



Collect Biotechnology Provides Corporate Update and Reports Third Quarter 2018 Financial Results

November 13, 2018

TEL AVIV, Israel, Nov. 13, 2018 /PRNewswire/ -- Collect Biotechnology Ltd. (NASDAQ: [APOP](#)), a developer of innovative technology which enables the functional selection of stem cells, today provided a corporate update and announced financial results for the third quarter ended September 30, 2018.

"During the third quarter, we have strengthened significantly our IP portfolio position with granted patents from the EU and Korea while closing an important partnership agreement with the Korean [Cell2in](#) and the German denovoMATRIX for collaborations to further improve stem cell selection," stated Dr. Shai Yarkoni, Collect's Chief Executive Officer.

"During the year we opened a second site for the Company's ongoing clinical trial which allowed us to expedite the recruitment of additional patients and as a result, half of the patients planned for the study have finished first month follow up and all such patients have shown 100% engraftment with no procedure related adverse events and the first three patients of the trial (cohort I) have completed the study period (180 days) with full safety and tolerability," continued Dr. Yarkoni. "We also achieved positive results on the use of fat derived cells in orthopedic treatments in an animal model, we completed the first prototype of the Apotainer, showing stable immobilization and good biological activity of FasL coated paramagnetic beads and we received a formal Notice of Allowance from the Japanese and Australian Offices for Patents & Trademarks," Dr. Yarkoni added.

"As we are getting nearer to commercialization of our technology, we are putting more and more emphasis on partnerships with key players in our industry. We intend to continue this path going forward and build one of the world's strongest IP portfolios for stem cell therapy related technologies and a line of partnerships that will take the company to the next level commercially within the next 24 months," summarized Dr. Yarkoni

During the third quarter, Collect accomplished the following: -

- Signed a collaboration and material transfer agreement with the denovoMATRIX group of the Technische Universität Dresden (TU Dresden), a leading center for stem cell research in Germany.
- Entered into a strategic manufacturing and supply agreement with Swiss Biotech Center (SBC) to secure production of FasL protein - Collect's main active ingredient in ApoGraft™ and the ApoTainer™ for planned clinical trials in the U.S
- European Patent Office has granted the Company a patent for its ApoTainer™ device which is used in conjunction with its platform ApoGraft™ technology titled, "Devices and Methods for Selecting Apoptosis-Signaling Resistant Cells, and Uses Thereof".
- Signed a collaboration agreement with [Cell2in](#), a South Korean company focused on improving the quality of cells. According to the agreement, the companies will conduct scientific evaluations combining Collect's technology platform ApoGraft™ with Cell2in's proprietary identification technology FreSHtracer™ which monitors stem cell quality by utilizing a fluorescent dye to characterize their oxidative stress state.
- Received a Notice of Allowance from the Korean Intellectual Property Office for its patent titled, "Devices and Methods for Selecting Apoptosis-Signaling Resistant Cells and Uses Thereof". This patent, recently granted to Collect in Europe, addresses the Company's ApoTainer™ device which is used in conjunction with its platform ApoGraft™ technology

Recent Corporate Highlights:

- Announced that it has reached half way through study recruitment - six of the patients finished first month follow up and all these patients have shown 100% engraftment with no procedure related adverse events. Further to the six patients one-month data detailed above, Collect reported that the first three patients of the trial (cohort I) have completed the study period (180 days) with full safety and tolerability.
- Announced that it has achieved positive results on the use of fat derived cells treated with the ApoGraft™ process in orthopedic treatments in an animal model.
- Announced that it has successfully developed for industrialization its first in kind new technology as an integral part of Collect's ApoTainer™. The new technology utilizes FasL-coated magnetic beads for maximizing efficacy and scalability of stem cell-based products' manufacturing. The Apotainer™ improves the uniformity and hence quality of the outcome thereby supporting the safety and efficacy of raw material for all cell therapy.
- Announced that CEO Dr. Shai Yarkoni will present at the 24th Annual Bio Europe Conference that was held in Copenhagen, Denmark from November 5-7, 2018.
- Announced that it has received a formal Notice of Allowance from the Japanese and Australian Offices for Patents & Trademarks (Japanese Application No. 2014-560516; Australian Application No. 20132s29008) covering a key composition of matter and method of use of Collect's ApoGraft technology in devices for stem cell selection.

Third Quarter 2018 Financial Results:

- Research and development (R&D) expenses for the third quarter of 2018 were \$1.13 million, compared to \$0.69 million in the second quarter of 2018 and \$0.79 million in the third quarter of 2017. The increase in the third quarter of 2018 as compared to the second quarter of 2018 was primarily due to increased expenses related to the Company's ongoing clinical trial and product development expenses.
- General and administrative (G&A) expenses for the third quarter of 2018 were \$1.08 million, compared to \$1.00 million in the second quarter of 2018 and \$0.96 million in the third quarter of 2017. The change in the third quarter of 2018 as compared to the second quarter of 2018 mainly derived from an increase in expenses related to business development in the third quarter of 2018, offset by a decrease in costs of share-based compensation.
- Financial income for the third quarter of 2018 was \$0.35 million, compared to financial income of \$0.03 million in the second quarter of 2018. The increase was primarily due to changes related to fair value of the tradable and non-tradable warrants issued in prior fundraisings.
- Net loss for the third quarter of 2018 was \$1.9 million, or \$0.014 per share and \$0.29 per ADS, compared to \$1.6 million, or \$0.013 per share and \$0.25 per ADS, in the second quarter of 2018, and \$2.2 million, or \$0.019 per share and \$0.39 per ADS, in the third quarter of 2017.

Balance Sheet Highlights:

- Cash and cash equivalents and marketable securities totaled \$6.45 million as of September 30, 2018, compared to \$8.26 million on June 30, 2018, and \$7.6 million on December 31, 2017. The change in the cash and cash equivalents and marketable securities was primarily due to net proceeds of \$3.5 million from a registered direct offering completed in January 2018, offset by cash used in operations during the period.
- Shareholders' equity totaled \$4.5 million as of September 30, 2018, compared to \$6.1 million on June 30, 2018, and \$5.2 million on December 31, 2017.

* 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, 2018 (U.S. \$1 = NIS 3.627).

The Company's consolidated financial results for the three and nine months ended September 30, 2018 are presented in accordance with International Financial Reporting Standards.

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 our IP portfolio and potential commercialization of our technology. 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 Collect Biotechnology Ltd.'s Annual Report on Form 20-F for the fiscal year ended December 31, 2017 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 | | September 30, 2018 | | September 30, 2017 | |
|--|---|-------------------|--------------------|--------------------|--------------------|--------------------|
| | Nine months ended | Nine months ended | September 30, 2018 | September 30, 2017 | September 30, 2018 | September 30, 2017 |
| | U.S. dollars | NIS | Unaudited | Unaudited | Unaudited | Audited |
| | (In thousands, except share and per share data) | | | | | |
| Research and development expenses | 2,612 | 9,473 | 8,099 | 4,125 | 2,872 | |
| General and administrative expenses | 3,033 | 11,001 | 9,524 | 3,929 | 3,478 | |
| Operating loss | 5,645 | 20,474 | 17,623 | 8,054 | 6,350 | |
| Financial expenses (income) due to warrants exercisable into ADS | (809) | (2,935) | 6,821 | (1,320) | 1,509 | |
| Other financial expenses (income), net | (325) | (1,177) | 411 | 64 | (57) | |
| Total comprehensive loss | 4,511 | 16,362 | 24,855 | 6,798 | 7,802 | |
| Loss per share: | | | | | | |
| Basic and diluted loss per share | 0.035 | 0.127 | 0.228 | 0.052 | 0.070 | |
| Basic and diluted loss per ADS | 0.7 | 2.54 | 4.56 | 1.04 | 1.40 | |
| Weighted average number of shares outstanding used to compute basic and diluted loss per share | 129,139,278 | 129,139,278 | 109,188,626 | 130,192,799 | 111,476,292 | |

Collect Biotechnology Ltd
Consolidated Balance Sheet Data
ASSETS

| Convenience translation | | |
|-------------------------|--------------------|-------------------|
| September 30, 2018 | September 30, 2018 | December 31, 2017 |
| Unaudited | Unaudited | Audited |
| U.S. dollars | NIS | |

(In thousands, except share and per share data)

CURRENT ASSETS:

| | | | |
|---------------------------|-------|--------|--------|
| Cash and cash equivalents | 6,447 | 23,385 | 13,734 |
| Marketable securities | - | - | 13,999 |
| Other receivables | 164 | 593 | 818 |
| | 6,611 | 23,978 | 28,551 |

NON-CURRENT ASSETS:

| | | | |
|------------------------------------|-------|--------|--------|
| Restricted cash | 92 | 333 | 305 |
| Other long-term assets | 39 | 142 | 173 |
| Property, plant and equipment, net | 458 | 1,661 | 1,344 |
| | 589 | 2,136 | 1,822 |
| | 7,200 | 26,114 | 30,373 |

LIABILITIES AND SHAREHOLDERS' EQUITY

CURRENT LIABILITIES:

| | | | |
|----------------|-----|-------|-------|
| Trade payables | 354 | 1,283 | 1,703 |
| Other payables | 584 | 2,120 | 2,396 |
| | 938 | 3,403 | 4,099 |

NON-CURRENT LIABILITIES:

| | | | |
|-----------------|-------|-------|-------|
| Warrants to ADS | 1,745 | 6,327 | 7,422 |
|-----------------|-------|-------|-------|

EQUITY:

Ordinary shares of no par value:

Authorized: 500,000,000 shares at December 31, 2017

and September 30 2018; Issued and outstanding: 120,185,659*) and 130,192,799*) shares as of December 31, 2017 and September 30, 2018, respectively.

| | | | |
|----------------------------|----------|----------|----------|
| | - | - | - |
| Additional Paid In Capital | 26,135 | 94,793 | 82,839 |
| Share-based payments | 3,121 | 11,321 | 9,381 |
| Treasury shares | (2,598) | (9,425) | (9,425) |
| Accumulated deficit | (22,141) | (80,305) | (63,943) |
| | 4,517 | 16,384 | 18,852 |
| | 7,200 | 26,114 | 30,373 |

*) 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 | | Three months ended | | |
| | September 30, 2018 | September 30, 2018 | September 30, 2017 | September 30, 2018 | September 30, 2017 |
| | Unaudited | | Unaudited | | |
| | U.S. dollars | | NIS | | |
| | (In thousands) | | | | |
| <u>Cash flows from operating activities:</u> | | | | | |
| Total comprehensive loss | (4,511) | (16,362) | (24,855) | (6,798) | (7,802) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | | | |
| Net financing expenses | (227) | (823) | 504 | 14 | (29) |
| Loss (gain) from revaluation of financial assets presented at fair value through profit and loss | (79) | (288) | 140 | (140) | (149) |
| Depreciation | 93 | 337 | 278 | 122 | 94 |
| Changes in fair value of traded and not traded warrants to ADS | (885) | (3,208) | 6,650 | (1,320) | 1,337 |
| Share-based payment | 895 | 3,247 | 4,016 | 1,063 | 1,572 |
| Decrease (increase) in other receivables | 70 | 256 | 362 | 343 | 126 |
| Increase (decrease) in other payables | (195) | (706) | (633) | 409 | (4) |
| Interest received | (13) | (47) | - | (32) | - |
| Net cash used in operating activities | (4,852) | (17,594) | (13,538) | (6,339) | (4,855) |
| <u>Cash flows from investing activities:</u> | | | | | |
| Short term deposits, net | 78 | 282 | 19,530 | 3,785 | 18,020 |
| Restricted deposit, net | (6) | (22) | (167) | 6 | (2) |
| (Purchase) Sales of marketable securities measured at fair value through profit and loss | 3,859 | 13,999 | (5,009) | 5,501 | (10,000) |
| Purchase of property, plant and equipment | (177) | (643) | (175) | (415) | (59) |
| Net cash provided by investing activities | 3,754 | 13,616 | 14,179 | 8,877 | 7,959 |

Cash flows from financing activities:

| | | | | | |
|--|--------------|---------------|---------------|---------------|---------------|
| Exercise of warrants and stock options into shares | 110 | 399 | 1,263 | - | 197 |
| Issue of share capital and warrants, net of issue costs | 3,408 | 12,360 | 14,893 | - | 14,893 |
| Net cash provided (used) by financing activities | 3,518 | 12,759 | 16,156 | - | 15,090 |
| Exchange differences on balances of cash and cash equivalents | 240 | 870 | (504) | 18 | 29 |
| Increase (decrease) in cash and cash equivalents | 2,660 | 9,651 | 16,293 | 2,556 | 18,223 |
| Balance of cash and cash equivalents at the beginning of the period | 3,787 | 13,734 | 6,279 | 20,829 | 4,349 |
| Balance of cash and cash equivalents at the end of the period | 6,447 | 23,385 | 22,572 | 23,385 | 22,572 |

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SOURCE Collect Biotechnology Ltd.

Related Links

<http://www.collect.co>