

Edgar Filing: Cellular Biomedicine Group, Inc. - Form 8-K

Cellular Biomedicine Group, Inc.
Form 8-K
December 28, 2018

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): December 21, 2018

CELLULAR BIOMEDICINE GROUP, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-36498	86-1032927
(State or other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

19925 Stevens Creek Blvd., Suite 100	95014
Cupertino, California	
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (408) 973-7884

(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 CFR 240.13e-4(c))

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 1.01 Entry into a Material Definitive Agreement

As previously reported, on September 25, 2018, Cellular Biomedicine Group, Inc. (the “Company”) together with certain of its subsidiaries and controlled entities entered into a License and Collaboration Agreement (the “Collaboration Agreement”) with Novartis Pharma AG (“Novartis AG”) pursuant to which the Company will manufacture and supply Novartis AG the Chimeric Antigen Receptor cell therapy Kymriah® (tisagenlecleucel) (the “Product”). Pursuant to the Collaboration Agreement, within 90 days of the date thereof, the Company shall enter into a manufacturing and supply agreement with Novartis that will govern the terms of manufacture and supply of the Product.

On December 21, 2018, the Company, Novartis AG, Shanghai Cellular Biopharmaceutical Group Ltd., a controlled entity of the Company (“CBMG Shanghai”; together with the Company, “CBMG”) and Beijing Novartis Pharma Co., Ltd., an affiliate entity of Novartis AG (“Novartis Beijing”; together with Novartis AG, “Novartis”) entered into a Toll Manufacturing and Supply Agreement (the “MSA”), pursuant to which CBMG will manufacture and supply the Product to Novartis. In exchange, CBMG will be entitled to a transfer payment equal to certain direct costs plus a mark-up, subject to price adjustment and reduction pursuant to certain mechanism set forth under the MSA.

Under the MSA, CBMG has the obligation to maintain certain minimum available capacity. CBMG has also agreed not to enter into any agreement relating to any additional manufacturing capacity without first offering Novartis the option to utilize such capacity during the initial term of the MSA. In addition, CBMG has agreed not to subcontract the performance of its obligations under the MSA to any third party without Novartis’ prior written consent.

Pursuant to the MSA, CBMG may only procure certain toll materials listed thereunder from Novartis and Novartis shall provide such toll materials to CBMG free of charge. CBMG also has the obligation to ensure that all materials used in the manufacturing of the Product are procured in compliance with applicable legal and contractual requirements. The MSA also set forth methodologies and minimum periods in relation to storage of materials used in manufacturing the Product and certain types of materials produced in the manufacturing process by CBMG. Pursuant to the MSA, prior to the commencement of manufacturing of the Product for clinical or commercial purposes, CBMG and Novartis will enter into a quality assurance agreement that will govern the quality standards and compliance related issues in connection with such manufacturing process.

Pursuant to the MSA, intellectual property rights of either CBMG or Novartis in existence as of the effective date thereof or arising outside of activities thereunder will continue to be owned by such party. Intellectual property developed in the course of activities under the MSA solely by or on behalf of CBMG or Novartis will be the exclusive property of such party.

The MSA will continue for certain period of time and then automatically renew for certain additional period of time unless Novartis provides notice of non-renewal. It also contains standard and customary termination rights and provides for termination by Novartis in other circumstances. In addition, the MSA contains customary indemnification and confidentiality provisions.

The foregoing descriptions of the MSA are only a summary and are qualified in their entirety by reference to the agreement, a copy of which is filed herewith as Exhibits 10.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

10.1

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Toll Manufacturing and Supply Agreement, dated December 21, 2018, by and among the Company, Novartis Pharma AG and other parties thereto.*

*Confidential treatment is requested for portions of this exhibit pursuant to 17 CFR Section 240.246-2.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Cellular Biomedicine Group,
Inc.

Date: December 28, 2018 By: /s/ Bizuo (Tony) Liu
Bizuo (Tony) Liu
Chief Executive Officer