrant's ability to file such report timely is affected by circumstances related to COVID-19.

The Company's operations and business have experienced disruptions due to the unprecedented conditions surrounding the COVID-19 pandemic that has spread throughout the United States and the world. These disruptions include, but are not limited to: office closures, limited access to required information and the unavailability of key Company personnel required to prepare the Part III Portion due to suggested, and mandated, social quarantining and work from home orders.

As such, the Company will be relying on the Order and will be making use of the 45-day grace period provided by the Order to delay filing of the Part III Portion. The Company plans to file the Part III Portion (which may be accomplished by filing its definitive proxy materials for its 2020 Annual Meeting of Stockholders and incorporating the information comprising the Part III Portion by reference from the definitive Proxy Statement) by no later than June 13, 2020, 45 days after the original due date of the Part III Portion.

The Company believes that the COVID-19 pandemic may affect its business in several ways. In the upcoming Annual Report on Form 10-K, the Company intends to update the Risk Factors to include the risks the Company can foresee associated with COVID-19. Currently, the Company expects that the principal Risk Factors (to be included in the Annual Report) that will reflect the potential effects and risks of the COVID-19 pandemic include the following:

***Our business is subject to risks arising from epidemic diseases, such as the recent global outbreak of the COVID-19 coronavirus.***

The recent outbreak of the coronavirus, COVID-19, which has been declared by the World Health Organization to be a pandemic has spread across the globe and is impacting worldwide economic activity. A pandemic, including COVID-19 or other public health epidemic, poses the risk that we or our employees, contractors, customers, suppliers, third party shipping carriers, government and other partners may be prevented from or limited in their ability to conduct business activities for an indefinite period of time, including due to the spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. While it is not possible at this time to estimate the impact that COVID-19 could have on our business, the continued spread of COVID-19 and the measures taken by the governments of states and countries affected could disrupt, among other things, the supply chain and the manufacture or shipment of our products. Our laboratory operations, including laboratory employees, may be subject to closure or shut down due to the spread of the disease within these individuals, or as part of a larger scale government recommendation or mandate. Any disruption in our laboratory operations would have a material adverse effect on our business and would impede our ability to manufacture and ship products to our customers in a timely manner, or at all. Additionally, the demand for our skincare products may significantly decline as COVID-19 continues to spread, including as a result of prioritization of customer financial resources toward essential household items or government imposed quarantines that impede the ability of our customers to purchase our professional skincare product line through spas and medical offices that may not be considered essential businesses and mandated to close for an indefinite amount of time. The occurrence of any of the foregoing events could have a material adverse effect on our business, financial condition and results of operations. The COVID-19 outbreak and mitigation measures have had and may continue to have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The extent to which the COVID-19 outbreak impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact.

*We have limited clinical testing and regulatory capabilities, and human clinical trials are subject to extensive regulatory requirements, very expensive, time-consuming and difficult to design and implement. Our products may*

*fail to achieve necessary safety and efficacy endpoints during clinical trials, which may limit our ability to generate revenues from therapeutic products.*

Due to the relatively early stage of our therapeutic products and stem cell therapy-based systems, we have not yet invested significantly in internal clinical testing and regulatory capabilities, including for human clinical trials. We cannot assure you that we will be able to invest or develop resources for these capabilities successfully or as expediently as necessary. In particular, human clinical trials can be very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is time consuming. We estimate that clinical trials of our product candidates will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be affected by several factors, including:

- unforeseen safety issues;
- determination of dosing issues;
- inability to demonstrate effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment;
- competitive developments, including changes in the standard of care treatment for an indication;
- inability or unwillingness of medical investigators to follow our clinical protocols; and
- developments related to the coronavirus outbreak and impact of it and COVID-19 on the costs and timing associated with the conduct of our clinical trials and other related activities.

In addition, we or the FDA (or other applicable regulatory agency) may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA or other regulatory agency finds deficiencies in our submissions or the conduct of these trials.

*The development and commercialization of our product candidates is subject to extensive regulation by the FDA and other regulatory agencies in the United States and abroad, and the failure to receive regulatory approvals for our product candidates would likely have a material and adverse effect on our business and prospects.*

The process of obtaining FDA and other regulatory approvals is expensive, generally takes many years and is subject to numerous risks and uncertainties, particularly with complex and/or novel product candidates such as our product candidates. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application or may make it easier for our competitors to gain regulatory approval to enter the marketplace. Ultimately, the FDA and other regulatory agencies have substantial discretion in the approval process and may refuse to accept any application or may decide that our product candidate data are insufficient for approval without the submission of additional pre-clinical, clinical or other studies. In addition, varying agency interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Any of the following factors, among others, could cause regulatory approval for our product candidates to be delayed, limited or denied:

- the product candidates require significant clinical testing to demonstrate safety and effectiveness before applications for marketing approval can be filed with the FDA and other regulatory authorities;
- data obtained from pre-clinical and nonclinical animal testing and clinical trials can be interpreted in different ways, and regulatory authorities may not agree with our respective interpretations or may require us to conduct additional testing;
- negative or inconclusive results or the occurrence of serious or unexpected adverse events during a clinical trial could cause us to delay or terminate development efforts for a product candidate;

- FDA and other regulatory authorities may require expansion of the size and scope of the clinical trials; and/or
- a pandemic, epidemic or outbreak of a contagious disease, such as the ongoing global pandemic of the novel coronavirus COVID-19 may refocus the FDA and other regulatory authorities to clinical trials that are of the utmost need.

Any difficulties or failures that we encounter in securing regulatory approval for our product candidates would likely have a substantial adverse impact on our ability to generate product sales, and could make any search for a collaborative partner more difficult

*Stock prices for biotechnology companies have historically tended to be very volatile.*

Stock prices and trading volumes for many biotechnology companies fluctuate widely for a number of reasons, including but not limited to the following factors, some of which may be unrelated to their businesses or results of operations:

- clinical trial results;
- the amount of cash resources and such company's ability to obtain additional funding;
- announcements of research activities, business developments, technological innovations or new products by competitors;
- entering into or terminating strategic relationships;
- changes in government regulation;
- disputes concerning patents or proprietary rights;
- changes in revenues or expense levels;
- public concern regarding the safety, efficacy or other aspects of the products or methodologies being developed;
- development of major public health concerns, including the novel coronavirus outbreak or other pandemics arising globally, and the current and future impact of it and COVID-19 on the financial markets;
- reports by securities analysts;
- activities of various interest groups or organizations;
- media coverage; and
- status of the investment markets.

This market volatility, as well as general domestic or international economic, market and political conditions, could materially and adversely affect the market price of our common stock

Cautionary Note Regarding Forward-Looking Statements

Certain of the statements contained in this report are forward-looking statements. For example, statements regarding our business strategy and other plans and objectives for product development and future operations, and assumptions and predictions about potential markets, future product demand, and the potential effects of the COVID -19 pandemic are all forward-looking statements. These statements are generally accompanied by words such as "intend," "anticipate," "believe," "estimate," "potential(ly)," "continue," "forecast," "predict," "plan," "may," "will," "could," "would," "should," "expect," or the negative of such terms or other comparable terminology.

We have based these forward-looking statements on our current expectations and projections about future events. We believe that the assumptions and expectations reflected in such forward-looking statements are reasonable, based on information available to us on the date hereof, but we cannot assure you that these assumptions and expectations will prove to have been correct or that we will take any action that we may presently be planning. However, these forward-looking statements are inherently subject to known and unknown risks and uncertainties. Actual results or experience may differ materially from those expected or anticipated in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, research and product development uncertainties, clinical trial results, regulatory policies and approval requirements, competition from other similar businesses, market and general economic factors, the availability of resources

and the other risks discussed in our Annual Report. This discussion should be read in conjunction with the consolidated financial statements and notes thereto included in our previous Annual Report and subsequent Quarterly Reports on Form 10-Q.

We have identified some of the important factors that could cause future events to differ from our current expectations and they are described in our Annual Report in the section entitled "Risk Factors" which you should review carefully. Please consider our forward-looking statements in light of those risks as you read our Annual Report. If one or more of these or other risks or uncertainties materialize, or if our underlying assumptions prove to be incorrect, actual results may vary materially from what we project. We do not undertake, and specifically decline any obligation, to update any forward-looking statements or to publicly announce the results of any revisions to any statements to reflect new information or future events or developments.

Signatures

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.

INTERNATIONAL STEM CELL CORPORATION

Date: April 28, 2020

By: /s/ Sophia Garnette

**Sophia Garnette**

**Vice President, Legal Affairs and Operations**