# 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): June 9, 2020

# **CRYO-CELL INTERNATIONAL, INC.**

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 0-23386 (Commission File Number)

700 Brooker Creek Blvd., Suite 1800, Oldsmar, FL (Address of principal executive offices) 22-3023093 (IRS Employer Identification No.)

> 34677 (Zip Code)

Registrant's telephone number, including area code: (813)749-2100

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 (see General Instructions 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))

D 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:

	Trading	Name of each exchange
Title of each class	Symbol(s)	on which registered
Common Stock, \$0.01 par value	CCEL	OTCQB

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  $\Box$ 

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.  $\Box$ 

# Item 1.01. Entry into a Material Definitive Agreement.

Effective June 9, 2020, Cryo-Cell International, Inc. ("Cryo-Cell") entered into a Patent Option Agreement (the "Option") with Duke University ("Duke"). The Option grants Cryo-Cell the exclusive option to obtain an exclusive license to certain of Duke's patent rights to make, have made, use, import, offer for sale, sell and otherwise commercially exploit (with the right to sublicense) certain licensed products and to practice certain licensed processes, and the exclusive right to use certain regulatory data and technical information in connection with such licensed patent rights, in the treatment, prevention, cure, reduction, mitigation or other management of diseases in humans, except, with regard to certain patent rights, in certain excluded fields of use and in certain territories, as well as a limited license to make, have made or use certain products, processes, data and information for the purpose of evaluating the market potential for such products and processes in the designated field of use, subject to Duke's reserved rights to practice the licensed rights for all research, public service, internal (including clinical) and/or educational purposes. Pursuant to the Option, the terms of any such license are to include the terms (including the fees and royalties) set forth in summary term sheet attached as Appendix A to the Option.

This exclusive Option is for a period of six (6) months from the effective date of the Option. As consideration for the Option, Cryo-Cell will pay Duke a non-refundable, option fee of Three Hundred Fifty Dollars (\$350,000). Such option fee, plus any extension fee, will be fully credited against the license fee under the future license agreement. The Option is subject to extension by Cryo-Cell for an additional six (6) months by payment of One Hundred Fifty Thousand Dollars (\$150,000) on or before the expiration of the initial six (6) month option period.

The foregoing summary of the Option is not complete and is qualified in its entirety by reference to the Option, a copy of which is attached hereto as Exhibits 10.1 and incorporated by reference.

# Item 9.01. Financial Statements and Exhibits.

(a) Exhibits.

- 10.1 Patent Option Agreement, dated June 9, 2020, between Duke University and Cryo-Cell International, Inc.
- 99.1 Press Release dated June 11, 2020

# **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 thereunto duly authorized.

CRYO-CELL INTERNATIONAL, INC.

Dated: June 11, 2020

By: /s/ David Portnoy David Portnoy

Chairman and Co-Chief Executive Officer

# PATENT OPTION AGREEMENT

Duke University File(s) #4719, 5000, 5191, 5204, 6381, 6382, 6478, 6479, 6480, 6622, 6623, 6624, 6625 and 7094

This Patent Option Agreement ("Agreement") is entered into on June 9, 2020 ("EFFECTIVE DATE"), between Duke University, a nonprofit educational and research institution organized under the laws of North Carolina ("DUKE") having the address in Article 8 below and Cryo-Cell International, Inc. ("COMPANY"), a corporation incorporated in the state of Delaware, located at 700 Brooker Creek Blvd, Suite 1800, Oldsmar, Florida 34677.

DUKE desires to grant COMPANY the right to license DUKE's patent rights, regulatory data, and proprietary processes related to cord blood, cord tissue and DUOC-01 on substantially the terms set forth in this Agreement and the SUMMARY TERM SHEET attached hereto at Attachment A, and COMPANY desires a period of time in which to enter into such license (the "License Agreement"). DUKE and COMPANY therefore agree as follows:

# ARTICLE 1 - DEFINITIONS

The following definitions apply to this Agreement:

1.1 "EXCLUDED FIELDS OF USE" means autologous specific therapeutics for autism, cerebral palsy and stroke.

1.2 "EXCLUDED TERRITORY" means Japan, South Korea, and Taiwan.

1.3 "FIELD OF USE" means the treatment, prevention, cure, reduction, mitigation or other management of any and all diseases and conditions in humans.

1.4 "LICENSED PRODUCT(S)" means any product sold by LICENSEE or SUBLICENSEE that: (a) but for the license under the License Agreement comprises an infringement of (including contributory or inducement), or is covered by, a VALID CLAIM contained in the PATENT RIGHTS in the country in which any such product or product part is made, used, imported, offered for SALE or sold; or (b) is manufactured or is required to be administered to a patient in the process of conducting a LICENSED PROCESS or is required to be employed to practice a LICENSED PROCESS; or (c) uses any of the REGULATORY DATA or TECHNICAL INFORMATION. For clarity, any product lawfully sold by a third party without license or authorization from LICENSEE or a SUBLICENSEE shall not be a LICENSED PRODUCT.

1.5 "LICENSED PROCESS(ES)" means any process or method or service employed by LICENSEE or SUBLICENSEE that: (a) but for the license under the License Agreement comprises an infringement of (including contributory or inducement), or is covered by a VALID CLAIM contained in the PATENT RIGHTS in the country in which such process or method or service is performed; or (b) employs a LICENSED PRODUCT; or (c) uses any of the REGULATORY DATA or TECHNICAL INFORMATION.

# 1.6 "LICENSED RIGHTS" means individually and collectively, REGULATORY DATA, TECHNICAL INFORMATION, and PATENT RIGHTS.

1.7 "PATENT RIGHTS" means DUKE's legal rights under the patent laws of the United States or relevant foreign countries for all of the following:

(a) the following United States and foreign patents and/or patent applications, and divisionals, continuations (including continuations-in-part only to the extent such continuations-in-part are entitled to claim priority to such patents or patent applications), and foreign counterparts of the same:

#### Patent Rights Group (A)

- METHODS OF TREATING BRAIN INJURY USING CORD BLOOD OR A COMPONENT THEREOF, US Application 16/477,110 (4719)
- COMPOSITIONS AND METHODS OF THE TREATMENT OF DEMYLINATING CONDITIONS, US Application 16/477,167, EP 18738872.3
   (5000/5191)
- METHODS FOR THE TREATMENT OF AUTISM SPECTRUM DISORDERS, PCT/US2018/022174, US Application 16/493,754 (5204)

#### Patent Rights Group (B)

- METHODS OF TREATING CEREBRAL PALSY USING HIGH DOSE ALLOGENEIC UMBILICAL CORD BLOOD, US Application 16/510,387 (6479)
- METHODS OF TREATING CEREBRAL PALSY AND HYPOXIC-ISCHEMIC ENCEPHALOPATHY USING HUMAN UMBILICAL CORD TISSUE-DERIVED MESENCHYMAL STROMAL CELLS, PCT/US2019/025796 (6381)
- METHODS FOR THE TREATMENT OF AUTISM SPECTRUM DISORDERS USING HUMAN UMBILICAL CORD TISSUE-DERIVED MESENCHYMAL STROMAL CELLS, PCT/US2019/025716 (6382)
- COMPOSITIONS AND METHODS FOR THE TREATMENT OF DEMYELINATING CONDITIONS US Application 16/510,395
- COMPOSITIONS COMPRISING MESESCHYMAL STROMAL CELLS FOR THE TREATMENT OF VIRAL INFECTIONS US application 63/017,290

(b) United States and foreign patents issued from the applications listed in subsection 1.8(a) above, including any reissued or reexamined patents based upon the same and all extensions, renewals, restorations and supplementary protection or any equivalent thereof.

# 1.8 "PRINCIPAL INVESTIGATOR" means Dr. Joanne Kurtzberg.

1.9 "REGULATORY DATA" means the underlying data, including any correspondence, records, filings and other documentation with any regulatory authority with respect to any LICENSED PROCESS, to the extent owned by and/or (if any) licensed (with the right to license COMPANY) to DUKE under United States and international law, in any protocols, Standard Operating Procedures, and case report forms collected or created in connection with DUKE's

pre-clinical studies, regulatory submissions, and clinical trials (specifically IND numbers 14360, 16615, 15949, 17313, 17921, 16274, and 14753) and further includes any additional relevant TECHNICAL INFORMATION related to studies with Protocol Numbers 00017801, 00065043, 00052449, 00070514, 00079241, 00059284, 00077580, 00000412, and 00066647 including related reports, manuscripts and correspondence and other records of regulatory interactions communicated by DUKE to LICENSEE under the License Agreement and at DUKE's sole discretion, with initial reference in DUKE Office of Licensing and Ventures File Nos: 6480, 6622, 6623, 6624, and 6625. REGULATORY DATA and TECHNICAL INFORMATION shall not include the private medical records of individuals, and shall not include any data or information that allows such individuals to be directly identified.

1.10 "TECHNICAL INFORMATION" means any non-patented scientific, technical, regulatory and other information to the extent owned by and/or (if any) licensed (with the right to license to COMPANY) to DUKE and necessary or used by the PRINCIPAL INVESTIGATOR for the conduct of any process covered by the PATENT RIGHTS. TECHNICAL INFORMATION does not include information in the public domain, as LICENSEE can show by documentary evidence.

1.11 "VALID CLAIM" means: (a) a claim in an issued patent within the PATENT RIGHTS which has not (i) expired, (ii) been finally adjudicated or admitted by DUKE as invalid or unenforceable, or (iii) been abandoned, or (b) a claim in a pending application within the PATENT RIGHTS which is still under prosecution; provided that if a claim of a pending patent application has not issued as a claim of an issued patent within seven (7) years after the filing date from which such claim takes priority, such claim shall not be a VALID CLAIM for purposes of this Agreement from the seven (7) year anniversary date of such priority date until such time as such claim does issue (at which point such claim shall be a VALID CLAIM for purposes of this Agreement. It is understood and agreed that a claim in a pending application that is subject to a restriction requirement during prosecution and is not yet being prosecuted as part of a divisional patent application will still be considered a VALID CLAIM until it is finally rejected or abandoned and subject to the prior sentence.

#### ARTICLE 2 - EVALUATION

2.1 During the OPTION PERIOD, COMPANY shall use commercially reasonable efforts to evaluate the market potential for LICENSED PRODUCTS and LICENSED PROCESSES in the FIELD OF USE.

# ARTICLE 3 - PATENT PROSECUTION AND MAINTENANCE

3.1 DUKE shall control all aspects of filing, prosecuting, and maintaining all of the patents and patent applications included within the PATENT RIGHTS. COMPANY shall fully cooperate in such activities. The parties shall negotiate in good faith the foreign countries in which to pursue patent protection. COMPANY shall not have any rights under this Agreement in countries with respect to which COMPANY does not agree to reimburse DUKE's documented, out-of-pocket patent expenses with respect to the prosecution and maintenance of the PATENT RIGHTS.

3.2 DUKE shall notify COMPANY of any significant information (including proposed responses or filings) received by DUKE relating to the filing, prosecution and maintenance of the patents and patent applications included within the PATENT RIGHTS, and shall make reasonable efforts to allow COMPANY to review, comment, and advise upon such information. COMPANY agrees to hold such information, including such information received before the EFFECTIVE DATE, confidential and to use the information provided by DUKE only for the purpose of advancing PATENT RIGHTS and shall return all such information to DUKE if the parties do not enter into the License Agreement hereunder. With written permission from DUKE (not to be unreasonably withheld), COMPANY may share such information with third parties who are obligated as to confidentiality and use to the same extent as COMPANY.

#### ARTICLE 4 - OPTION

DUKE grants COMPANY an exclusive option to obtain:

(a) an exclusive worldwide license under Patent Rights B to make, have made, use, import, offer for sale, sell and otherwise commercially exploit LICENSED PRODUCTS and to practice LICENSED PROCESSES, and the exclusive right to use REGULATORY DATA and TECHNICAL INFORMATION in connection with such licensed patent rights, in the FIELD OF USE and TERRITORY; and

(b) an exclusive license under Patent Rights A to make, have made, use, import, offer for sale, sell and otherwise commercially exploit LICENSED PRODUCTS and to practice LICENSED PROCESSES, and the exclusive right to use REGULATORY DATA and TECHNICAL INFORMATION in connection with such licensed patent rights, in the FIELD OF USE and TERRITORY except for the EXCLUDED FIELDS OF USE in the EXCLUDED TERRITORY. For clarity, COMPANY shall have no LICENSED RIGHTS under Patent Rights A for the EXCLUDED FIELDS OF USE in the EXCLUDED TERRITORY; and

(c) in each case above with the right to sublicense; and

(d) subject to DUKE's reserved rights to practice the LICENSED RIGHTS for all research, public service, internal (including clinical) and/or educational purposes; provided that PRINCIPLE INVESTIGATOR shall keep COMPANY reasonably informed with respect to any such practice and the results thereof and the COMPANY agrees to such activities, not to be unreasonably withheld.

The following terms shall apply to the option:

4.1 <u>OPTION FEE</u>. As consideration for the option granted herein, COMPANY shall pay DUKE anon-refundable, option fee of Three Hundred Fifty Thousand Dollars (\$350,000) within three (3) days of execution of this Agreement. Such option fee and the extension fee (described below), if paid, shall be fully credited against the License Fee under the future

License Agreement. Payments drawn directly on a U.S. bank may be made by either check made payable to "Duke University" or wire transfer. Any payment drawn on a foreign bank or foreign branch of a U.S. bank shall be made only by wire transfer. Wire transfers shall be made in accordance with the following or any other instructions as may be specified by DUKE. If payments are made by wire, the wiring instructions below must be followed. The option granted herein shall not be effective until such delivery.

Bank:	Wells Fargo Bank, N.A.
	301 S. Tryon Street
	Charlotte, NC 28282, USA
ABA #:	121000248 (Domestic wires only)
Swift Code:	WFBIUS6S (Foreign wires only)
Beneficiary:	Duke University Concentration Account
Account #:	202374-0253053
Attention:	Office of Licensing & Ventures, 919-681-7583* FILE NUMBER: 4719, 5000, 5191, 5204, 6381, 6382, 6478, 6479, 6480, 6622,
	6623, 6624, 6625 and 7094

4.2 <u>OPTION PERIOD</u>. This exclusive option shall be for a period of six (6) months from the EFFECTIVE DATE, subject to extension by COMPANY as provided below (the "OPTION PERIOD"). Until expiration of the OPTION PERIOD, DUKE shall not enter into any discussions with any third party for any arrangement that if consummated would prevent from or interfere with DUKE negotiating or entering into or carrying out the obligations contemplated in the terms and conditions described in Attachment A.

4.3 <u>LIMITED LICENSE</u>. During the OPTION PERIOD, DUKE grants COMPANY the license to make, have made, or use the LICENSED PRODUCTS, LICENSED PROCESSES, REGULATORY DATA and TECHNICAL INFORMATION for the purposes described in Article 2 above. This limited license does not include the right to grant any sublicenses, or to sell or otherwise provide LICENSED PRODUCTS or LICENSED PROCESSES to any third party.

4.4 <u>LICENSE NEGOTIATION</u>. For a reasonable period of up to six (6) months after the EFFECTIVE DATE, (as may be extended by COMPANY for an additional six (6) months by payment of a non-refundable \$150,000 extension fee on or before the expiration of such six (6) months) the parties agree to negotiate exclusively in good faith to enter into the License Agreement granting COMPANY exclusive rights to make, have made, import, use, market, offer for sale, and sell LICENSED PRODUCTS, and practice LICENSED PROCESSES under terms customary in the trade and including substantially the definitions and terms in Attachment A.

4.5 <u>NOTIFICATION OF LACK OF COMMERCIAL INTEREST</u>: COMPANY shall promptly notify DUKE, during the OPTION PERIOD, in the event that it determines that it has no commercial interest in the PATENT RIGHTS.

5.1 Except as otherwise provided herein, this Agreement shall terminate at the end of the OPTION PERIOD or upon execution of the License Agreement, whichever occurs first.

5.2 If COMPANY ceases to operate its business, this Agreement shall immediately terminate upon DUKE's delivery of a termination notice to the address for notices provided herein.

5.3 Except as otherwise provided herein, if COMPANY fails to make any payment due to DUKE within ten (10) days' written notice by DUKE, this Agreement shall automatically terminate unless DUKE specifically extends such date in writing. Such termination shall not foreclose DUKE from collection of any amounts remaining unpaid or seeking other legal relief.

5.4 Upon any material breach or default of this Agreement by COMPANY (other than as specifically provided herein, including Section 5.3 above), the terms of which shall take precedence over the handling of any other material breach or default under this Section 5.4), DUKE has the right to terminate this Agreement effective on thirty (30) days' written notice to COMPANY, unless COMPANY cures the material breach or default before the period expires.

5.5 If COMPANY asserts the invalidity or unenforceability of any claim included in the PATENT RIGHTS, including by way of litigation or administrative proceedings, either directly or through any other party, then DUKE shall have the right to immediately terminate this Agreement upon written notice to COMPANY.

# ARTICLE 6 - NO WARRANTIES; LIMITATION ON DUKE'S LIABILITY

6.1 DUKE, including its trustees, fellows, officers, employees and agents, makes no representations or warranties that PATENT RIGHTS are or will be held valid, or that the manufacture, importation, use, offer for sale, sale or other distribution of any LICENSED PRODUCTS or LICENSED PROCESSES will not infringe upon any patent or other rights.

6.2 DUKE, INCLUDING ITS TRUSTEES, FELLOWS, OFFICERS, EMPLOYEES AND AGENTS, MAKES NO REPRESENTATIONS, EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND ASSUMES NO RESPONSIBILITIES WHATEVER WITH RESPECT TO DESIGN, DEVELOPMENT, MANUFACTURE, USE, SALE OR OTHER DISPOSITION BY COMPANY OF LICENSED PRODUCTS OR LICENSED PRODUCTS AND LICENSED PRODUCTS AND LICENSED PRODUCTS AND LICENSED PROCESSES. It is expected that DUKE will make standard and customaryrepresentations and warranties with respect to the subject matter of the License Agreement.

6.3 DUKE including its respective trustees, fellows, officers, employees and agents, shall not be responsible or liable for any indirect, special, incidental, or consequential damages or lost profits or other economic loss or damage with respect to LICENSED PRODUCTS, LICENSED PROCESSES, or the PATENT RIGHTS licensed to COMPANY under this Agreement, or other subject matter thereof, regardless of legal or equitable theory. The above limitations on liability apply even though DUKE, its trustees, fellows, officers, employees or agents may have been advised of the possibility of such damage or such damage may have been foreseeable.

# ARTICLE 7 - INDEMNIFICATION

7.1 COMPANY shall defend, indemnify and hold harmless DUKE, including its trustees, officers, fellows, employees, students, contractors, subcontractors, and agents against any and all damages, losses, and expenses of any nature (including attorney's fees and other litigation expenses), resulting from including, but not limited to as a result of, death, personal injury, illness, property damage, economic loss or products liability, including errors and omissions, arising from or in connection with any of the following: (1) any manufacture, use, sale, or other disposition by COMPANY of LICENSED PRODUCTS or LICENSED PROCESSES; (2) the use by any person of LICENSED PRODUCTS or LICENSED PROCESSES made, used, sold, authorized, or otherwise distributed by COMPANY; (3) the use or practice of any invention related to the PATENT RIGHTS; provided that DUKE provides COMPANY with prompt written notice of any such Claim, and cooperates with COMPANY as reasonably requested in any such defense or settlement; except in each case, to the extent a court of competent jurisdiction finds the sole cause of said Claim to have been DUKE's breach of this Agreement or the gross negligence or willful misconduct of DUKE, its employees or agents. This section does not confer any license rights on COMPANY, and shall survive termination or expiration of the Agreement.

# ARTICLE 8 - NOTICES

8.1 Any notice, request, or report required or permitted to be given or made under this Agreement by either party is effective when mailed if sent by recognized overnight carrier, certified or registered mail, or electronic mail followed by confirmation by U.S. mail, to the address set forth below or such other address as such party specifies by written notice given in conformity herewith. Any notice, request, or report not so given is not effective until actually received by the other party.

To DUKE:

For delivery via the U.S. Postal Service

Office of Licensing & Ventures Box 90083 Durham, NC 27708 Attention: Agreement Manager/File No. 4719, 5000, 5191, 5204, 6381, 6382, 6478, 6479, 6480, 6622, 6623, 6624, and 6625

For delivery via nationally/internationally recognized courier

DUKE UNIVERSITY Office of Licensing & Ventures To COMPANY:

Cryo-Cell International, Inc. 700 Brooker Creek Blvd Oldsmar, FL 34677 Attn: CEO

2812 Erwin Road, Suite 406 Durham, NC 27705 Attn: Agreement Manager/File No. 4719, 5000, 5191, 5204, 6381, 6382, 6478, 6479, 6480, 6622, 6623, 6624, and 6625

For delivery via electronic mail

agreements-olv@duke.edu

# ARTICLE 9 - MISCELLANEOUS PROVISIONS

9.1 Each party agrees to accept all information, samples, documents, and other disclosures from the other party hereunder (hereinafter "Confidential Information") on a confidential basis only, and may not use Confidential Information of the other party for such party's commercial benefit (except for technical and economic evaluation internal to COMPANY). Each party further agrees that it will keep in confidence and not disclose Confidential Information of the other party to a third party or parties for a period of five (5) years from the end of the OPTION PERIOD. Any obligation set forth in this Section 9.1 does not apply to any information which: (a) are or hereafter become a part of the public knowledge through no fault of the receiving party; (b) the receiving party can demonstrate were in its possession prior to the time of disclosure by the disclosing party; (c) the receiving party can demonstrate by written evidence were developed by it from a third party who has a legal right to make such a disclosure; or (d) the receiving party can demonstrate by written evidence were developed by it independently of the disclosure of Confidential Information by the disclosing party.

9.2 COMPANY shall not use, either directly or indirectly, the name of DUKE or any of its trustees, officers, fellows or employees in any publicity or advertising unless a copy of the same is submitted to and approved in writing by DUKE prior to any such use.

9.2 This Agreement shall be governed by and construed under the laws of the state of North Carolina without regard for principles of choice of law. Any claims, demands, or actions asserted against DUKE, its trustees, fellows, officers, employees or agents shall only be brought in the North Carolina Court of Claims. COMPANY, its successors, and assigns consent to the jurisdiction of a court with applicable subject matter jurisdiction sitting in the state of North Carolina with respect to any claims arising under this Agreement or the relationship between the parties.

9.3 COMPANY may not assign this Agreement without the prior written consent of DUKE and shall not pledge any of the license rights granted in this Agreement as security for any creditor; . Any attempted pledge of any of the rights under this Agreement or assignment of this Agreement without the prior consent of DUKE will be void from the beginning. No assignment by COMPANY will be effective until the intended assignee agrees in writing to accept all of the terms and conditions of this Agreement, and such writing is provided to DUKE.

9.4 DUKE and COMPANY agree that this Agreement, together with Attachment A, sets forth their entire understanding concerning the subject matter of this Agreement, and no modification of the Agreement will be effective unless both DUKE and COMPANY agree to it in writing.

9.5 If a court of competent jurisdiction finds any term of this Agreement invalid, illegal or unenforceable, that term will be curtailed, limited or deleted, but only to the extent necessary to remove the invalidity, illegality or unenforceability, and without in any way affecting or impairing the remaining terms.

The authorized signatures for DUKE and COMPANY below signify their acceptance of the terms of this Agreement.

FOR COMPANY

By: /s/ David Portnoy (authorized representative)

Typed Name David Portnoy

Title Chairman & Co-CEO

Date June 9, 2020

FOR DUKE UNIVERSITY

By: <u>/s/ Robin L. Rasor</u> Robin L. Rasor Executive Director

Date June 9, 2020

#### APPENDIX A. SUMMARY TERMSHEET

# DUKE FILE #'s 4719, 5000, 5191, 5204, 6381, 6382, 6478, 6479, 6480, 6622, 6623, 6624, and 6625

#### General

Technology:

Kurtzberg Cord Blood and Tissue Cell Products

Patent Rights Group (A)

- METHODS OF TREATING BRAIN INJURY USING CORD BLOOD OR A COMPONENT THEREOF, US Application 16/477,110 (4719)
- COMPOSITIONS AND METHODS OF THE TREATMENT OF DEMYLINATING CONDITIONS, US Application 16/477,167, EP 18738872.3 (5000/5191)
- METHODS FOR THE TREATMENT OF AUTISM SPECTRUM DISORDERS, PCT/US2018/022174, US Application 16/493,754 (5204)

Patent Rights Group (B)

- METHODS OF TREATING CEREBRAL PALSY USING HIGH DOSE ALLOGENEIC UMBILICAL CORD BLOOD, US Application 16/510,387 (6479)
- METHODS OF TREATING CEREBRAL PALSY AND HYPOXIC-ISCHEMIC ENCEPHALOPATHY USING HUMAN UMBILICAL CORD TISSUE-DERIVED MESENCHYMAL STROMAL CELLS, PCT/US2019/025796 (6381)
- METHODS FOR THE TREATMENT OF AUTISM SPECTRUM DISORDERS USING HUMAN UMBILICAL CORD TISSUE-DERIVED MESENCHYMAL STROMAL CELLS, PCT/US2019/025716 (6382)
- COMPOSITIONS AND METHODS FOR THE TREATMENT OF DEMYELINATING CONDITIONS US Application 16/510,395
- COMPOSITIONS COMPRISING MESESCHYMAL STROMAL CELLS FOR THE TREATMENT OF VIRAL INFECTIONS US application 63/017,290

DUKE will control the prosecution of any patent applications, provided DUKE will consult LICENSEE on the prosecution of PATENT RIGHTS under this agreement and keep LICENSEE fully informed with respect thereto. LICENSEE will reimburse DUKE for its costs not yet reimbursed in seeking, prosecuting and maintaining PATENT RIGHTS and for its costs incurred during the term of the license agreement.

"REGULATORY DATA"	includes copyrights and other intellectual property rights, to the extent owned by and/or (if any) licensed to DUKE under United States and international law, in any protocols, Standard Operating Procedures, case report forms, and published data collected or created in connection with DUKE's pre-clinical studies, regulatory submissions, and clinical trials (specifically IND numbers 14360, 16615, 15949, 17313, 17921, 16274, and 14753) and further includes any additional relevant TECHNICAL INFORMATION related to studies with Protocol Numbers 00017801, 00065043, 00052449, 00070514, 00079241, 00059284, 00077580, 00000412, and 00066647 including related reports, manuscripts and correspondence and other records of regulatory interactions communicated by DUKE to LICENSEE under this License Agreement and at DUKE's sole discretion, with initial reference in DUKE Office of Licensing and Ventures File Nos: 6480, 6622, 6623, 6624, and 6625. REGULATORY DATA and TECHNICAL INFORMATION shall not include the private medical records of individuals, and shall not include any data or information that allows such individuals to be directly identified.
Technical Information:	means any non-patented scientific, technical, regulatory and other information to the extent owned by and/or (if any) licensed to DUKE and disclosed by DUKE to LICENSEE under this License Agreement and at DUKE's sole discretion. TECHNICAL INFORMATION does not include information that belongs in the public domain, as LICENSEE can show by documentary evidence.
Licensed Rights:	
	an exclusive worldwide license under Patent Rights B to make, have made, use, import, offer for sale, sell and otherwise commercially exploit LICENSED PRODUCTS and to practice LICENSED PROCESSES, and the exclusive right to use REGULATORY DATA and TECHNICAL INFORMATION in connection with such licensed patent rights, in the FIELD OF USE and TERRITORY; and

an exclusive license under Patent Rights A to make, have made, use, import, offer for sale, sell and otherwise commercially exploit LICENSED PRODUCTS and to practice LICENSED PROCESSES, and the exclusive right to use REGULATORY DATA and TECHNICAL INFORMATION in connection with such licensed patent rights, in the FIELD OF USE and

TERRITORY except for the EXCLUDED FIELDS OF USE in the EXCLUDED TERRITORY. For clarity, COMPANY shall have no LICENSED RIGHTS under Patent Rights A for the EXCLUDED FIELDS OF USE in the EXCLUDED TERRITORY; and

in each case above with the right to sublicense; and

subject to DUKE's reserved rights to practice the LICENSED RIGHTS for all research, public service, internal (including clinical) and/or educational purposes; provided that DUKE shall keep COMPANY reasonably informed with respect to any such practice and the results thereof and the COMPANY agrees to such activities, not to be unreasonably withheld.

License is subject to any rights required to be granted under prior research or sponsorship agreements, or retained by the U.S. government, for example in accordance with Chapter 18 or Title 35 of USC 200-212 and the regulations thereunder (37 CFR Part 401), when applicable.

Autologous specific therapeutics for autism, Cerebral Palsy and stroke.

Japan, South Korea, and Taiwan

Unless earlier terminated, will continue through the expiration of the royalty term upon which all licenses granted to COMPANY will become fully-paid up and irrevocable.

Human Therapeutics

will be defined in more detail in the License Agreement to include the amounts received, on sales, however characterized, by LICENSEE and/or SUBLICENSEES of LICENSED PRODUCTS and uses of LICENSED PROCESSES, less customary discounts including the following deductions (but only to the extent such deductions are otherwise included in NET SALES and are not obtained in view of other consideration received by LICENSEE):

- (a) cash discounts, rebates and chargebacks actually granted to customers in such invoices for SALE of LICENSED PRODUCTS, but only in amounts customary in the trade;
- (b) sales taxes, tariff duties and/or use taxes separately stated in such bills or invoices with reference to particular SALES and actually paid by LICENSEE to a governmental unit;

# 12

Excluded Territory: Term of the License and Agreement:

Excluded Field of Use:

Field of Use: Net Sales:

	(c) actual freight expenses between LICENSEE and customers, to the extent such expenses are not charged to or reimbursed by customers; or
	(d) amounts actually refunded or credited on returns.
Licensed Products:	means any product sold by LICENSEE or SUBLICENSEE that: (a) but for this Agreement comprises an infringement of (including contributory or inducement), or is covered by, a VALID CLAIM contained in the PATENT RIGHTS in the country in which any such product or product part is made, used, imported, offered for SALE or sold; or (b) is manufactured or is administered to a patients by using a LICENSED PROCESS or is employed to practice a LICENSED PROCESS; or (c) uses any of the REGULATORY DATA or TECHNICAL INFORMATION.
Licensed Process:	means any process or method or service employed by LICENSEE or SUBLICENSEE that: (a) but for this Agreement, comprises an infringement of (including contributory or inducement or is covered by a VALID CLAIM contained in the PATENT RIGHTS in the country in which such process or method or service is performed; or (b) employs a LICENSED PRODUCT; (c) uses any of the REGULATORY DATA or TECHNICAL INFORMATION.
Valid Claim	means (a) a claim in an issued patent which has not (i) expired, (ii) been finally adjudicated or admitted by DUKE as invalid or unenforceable, or (iii) been abandoned, or (b) a claim in a pending application which is still under prosecution. It is understood and agreed that a claim in a pending application that is subject to a restriction requirement during prosecution and is not yet being prosecuted as part of a divisional patent application will still be considered a Valid Claim until it is finally rejected or abandoned.
First Commercial Sale:	means the first SALE through a bona fide arm's length transaction of any LICENSED PRODUCT or first commercial use of any LICENSED PROCESS by LICENSEE or a SUBLICENSEE, excluding the SALE of a LICENSED PRODUCT or use of a LICENSED PROCESS for use in trials, as a sample, or that is of temporary availability.
Market Cap:	means, with respect to a particular trading day, the closing price per share of common stock on such trading day multiplied by the number of outstanding shares.
Royalty Term	Means 15 years post first commercial sale or expiration of the last VALID CLAIM, whichever comes later.

#### Consideration

License Fee: \$12,000,000 (12 million dollars) of which \$5 million will be due upon signing, \$5 million will be due on the first anniversary of the LICENSE EFFECTIVE DATE and \$2 million will be on the second anniversary date of the License EFFECTIVE DATE. License Fee shall be non-refundable, non-creditable. If LICENSEE terminates the License Agreement prior to three (3) years from the EFFECTIVE DATE, LICENSEE will pay DUKE the balance of License Fee owed above within thirty (30) days of said termination and receipt of invoice therefor.

Board Observation Rights.

DUKE shall have observation rights at any of LICENSEE's Board of Directors meetings. At such meetings, DUKE, at its option, shall be permitted to have a non-voting designee (the "Observer") attendin-person or via telephone for sessions covering matters relating to LICENSEE's business, provided that: (i) the Observer will be excused from any Board activities involving attorney-client privilege or otherwise determined by the Board consistent with good corporate governance (including any executive or closed sessions) and (ii) such rights shall terminate on the earliest of a Change of Control of LICENSEE, or such time as DUKE's equity interest in LICENSEE is less than two percent (2%) (on a fully-diluted basis). Any such Observer will enter into an agreement with LICENSEE on customary terms for observers to protect confidential information of LICENSEE.

Royalties:

# For NET SALES of LICENSED PROCESS:

7% of annual NET SALES up to \$75M
10% on annual NET SALES at or above \$75M and up to \$200M
12.5% on annual NET SALES at or above \$200M
\*Royalties shall be reduced to 75% of the above rates after expiration of all PATENT RIGHTS but prior to 15 years post FIRST COMMERCIAL SALE.

# For NET SALES of LICENSED PRODUCT:

7.5%

\*Royalty reduced to 2.5% after expiration of all PATENT RIGHTS but prior to 15 years post FIRST COMMERCIAL SALE.

If, in the performance of a LICENSED PROCESS, a LICENSED PRODUCT is administered, the NET SALES of such LICENSED PROCESS shall be <u>in addition</u> to the use or administration of such LICENSED PRODUCT. For purposes of calculating

royalties for the use or administration of a LICENSED PRODUCT by LICENSEE or its Affiliates in the performance of said LICENSED PROCESS shall constitute a third party sale of said LICENSED PRODUCT. NET SALES in such an instance shall be the average selling price of like quantities of LICENSED PRODUCTS sold in the United States during the reporting period in which such LICENSED PRODUCT was used or administered in the performance of such LICENSED PROCESS. The License Agreement will include customary combination sales terms for standard allocation of Net Sales.

If LICENSEE is obligated or reasonably deems it necessary to pay consideration to any Third Party that holds a patent(s) that would, in the reasonable judgment of LICENSEE be infringed by the manufacture, importation, use, offer for sale or sale of a LICENSED PRODUCT or LICENSED PROCESS, then LICENSEE shall be entitled to deduct fifty percent (50%) of such consideration paid to such Third Party from the royalties payable to DUKE. However, in no event shall the royalty payable to DUKE for any ROYALTY PERIOD be reduced to less than fifty percent (50%) of the agreed upon royalty rates of NET SALES. LICENSEE shall provide DUKE with a copy of any agreement with a Third Party that triggers the royalty reduction, provided that LICENSEE may redact from such copy any provisions LICENSEE considers confidential or proprietary that are not necessary to verify the accuracy of such deductions When LICENSEE finalizes the formulation of any LICENSED PRODUCT during the product development cycle, LICENSEE shall promptly inform DUKE of any Third Party patent rights required for the LICENSEE PRODUCT and the applicable royalty rates therefore. In addition, should LICENSEE subsequently determine that any additional Third Party patent rights are required, LICENSEE shall promptly inform DUKE.

Sublicensing Income 35% of any consideration not based on NET SALES (e.g., license issue fees, milestone payments, maintenance or annual minimum fees, other royalties) received from Sublicensees in consideration for the LICENSED RIGHTS, other than R&D funds and other customary carveouts to be specified in the License Agreement.

Minimum Annual Royalties: Such minimum annual royalties to be paid provided the FDA allows the IND transfer and does not revoke the expanded access for reasons unrelated to LICENSEE

- (1) In year 2: \$500,000(2) In Year 3: \$1.0M
- (3) In Year 4: \$2.5 M
- (4) In Year 5 and Beyond: \$5.0 M

Minimum Annual Royalties shall be credited against Running Royalties due on NET SALES made during the calendar year for which the Minimum Annual Royalties apply. Minimum Annual Royalties paid in excess of running royalties shall be creditable to amounts due for future years.

#### Milestone Payments:

# <u>Cash</u>

• \$2.0M upon initiation of a Phase III clinical trial for an indication other than Autism Spectrum Disorder for a Licensed Product comprising cord tissue derived MSC

# CryoCell Stock

- 5.0% of common stock upon execution of License Agreement
- 2.5% of common stock upon cumulative NET SALES of LICENSED PRODUCT and LICENSED PROCESS of \$10M
- 2.5% of common stock upon cumulative NET SALES LICENSED PRODUCT and LICENSED PROCESS of \$75M
- 2.5% of common stock at each of the following market cap of LICENSEE triggers:
  - (1) at \$300M as long as this milestone is reached within 18 months of the execution of the agreement

(2) at 500M as long as this milestone is reached within 24 months of the execution of the agreement

In the event a Sublicensee pays LICENSEE a fee for achieving one of the milestone events listed above or under earned royalties, or a substantially similar milestone, LICENSEE shall pay 35% of the higher of: (i) the milestone payment or (ii) the Non-Sales Based Sublicense Income fee due on such Milestone Payment.

Milestone payments are non-refundable and non-creditable.

# Diligence

LICENSEE shall use commercially reasonable efforts to bring LICENSED PRODUCTS to market or one or more LICENSED PROCESSES to commercial use through use of commercially reasonable efforts to (i) implement a thorough, vigorous and diligent program for exploiting the PATENT RIGHTS and (ii) to continue active, diligent marketing efforts throughout the life of this Agreement.

Milestones:

Performance milestones are established to ensure that the technology is assiduously developed and to ensure broad public utilization of the technology.

In fulfillment of such milestones, LICENSEE agrees to reach the following commercialization and research and development milestones by the following dates: 1) Auto- Milestones to be agreed upon between DUKE and LICENSEE (development/sales/clinic driven) 2) Allo- Milestones to be agreed upon between DUKE and LICENSEE (development/sales/clinic driven) 3) MSC- Milestones to be agreed upon between DUKE and LICENSEE (development/manufacturing/sales driven) Other Terms Prior to any distribution or commercial use of LICENSED PRODUCTS or LICENSED PROCESSES resulting from Insurance: PATENT RIGHTS by LICENSEE, LICENSEE shall purchase and maintain in effect policies of product liability, completed operations, and errors and omissions insurance. Indemnification: LICENSEE shall defend, indemnify and hold harmless and shall require SUBLICENSEES to defend, indemnify and hold harmless DUKE for and against any and all claims, demands, damages, losses, and expenses of any nature (including attorneys' fees and other litigation expenses) (hereinafter "Claim"), resulting from, but not limited to, death, personal injury, illness, property damage, economic loss or products liability, including errors and omissions, arising from or in connection with, any of the following: (1) Any manufacture, use, SALE or other disposition by LICENSEE, SUBLICENSEES or transferees of LICENSED PRODUCTS or LICENSED PROCESSES; (2) The use by any person of LICENSED PRODUCTS made, used, sold or otherwise distributed by LICENSEE or SUBLICENSEES; (3) The use or practice by LICENSEE or SUBLICENSEES of any invention or computer software related to the PATENT RIGHTS; and (4) any Claim of infringement and/or invalidity of any claim(s) of the PATENT RIGHTS. The process for such indemnification to be set forth in the License Agreement. LICENSEE agrees that these license rights are not assignable without written consent from DUKE except in connection with Assignment a change of control (to be defined in the License Agreement). If LICENSEE takes part in the formation of a Spinout for purposes of exploiting the license granted to LICENSEE, Spin-out LICENSEE shall cause the Spinout to transfer to DUKE by the later of (a) sixty (60) days after a sublicense to the PATENT RIGHTS or assignment of this LICENSE AGREEMENT becomes effective between LICENSEE and the Spinout,

	or (b) the Spinout is first capitalized with at least \$X million by a Third Party investor(s), a total of X percent (%) share of the equity interest in the Spinout. The equity received by DUKE in the Spinout shall be of the same type (e.g., class of stock) received by LICENSEE under the relevant sublicense transaction. If the Spinout is a corporation, then the parties agree that LICENSEE, or the Spinout, shall make such transfer of equity pursuant to, and subject to the terms of, an agreement substantially in the form of a Stock Transfer Agreement as attached in Appendix X. If the Spinout is of another legal form, then the parties shall negotiate in good faith as to the terms of the transfer of equity.	
Warranty:	EXCEPT FOR THOSE REPRESENTATIONS AND WARRANTIES THAT ARE CUSTOMARY FOR SIMILAR TRANSACTIONS, DUKE, INCLUDING ITS TRUSTEES, OFFICERS, EMPLOYEES STUDENTS AND AGENTS, MAKES NO REPRESENTATIONS, EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND ASSUMES NO RESPONSIBILITIES WHATEVER WITH RESPECT TO DESIGN, DEVELOPMENT, MANUFACTURE, USE, SALE OR OTHER DISPOSITION BY LICENSEE OR SUBLICENSEES OF LICENSED PRODUCTS OR LICENSED PROCESSES.	
	LICENSEE, AND SUBLICENSEES ASSUME THE ENTIRE RISK AS TO PERFORMANCE OF LICENSED PRODUCTS AND LICENSED PROCESSES. In no event shall DUKE, including its trustees, fellows, officers, employees and agents, be responsible or liable for any indirect, special, incidental, or consequential damages or lost profits or other economic loss or damage with respect to LICENSED PRODUCTS or LICENSED PROCESSES, to LICENSEE, Sublicensees or any other individual or entity regardless of legal or equitable theory.	
Other Terms:	Other typical terms to be negotiated.	
18		

Contact: David Portnoy, Chairman and Co-CEO Cryo-Cell International, Inc. 813-749-2100 dportnoy@cryo-cell.com

# CORD BLOOD BANKING LEADER CRYO-CELL ENTERS INTO PATENT OPTION AGREEMENT WITH DUKE UNIVERSITY

**OLDSMAR, FL – June 11, 2020 – Cryo-Cell International, Inc. (OTC:QB Markets Group Symbol: CCEL)** (the "Company"), the world's first private cord blood bank to separate and store stem cells in 1992, announced that effective June 9, 2020, the Company has entered into a patent option agreement with Duke University. The six-month exclusive option agreement gives Cryo-Cell an option to obtain a license to manufacture and sell products based on Dr. Joanne Kurtzberg's patents. Please see the Company's Form 8-K filed with the Securities and Exchange Commission on June 11, 2020 for more details.

David Portnoy, Chairman of the Board and Co-CEO, said, "Cryo-Cell is honored to have entered into this option agreement with Dr. Kurtzberg and Duke University and believes that this is a significant step in the transformation of the Company. We look forward to Duke becoming a major shareholder and partner of the Company for many years to come."

"We are excited to enter into this exclusive option agreement with Cryo-Cell and are looking forward to working together to bring novel cord blood and birthing tissue based cellular therapeutics to the clinic," said Joanne Kurtzberg, MD, who is the Jerome S. Harris distinguished professor of pediatrics and a pioneer in cell therapies based on umbilical cord blood. Dr. Joanne Kurtzberg is an internationally renowned expert in pediatric hematology/oncology, pediatric blood and marrow transplantation, umbilical cord blood banking and transplantation, and novel applications of cord blood in the emerging fields of cellular therapies and regenerative medicine.

# About Cryo-Cell International, Inc.

Founded in 1989, Cryo-Cell International, Inc. is the world's first private cord blood bank. More than 500,000 parents from 87 countries have entrusted Cryo-Cell International with their baby's cord blood and cord tissue stem cells. In addition to its family bank, Cryo-Cell International has a public banking program in partnership with Duke University. Cryo-Cell's public bank has provided cord blood for more than 600 transplantations and operates cord blood donation sites across the U.S in prominent hospitals such as Cedars–Sinai Hospital in Los Angeles and Baptist Hospital in Miami. Cryo-Cell's mission is to provide clients with state-of-the-art cord blood and cord tissue cryopreservation services, raise awareness of the opportunity for expectant parents to bank or donate their baby's cord blood and support the advancement of regenerative medicine. Cryo-Cell operates in a facility that is FDA registered, cGMP-/cGTP-compliant and licensed in all states requiring licensure. Besides being AABB accredited as a cord

blood facility, Cryo-Cell was also the first U.S. (for private use only) cord blood bank to receive FACT accreditation for adhering to the most stringent cord blood quality standards set by any internationally recognized, independent accrediting organization. In addition, Cryo-Cell is ISO 13485:2003– certified by TÜV, an internationally recognized, quality assessment organization. Cryo-Cell is a publicly traded company, OTCQB:CCEL. For more information, please visit www.cryo-cell.com.

#### Forward-Looking Statement

Statements herein the terms "believes", "intends", "projects", "anticipates", "expects", and similar expressions as used are intended to reflect "forward-looking statements" of the Company. The information contained herein is subject to various risks, uncertainties and other factors that could cause actual results to differ materially from the results anticipated in such forward-looking statements or paragraphs, many of which are outside the control of the Company. These uncertainties and other factors include the impact of the COVID-19 pandemic on our sales, operations and supply chain, the success of the Company's global expansion initiatives and product diversification, the Company's actual future ownership stake in future therapies emerging from its collaborative research partnerships, the success related to its IP portfolio, the Company's ability to enter into a definitive license agreement with Duke, the Company's future competitive position in stem cell innovation, future success of its core business and the competitive impact of public cord blood banking on the Company's business, the Company's ability to minimize future costs to the Company's menstrual stem cell technology license agreements and umbilical cord blood license agreements and their ability to provide the Company with royalty fees, the ability of the reproductive tissue storage to generate new revenues for the Company and those risks and uncertainties contained in risk factors described in documents the Company files from time to time with the Securities and Exchange Commission, including the most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and any Current Reports on Form 8-K filed by the Company. The Company disclaims any obligations to subsequently revise any forward-looking statements to reflect events or circumstances after the date of such statements.