

**Quarterly update - Q3 report**

December 19, 2017

**Cellect Biotechnology Ltd.: Significant recently reported findings open the ApoGraft™ platform to also be used in the fat-derived stem cell segment; price target raised to \$16.9**

Exchange: NASDAQ

Symbol: APOP

Sector: Biotechnology

Sub-sector: Stem cells

ADS price target: \$16.90

As of December 18, 2017

(Source: Yahoo Finance):

Closing price: \$6.97

Market cap: \$41.8M

# of ADSs: 5.99M

Stock performance (YTD): 153%

Daily-trading-vol. (3 months):  
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\*) Frost & Sullivan,E-mail: equity.research@frost.com  
Tel. : +972-9-9502888**Company overview**

Cellect Biotechnology Ltd. (hereinafter: "Cellect" or "the company") is developing a technological platform, the "ApoGraft", which functionally selects stem cells from a mixed population of cells based on their sensitivity to apoptosis. The first product under development is the *Apotainer* selection kit. The company is currently conducting a proof-of-concept phase I/II trial with leukemia patients in Israel, which is expected to be completed by the end of Q3-2018. Based on trial results and safety issues, the company plans to integrate its technology into a range of procedures that utilize stem cells, as well as into the manufacturing process of adult stem cell based products.

**Highlights**

On November 22, the company published its Q3-2017 report, which reported the following events:

- Positive results from a 20 patient trial at Tel Aviv's Ichilov Medical Center, in which the ApoGraft™ process has shown significant beneficial effect on stem cells derived from fat tissue.
- Cellect announced that it has nominated Dr. Ronit Bakimer-Kleiner as Chief Development Officer replacing Dr. Yaron Pereg.
- The company's CEO, Dr. Shai Yarkoni, was chosen to present Cellect's technology and its recent advancements at the 2017 Bio-Europe conference in Berlin, and participated in a panel discussion on Cell Therapy. Dr Yarkoni was also invited to give the keynote presentation at the Asian Conference of Stem Cells and Regenerative Medicine in Singapore.

**Analysis**

- **The significance of the findings indicates the potential for the ApoGraft™ platform** to be employed by a much wider array of companies and medical centers developing stem cell based products and treatments. Specifically, to aesthetic and orthopedic indications where fat-derived stem cells are the main raw material.
- Market opportunities are extensive, but should be carefully considered for adipose tissue derived stem cells prior to selecting an indication. Non-uniformity and reduced potency of the cell product, which typically characterizes this segment, also needs to be addressed. Cellect will need to strategically address these issues in order to prove the superiority of its products and penetrate new market niches and geographies, and set target indications for treatment in accordance.
- **The company is on track to meet its clinical and strategic goals. We assume this progress will allow Cellect to advance the development of its technological platform to target new markets such as aesthetic and orthopedic indications.**
- **Should the company see positive results in its ongoing trial (ApoGraft POC final results estimated in Q3-2018), the financial potential of their stock is projected to increase company's share.**
- **We estimate the company's equity value at \$101.4M (higher from our previous valuation of \$86.3M); its price target ranges between \$15.40 and \$18.70; a mean of \$16.90.**

## Quarterly Update

The company published a quarterly report on November 22, 2017. We addressed several issues in our immediate report published on the 8<sup>th</sup> of November, 2017:

- October 25, 2017 - Collect announced the conclusion of an extensive study into the use of the ApoGraft™ on stem cells derived from fat tissues. The study was conducted with "Ichilov Medical Center" (Tel Aviv, Israel) and showed positive results for fat-derived stem cells taken from fat tissues in more than 20 patient samples. According to the company, the findings are significant as they open the ApoGraft™ to a much larger global industry; the development of stem cell-based products and treatments. Aesthetic and orthopaedic indications are particularly promising given that fat-derived stem cells are the main raw material.
- September 7, 2017 – The company announced that it had entered into securities purchase agreements with certain accredited investors to receive gross proceeds of \$4.3M (\$4.0M net). Collect will issue 531,136 American Depository Shares (ADSs) at a purchase price reflecting the average share price of six days prior to September 6, 2017 with a 4% discount representing \$8.10 per ADS in a registered direct offering. Additionally, for each ADS purchased, the investors will receive an unregistered 12 month warrant to purchase 50% of the amount raised at an exercise price of \$12.07 per ADS.
- September 5, 2017 – The FDA granted Orphan Drug Status to Collect's ApoGraft™ for Acute and Chronic GvHD.

## Third Quarter 2017 Financial Results:

Research and development (R&D) expenses for the third quarter of 2017 were \$0.81 million, compared to \$0.69 million in the second quarter of 2017 and \$0.58 million in the third quarter of 2016. The increase in the third quarter of 2017 as compared to the second quarter of 2017 mainly derived from a grant received from the BIRD foundation totaling \$0.12 million in the second quarter of 2017 which was not received in the third quarter of 2017.

General and administrative (G&A) expenses for the third quarter of 2017 were \$0.99 million, compared to \$1.0 million in the second quarter of 2017 and \$0.77 million in the third quarter of 2016. The change in the third quarter of 2017 as compared to the second quarter of 2017 mainly derived from an increase in expenses related to business development and professional fees in the third quarter of 2017, offset by a decrease in costs of delisting from the second quarter of 2017.

Financial expenses for the third quarter of 2017 were \$0.41 million, compared to financial income of \$0.37 million in the second quarter of 2017. The change was primarily due to changes related to fair value of the tradable and non-tradable warrants issued in prior financings. Net loss for the third quarter of 2017 was \$2.2 million, or \$0.02 per share and \$0.40 per ADS, compared to \$1.3 million, or \$0.012 per share and \$0.24 per ADS, in the second quarter of 2017 and \$1.5 million, or \$0.016 per share and \$0.30 per ADS, in the third quarter of 2016.

Cash and cash equivalents, marketable securities and short-term deposits totaled \$9.2 million as of September 30, 2017, compared to \$6.3 million on June 30, 2017, and \$8.8 million on December 31, 2016. The increase from June 30, 2017, was primarily due to proceeds of \$4.2 million (after deducting placement agents' fees) raised through a registered direct offering and concurrent private placement completed in September 2017, offset by cash used in operations during the period.

Shareholders' equity totaled \$5.9 million as of September 30, 2017, compared to \$8.1 million on December 31, 2016.

\* For the convenience of the reader, the amounts above have been translated from NIS into U.S. dollars, at the representative rate of exchange on September 30, 2017 (the U.S. \$1 = NIS 3.529).

## Analysis

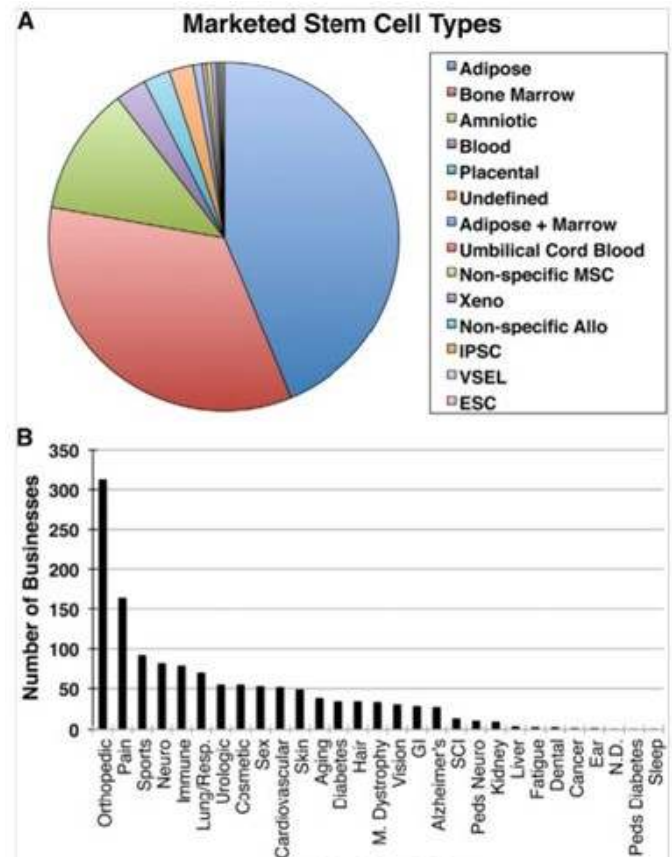
Collect’s approach focuses on the selection of pure, high quality stem cells that require less time for cell expansion than other processes currently deployed in the industry. This highly specific and personal manufacturing approach may have advantages in terms of efficacy, cost, and time-to-treatment. To some extent, it permits the preparations of the cell therapy product **on-site** rather than large scale central manufacturing. Its platform offers purification and efficient quantification of stem and progenitor cells through an improved and rapid selection process that significantly decreases complications that exist with standard selection techniques. In the case of Hematopoietic stem cells (HSCs), this process potentially eliminates the immune related toxicity in allogeneic transplantation. In the case of fat derived stem cells (where most of its uses are autologous), it improves the number, uniformity and potency of the Mesenchymal stem cells (MSCs).

### The use of the ApoGraft™ of stem cells derived from fat tissues

As written above, Collect announced positive results for the use of its platform technology ApoGraft™ on stem cells derived from fat tissues. The study, conducted with fat tissue samples obtained via liposuction from over twenty adult patients, has shown a significant beneficial effect of the ApoGraft™ process on both the number and activity of the adipose-derived stem cells. In addition, differentiation into bone (osteoid) and fat (lipoid) tissues was assessed. Although the extent to which these results can be used to support FDA requirements remains unclear, these results are promising. They indicate that the ApoGraft may be used to provide high quality mesenchymal and/or stromal stem cells for subsequent expansion and use for a variety of indications.

These findings further enlarge the bandwidth of Collect’s platform, and together with the bone marrow program, covers most of the raw materials for stem cells used in the industry. Thus, it increases potential strategic alliances for commercialization of Collect’s ApoGraft platform, specifically in the orthopedic and aesthetic domains, two lucrative industries with substantial demand.

Data by Turner and Knoepfler shows that the majority of cell therapy offerings available to patients in the US today are for orthopaedic applications.<sup>1</sup> In the US, the use of autologous adipose tissue-derived stem cells for cosmetic and orthopaedic indications has been increasing over the last 5 years. In 2016, there were at least 351 companies across the United States that were marketing stem cell products at 570 different clinics for a wide range of medical indications including pulmonary, spinal cord (and other neural), orthopaedic and cosmetic conditions.<sup>2</sup> Over 300 of the businesses marketed interventions for orthopaedic issues, 150 advertised for pain, 90 for sports injuries, 80 for neurological diseases and 75 for immune disorders. With regards to the type of stem cells, 61% of the clinics used stem cells from adipose tissue, 48% from bone marrow,



Source: Leigh Turner and Paul Knoepfler, Cell Stem Cell 19, August 4, 154-157 (2016).

<sup>1</sup> Leigh Turner and Paul Knoepfler, Cell Stem Cell 19, August 4, 154-157 (2016)

<sup>2</sup> DOI: 10.1016 / J. stem. 2016.) <https://www.sciencedaily.com/releases/2016/06/160630135852.html>

with other various sources such as iPS cells, embryonic and xenogenic being offered by a small number of clinics.

This increased stem cell offerings in the US has been due, in part, to the unregulated nature of autologous use, without FDA oversight. In recent years, the FDA has stated that only “minimal manipulation” of autologous tissues/cells would be allowed. In November 2017, the FDA issued its final guidelines for minimal manipulation and homologous use of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).<sup>3</sup> It should be noted that “final FDA guidelines” do not establish legal, enforceable responsibilities, however, they most often become FDA rulings within a “reasonable” period of time.

The FDA’s new strict regulations with regards to adipose stem cells state that any isolation of them will be considered more than minimally manipulative. These new FDA regulations will require clinics that make use of autologous treatment to submit an IND (investigational new drug) application. In that term, Collect may need an IND for the adipose cell product, or otherwise the physician who uses the product will need to settle this requirement instead.

In addition, the FDA has homologous requirements. If the cells are used as support such as in cosmetic uses, that would be homologous, but if they are used for orthopaedic conditions, it would be considered non-homologous.<sup>4</sup> Collect will need to address these issues as well.

Another major issue would be the purity of the fat stem cell suspensions currently used for clinical applications. The fat-derived stem cells are a relatively new, yet fast growing segment in the adult stem cell domain. One of the challenges in this segment is obtaining pure high-quality adipose-derived stem cells from a heterogeneous population. Because separation techniques are often inadequate, there is an issue with non-uniformity of the resulting products used to treat patients. In this sense, Collect offers a well-controlled selection process and a batch release criteria product, specifically addressing this drawback. The functional selection technology and the results achieved in the preliminary studies support a more characterized product with better uniformity and potential for improved potency.

Cytori Therapeutics is an example of a later-stage cell therapy company with an innovative technology platform that is based on the use of human adipose tissue as the raw material to develop cellular therapy models. Cytori was the first company to introduce a technology platform that uses cells from adipose tissue. It is focused on the development of autologous cell therapies from adipose tissue to treat a variety of medical conditions. Its product development pipeline covers a broad spectrum of therapeutic areas including orphan and rare diseases, genitourinary disorders, orthopedics, cardiovascular disease, and acute and chronic wound care. Having said that, non-significant results in Phase III studies at the clinical trials are in part the result of the lack of selection and heterogeneity of the adipose-derived stem cell products.

**In summary, the market opportunities are extensive, but should be carefully considered for adipose tissue-derived stem cells prior to selecting an indication.** Physicians must see a viable revenue stream from the use of fat tissue-derived stem cell products compared to other products they are using, in terms of price and physician "time". Reimbursement and hospital compensation are also important issues to address (cosmetic products are not reimbursed). Collect will need to strategically address these issues in order to prove the superiority of its products and penetrate new customer niches and geographies, choosing its indications for treatment in accordance. To wit, we include this economic potential in our model.

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<sup>3</sup><https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM585403.pdf>

<sup>4</sup><https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM585403.pdf> (pg 18-19)

### Orphan Drug Status to Collect's ApoGraft™ for Acute and Chronic GvHD

On September 5, 2017 Collect announced that the FDA had granted Orphan Drug Status to Collect's ApoGraft™ for both Acute and Chronic GvHD. Orphan drug designation is a regulatory path that includes tax credits related to clinical trial expenses, an exemption from the FDA user fee, FDA assistance in clinical trial design, an accelerated path to market and potential market exclusivity for seven years following approval.

Collect continues with its ongoing trial of stem cells transplant procedure using its ApoGraft™ technology in Phase I/II clinical trials for the prevention of GvHD in blood cancer patients. In this trial, the company is testing allogeneic stem cells transplanted from mobilized peripheral blood of a matched related donor with the primary objective of assessing the safety and efficacy of the ApoGraft product. Completion of enrollment is expected by Q1-2018 followed by another 6 month follow-up period after transplantation, with an estimated completion by Q3-2018.

**To conclude, the company is on track to meet its clinical and strategic goals. We assume this progress will accelerate capital raising and out licensing deals, allowing Collect to advance the development of its technological platform, using fat-derived stem cells to target new markets such as aesthetic and orthopedic indications.**

**To wit, should the company also show positive results in its ongoing trial (ApoGraft POC final results estimated in Q3-2018), it will generate additional economic potential for the company's share. We estimate the company's equity value at \$101.4M (higher from our previous valuation of \$86.3M); the price target ranges between \$15.40 and \$18.70; a mean of \$16.90.**

Collect's expected upcoming events are displayed below:

Project	Event	Significance	Timeline
<b>ApoGraft</b>	ApoGraft POC interim results	High	<b>Q4/2017</b>
	Completion of ApoTainer prototype	Medium	<b>Q1/2018</b>
	ApoGraft POC final results	High	<b>Q3/2018</b>

Below is the stock overview YTD (Source: Yahoo Finance):



## Appendix - Financial Reports

<b>Balance Sheet (\$000s)</b>		
<b>Current Assets:</b>	<u>31.12.2016</u>	<u>30.09.17</u>
Cash and cash equivalents	1,633	6,396
Short term deposits	5,113	-
Marketable securities	1,300	2,833
Accounts receivable	380	284
<b>Total Current Assets</b>	<b>8,426</b>	<b>9,513</b>
<b>Non-Current Assets</b>		
Restricted cash	36	87
Other long term assets	0	27
PPE, net	357	360
<b>Total Assets</b>	<b>8,819</b>	<b>9,987</b>
<b>Current Liabilities</b>		
Trade payables	364	575
Other accounts payable	542	368
<b>Non Traded Warrants to ADS</b>	<b>0</b>	<b>693</b>
<b>Non-Current Liabilities</b>		
Traded Warrants to ADS	504	2,443
<b>Total Liabilities</b>	<b>1,410</b>	<b>4,079</b>
<b>Total Equity</b>	<b>7,409</b>	<b>5,908</b>
<b>Total Liabilities</b>	<b>8,819</b>	<b>9,987</b>

<b>Statement of Profit and Loss (\$000s)</b>				
<b>Reporting Period (ending):</b>	31.12.2015	31.12.2016	30.09.16	30.09.17
Research and development expenses	1,517	2,147	1,494	2,295
General and administrative expenses	1,082	2,072	1,735	2,699
Other Income	0	73	-78	0
<b>Total Operating expenses</b>	<b>2,598</b>	<b>4,146</b>	<b>-78</b>	<b>4,994</b>
<b>Operating loss</b>	<b>2,598</b>	<b>4,073</b>	<b>3251</b>	<b>4,994</b>
Financial expenses due to warrants exercisable into ADS	1	172	148	1,933
Other financial expenses (income), net	20	9	55	116
<b>Total loss</b>	<b>2,618</b>	<b>3,910</b>	<b>3,454</b>	<b>7,043</b>

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