



Collect Biotechnology Reports Third Quarter 2019 Financial and Operating Results

November 19, 2019

TEL AVIV, Israel, Nov. 19, 2019 /PRNewswire/ -- Collect Biotechnology Ltd. (NASDAQ: [APOP](#)), a developer of innovative technology which enables the functional selection of stem cells, today reported financial and operating results for the third quarter ended September 30, 2019 and provided a corporate update.

Recent Highlights

- Received an Investigational New Drug (IND) approval from the U.S. Food and Drug Administration (FDA) for the commencement of a clinical trial to determine the safety and tolerability of the ApoGraft technology for haploidentical bone marrow transplantations. This development represents the Company's first-ever clinical trial approval in the U.S. using its ApoGraft stem cell selection technology, which is designed to significantly reduce acute graft-versus-host disease (aGVHD) following bone marrow transplantation.
- Successfully validated the Company's technology in collaboration with a regenerative medicine company. The study, when combined with others and internal findings increase the body of evidence supporting the Company's technology and add further proof to support Collect ASCs derived stem cells program. Biocompatibility with certain collagen-based matrixes successfully demonstrated that cells grown utilizing the Company's protocol can be incorporated into matrixes for expansion, transplantation and tissue regeneration.

"Our clinical and regulatory teams remained focused during the third quarter and the more recent positive developments position us to achieve our goals, both in the U.S. and Israel," commented Dr. Shai Yarkoni, Chief Executive Officer. "In the U.S., the IND approval is a significant achievement and represents our first-ever FDA IND in the U.S., with Washington University School of Medicine. In Israel, our Phase 1/2 clinical study of ApoGraft™ is progressing slowly and we expect to complete the recruitment around the end of the year."

"With our prudent use of cash during the third quarter and the anticipated cash usage needs over the coming quarters, we continue to believe we have the resources to execute our clinical and regulatory plans for the foreseeable future," said Eyal Leibovitz, Chief Financial Officer.

Third Quarter 2019 Financial Results:

- Research and development (R&D) expenses for the third quarter of 2019 were \$0.71 million compared to \$1.18 million in the third quarter of 2018. The Company remains committed to the ongoing clinical trials in Israel as well as pursuing the regulatory approval from the FDA to commence its US-based trial.
- General and administrative (G&A) expenses for the third quarter of 2019 were \$0.80 million compared to \$1.13 million in the third quarter of 2018. The decrease reflects the cost cutting initiatives implemented by the Company during the third quarter of 2019.
- Finance income for the third quarter of 2019 were \$0.12 million compared to finance income of \$0.36 million in the third quarter of 2018. The decrease was primarily due to changes related to fair value of the tradable and non-tradable warrants issued in prior fundraising.
- Net loss for the third quarter of 2019 was \$1.4 million, or \$0.01 per share and \$0.12 per ADS, compared to \$1.9 million, or \$0.014 per share and \$0.29 per ADS, in the third quarter of 2018.
- Cash and cash equivalents, \$6.27 million as of September 30, 2019.

*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, 2019 (U.S. \$1 = NIS 3.482).

Strategic Review Progress Update

On May 16, 2019, the Company disclosed that it commenced plans to explore strategic alternatives to maximize shareholder value. Potential strategic alternatives that may be evaluated include, but are not limited to, an acquisition, merger, business combination, including in other business fields than the Company's in-licensing, or other strategic transaction involving the Company or its assets. The Company continues to evaluate business development opportunities and will keep investors informed as they mature or warrant investor disclosure.

About Collect Biotechnology Ltd.

Collect Biotechnology ([APOF](#)) 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 researchers, clinical community 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. 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; or maintain its current operations; uncertainties involving any strategic transaction the Company may decide to enter into as the result of its current efforts to explore new strategic alternatives; 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 Collect Biotechnology Ltd.'s Annual Report on Form 20-F for the fiscal year ended December 31, 2018 filed with the U.S. Securities and Exchange Commission, or SEC, which is available on the SEC's website, www.sec.gov, and in the Company's periodic filings with the SEC.

Collect Biotechnology Ltd

Consolidated Statement of Operation

	Convenience translation				
	Nine months ended	Nine months ended	Three months ended		
	September 30,	September 30,	September 30,		
	2019	2019	2019	2018	
	Unaudited	Unaudited			
	U.S. dollars	NIS			
	(In thousands, except share and per share data)				
Research and development expenses	2,743	9,551	9,473	2,465	4,125
General and administrative expenses	2,249	7,832	11,001	2,768	3,929
Operating loss	4,992	17,383	20,474	5,233	8,054
Financial expenses (income) due to warrants exercisable into shares	(2,303)	(8,020)	(2,935)	(910)	(1,320)
Other financial expenses (income), net	393	1,369	(1,177)	489	64

Total comprehensive loss	3,082	10,732	16,362	4,812	6,798
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Loss per share:

Basic and diluted loss per share	0.015	0.051	0.127	0.021	0.052
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Basic and diluted loss per ADS	0.30	1.02	2.54	0.42	1.04
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Weighted average number of shares outstanding used to compute basic and diluted loss per share	208,771,303	208,771,303	129,139,278	224,087,799	130,192,799
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Collect Biotechnology Ltd.
Consolidated Balance Sheet Data

ASSETS

Convenience translation

September 30, September 30, December 31,

2019	2019	2018
Unaudited	Unaudited	Audited
U.S. dollars	NIS	
(In thousands, except share and per share data)		

CURRENT ASSETS:

Cash and cash equivalents	6,275	21,849	17,809
Other receivables	201	700	816
	6,476	22,549	18,625

NON-CURRENT ASSETS:

Restricted cash	94	329	337
Right-of-use assets	332	1,156	-
Other long-term receivables	30	103	132
Property, plant and equipment, net	396	1,379	1,544
	852	2,967	2,013
	7,328	25,516	20,638

LIABILITIES AND SHAREHOLDERS' EQUITY

CURRENT LIABILITIES:

Trade payables	245	852	887
Other payables	629	2,192	4,012

Current maturities of lease liability	123	428	-
	997	3,472	4,899

NON-CURRENT LIABILITIES:

Warrants	808	2,812	1,816
Lease liability	219	764	-
	1,027	3,576	1,816

EQUITY:

Ordinary shares of no par value:

Authorized: 500,000,000 shares at December 31, 2018 and 10,000,000 shares at September 30, 2019; Issued - and outstanding: 130,414,799*) and 224,087,799*) shares as of December 31, 2018 and September 30, 2019, respectively.

Additional Paid in Capital	31,104	108,305	95,085
Share-based payments	4,129	14,375	12,319
Treasury shares	(2,707)	(9,425)	(9,425)
Accumulated deficit	(27,222)	(94,787)	(84,056)
	5,304	18,468	13,923
	7,328	25,516	20,638

*) Net of 2,641,693 treasury shares of the Company held by the Company.

Collect Biotechnology Ltd
Consolidated Cash Flow Data

**Convenience
translation
Nine months
ended**

Nine months ended Three months ended

September 30, September 30, September 30,

2019 2019 2018 2019 2018

Unaudited Unaudited

U.S. dollars NIS
(In thousands)

Cash flows from operating activities:

Total comprehensive loss	(3,082)	(10,732)	(16,362)	(4,812)	(6,798)
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Adjustments to reconcile net
loss to net cash used in operating activities:

Net financing expenses	312	1,087	(823)	272	14
Loss (gain) from revaluation of financial assets presented at fair value through profit and loss	2	8	(288)	2	(140)
Depreciation	82	285	337	93	122

Changes in fair value of traded and not traded warrants	(2,686)	(9,351)	(3,208)	(910)	(1,320)
Share-based payment	546	1901	3,247	1,371	1,063
Decrease (increase) in other receivables	42	146	256	-	343
Increase (decrease) in other payables	(533)	(1,855)	(706)	(1,138)	409
Decrease in right-of-use assets	131	457	-	143	-
Interest received during the period	(21)	(75)	(47)	(29)	(32)
Net cash used in operating activities	(5,207)	(18,129)	(17,594)	(5,008)	(6,339)

Cash flows from investing activities:

Short term deposits, net	-	-	282	-	3,785
Restricted deposit, net	-	-	(22)	-	6
Sales of marketable securities measured at fair value through profit and loss	-	-	13,999	-	5,501
Purchase of property, plant and equipment	(34)	(120)	(643)	-	(415)
Net cash provided by investing activities	(34)	(120)	13,616	-	8,877

Cash flows from financing activities:

Exercise of warrants and stock options into shares	-	-	399	-	-
Leases liabilities	(121)	(422)	-	(143)	-
Issue of share capital and warrants, net of issue costs	6,813	23,723	12,360	-	-
Net cash provided (used) by financing activities	6,692	23,301	12,759	(143)	-
Exchange differences on balances of cash and cash equivalents	(291)	(1,012)	870	(243)	18
Increase (decrease) in cash and cash equivalents	1,160	4,040	9,651	(5,394)	2,556
Balance of cash and cash equivalents at the beginning of the period	5,115	17,809	13,734	27,243	20,829
Balance of cash and cash equivalents at the end of the period	6,275	21,849	23,385	21,849	23,385

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