
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Form 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16 UNDER
THE SECURITIES EXCHANGE ACT OF 1934

For the month of January 2019
Commission File Number 001-37846

CELLECT BIOTECHNOLOGY LTD.
(Translation of registrant's name into English)

23 Hata'as Street
Kfar Saba, Israel 44425
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(7):

Attached hereto as Exhibit 99.1 and incorporated by reference herein is a press release issued by the Registrant entitled “Collect Biotechnology Reports Clinical and Regulatory Milestone Targets.”

Exhibit

99.1 [Press Release, dated January 23, 2019](#)

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, thereunto duly authorized.

Collect Biotechnology Ltd.

By: /s/ Eyal Leibovitz

Name: Eyal Leibovitz

Title: Chief Financial Officer

Date: January 23, 2019



Cellect Biotechnology Reports Clinical and Regulatory Milestone Targets

Recent FDA Hiring Decision Highlights Growing Importance of Cell and Gene Therapy Companies

Tel Aviv, Israel – January 23, 2019 – Cellect Biotechnology Ltd. (Nasdaq: APOP), a novel regenerative and cell therapy company with production technology, today provided its milestone targets through the second quarter of 2020. After achieving milestones during 2018, Cellect Biotechnology is positioned to achieve the following milestones in order to maximize shareholder valuation.

“We expect 2019 to be a significant year for Cellect and the progression of our global clinical development program, and the recent decision by the US Food and Drug Administration (FDA) to hire 50 new clinical reviewers to assess cell and gene therapies, gives us greater confidence we can achieve our clinical and regulatory milestones for the next 12 to 18 months,” commented Shai Yarkoni, Chief Executive Officer. “I believe the special attention and resources being allocated by the FDA will allow us to further advance our cell therapy programs as we intend to submit an IND for a Phase I/II study in the United States and an IDE for our second product (the Apotainer™) and complete the preclinical effort towards a third indication by the end of 2019.”

MILESTONE TARGETS THROUGH JUNE 2020*

HSCs - Hematopoietic Stem Cells (blood cancers, such as leukemia and lymphoma)

- Enter into a collaboration agreement with a leading academic institution to initiate a US-based clinical trial for the Company’s ApoGraft™ technology for patients with hematological malignancies in an allogeneic hematopoietic stem cell transplantation (HSCT). The Company is currently in advanced discussions with a leading academic institution.
 - Receive Investigational New Drug (IND) approval by the US Food and Drug Administration (FDA) for a Phase I/II study with the aim of commencing first patient enrollment during 2019.
 - Announce further interim data for the Phase I/II study being conducted in Israel for the Company’s ApoGraft™ technology for patients with hematological malignancies in an allogeneic HSCT.
 - Following the completion of the Phase I/II study in Israel, which is expected to conclude by the end of the second quarter of 2019, and following the 180-day evaluation period, the Company expects to report topline results in late 2019 or early 2020.
 - Submit an Investigational Device Exemption (IDE) to the FDA for the ApoTainer selection kit, an easy to use, cost effective, off-the-shelf stem cell selection kit based on the Company’s ApoGraft technology platform.
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MSCs - Mesenchymal Stem Cells (broad stem cell applications)

- Expects to announce in the first half of 2019 the pre-clinical results for the use of human fat derived stem cells treated with ApoGraft™ in the orthopedic treatments of animals.
- Following the preclinical package completion, which is expected in the second half of 2019, the Company plans to submit an IND application with the FDA for the initiation of a Phase I/II trial of Apograft for anti-inflammatory and tissue engineering, such as shoulder rotator cuff tears that are common musculoskeletal injuries occurring mainly in aging populations.

Corporate

- Finalize plans to scale up the development and manufacturing of clinical grade Fas Ligand (FasL), in collaboration with an outsourced supplier. FasL is a type-II transmembrane protein that belongs to the tumor necrosis factor family.
- Strengthen the Company's balance sheet to provide the resources to execute its development, clinical and regulatory objectives.

*** Subject to sufficient financing.**

About Collect Biotechnology Ltd.

Collect Biotechnology (NASDAQ: APOP) has developed a breakthrough technology for the selection of stem cells from any given tissue that aims to improve a variety of stem cell-based therapies. The Company's technology is expected to provide research, hospitals and pharma companies with the tools to rapidly isolate stem cells in quantity and quality allowing stem cell-based treatments and procedures in a wide variety of applications in regenerative medicine. The Company's current clinical trial is aimed at bone marrow transplantations in cancer treatment.



Forward Looking Statements

This press release contains forward-looking statements about the Company’s expectations, beliefs and intentions. Forward-looking statements can be identified by the use of forward-looking words such as “believe”, “expect”, “intend”, “plan”, “may”, “should”, “could”, “might”, “seek”, “target”, “will”, “project”, “forecast”, “continue” or “anticipate” or their negatives or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. For example, forward-looking statements are used in this press release when we discuss the Company’s milestone targets and the timing thereof. These forward-looking statements and their implications are based on the current expectations of the management of the Company only and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. In addition, historical results or conclusions from scientific research and clinical studies do not guarantee that future results would suggest similar conclusions or that historical results referred to herein would be interpreted similarly in light of additional research or otherwise. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: the Company’s history of losses and needs for additional capital to fund its operations and its inability to obtain additional capital on acceptable terms, or at all; the Company’s ability to continue as a going concern; uncertainties of cash flows and inability to meet working capital needs; the Company’s ability to obtain regulatory approvals; the Company’s ability to obtain favorable pre-clinical and clinical trial results; the Company’s technology may not be validated and its methods may not be accepted by the scientific community; difficulties enrolling patients in the Company’s clinical trials; the ability to timely source adequate supply of FasL; risks resulting from unforeseen side effects; the Company’s ability to establish and maintain strategic partnerships and other corporate collaborations; the scope of protection the Company is able to establish and maintain for intellectual property rights and its ability to operate its business without infringing the intellectual property rights of others; competitive companies, technologies and the Company’s industry; unforeseen scientific difficulties may develop with the Company’s technology; and the Company’s ability to retain or attract key employees whose knowledge is essential to the development of its products.. Any forward-looking statement in this press release speaks only as of the date of this press release. The Company undertakes no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by any applicable securities laws. More detailed information about the risks and uncertainties affecting the Company is contained under the heading “Risk Factors” in the Company’s Annual Report on Form 20-F for the fiscal year ended December 31, 2017 filed with the U.S. Securities and Exchange Commission (“SEC”), which is available on the SEC’s website, <http://www.sec.gov>, and in the Company’s periodic filings with the SEC.

Contact

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