
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): March 28, 2019

BIOCEPT, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-36284
(Commission
File Number)

80-0943522
(I.R.S. Employer
Identification No.)

5810 Nancy Ridge Drive, San Diego, CA
(Address of principal executive offices)

92121
(Zip Code)

Registrant's telephone number, including area code: (858) 320-8200

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))
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Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 2.02 Results of Operations and Financial Condition.

On March 28, 2019, we issued a press release announcing our financial results for the three months and year ended December 31, 2018. A copy of the press release and accompanying information is attached as Exhibit 99.1 to this current report.

The information in this Item 2.02, and Exhibit 99.1 attached hereto, is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this current report shall not be incorporated by reference into any registration statement or other document filed with the Securities and Exchange Commission, whether filed before or after the date hereof regardless of any general incorporation language in any such filing, unless we expressly set forth in such filing that such information is to be considered “filed” or incorporated by reference therein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 [Press Release dated March 28, 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 hereunto duly authorized.

Dated: March 28, 2019

BIOCEPT, INC.

By: /s/ Timothy C. Kennedy

Name: Timothy C. Kennedy

Title: Chief Financial Officer, Senior Vice President of
Operations and Corporate Secretary

Biocept Reports 2018 Fourth Quarter and Full Year Financial Results

Progress made implementing the Company's commercial strategy highlighted by 7% sequential quarterly growth in billable test volume in the fourth quarter of 2018 compared to the third quarter of 2018

Capitalized to deliver on key initiatives in 2019 including growth from pathology partnership and liquid biopsy kit strategies, as well as launch of molecular oncology liquid biopsy panel

Conference call begins at 4:30 p.m. Eastern time today

SAN DIEGO (March 28, 2019) – Biocept, Inc. (NASDAQ: BIOC), a leading commercial provider of liquid biopsy tests designed to provide physicians with clinically actionable information to improve the outcomes of cancer patients, reports financial results for the three and 12 months ended December 31, 2018, and provides an update on its business progress.

“Revenues and billable samples for the fourth quarter reached their highest levels in 2018, as we benefited from our refocused commercial strategy,” said Michael Nall, President and CEO of Biocept. “Our efforts to enhance our growth in test volumes has continued into 2019.

“A key driver of growth is the relaunch of our EmpowerTC™, or pathology partnership, service, which enables local pathologists to access our Target Selector™ circulating tumor cell (CTC) platform and integrate it into their practice,” he added. “We recently expanded this offering into the uro-oncology market segment with the addition of new prognostic and predictive biomarker tests to aid physicians in the treatment of prostate cancer. We also are benefitting from physician interest in the use of our CTC platform to evaluate patients with breast cancer, supported by a renewed interest in CTCs as a diagnostic specimen in the past couple of years. In 2017 alone, over 1,500 papers were published on CTC analysis, and the ability of our platform to analyze biomarkers in CTCs, as well as capture and quantify the number of CTCs in a given patient sample, sets Biocept apart from most other liquid biopsy companies.

“We have raised more than \$18 million in equity capital since the beginning of 2019, and we now believe that we have the financial resources to implement our business strategy throughout the year. In addition to the expected growth in our U.S. laboratory testing business, we plan to increase additional Biocept testing in non-U.S. territories with our liquid biopsy kit strategy and to launch our molecular oncology multi-gene testing panel in the second quarter of 2019 to address the needs of our clinical, research and pharmaceutical company customers and prospective customers. We made good progress last year, and believe that this year is going to be an exciting and productive year for Biocept,” he added.

2018 and Recent Highlights

Commercial Launches

- Announced the availability of research-use-only (RUO) kits, which enable molecular laboratories around the world to utilize Target Selector™ circulating tumor DNA (ctDNA) assays to perform liquid biopsy testing.
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- Launched CEE-Sure® blood collection tubes (BCTs) for RUO under an exclusive global distribution agreement with VWR, a leading provider of products and services to laboratory and production customers. CEE-Sure® BCTs allow for the transport and preservation of CTCs and circulating free DNA (cfDNA) at room temperature from the clinic to central laboratories in the same tube.
- Launched expanded pathology partnership service, EmpowerTC, with additional prognostic and predictive biomarker tests. The expanded service provides the capability to perform tests that can aid physicians and pathologists in the management of patients diagnosed with prostate cancer.

Collaborations

- Entered into an agreement with Prognos, Inc. to utilize its proprietary de-identification software to collect and transmit data to assist pharmaceutical and life science clients in ensuring patients receive the correct therapies.
- Announced a partnership with Thermo Fisher Scientific to validate its OncoPrint™ next-generation sequencing panel in Biocept's CLIA laboratory. Following validation, Biocept has the opportunity to become a Thermo Fisher Liquid Biopsy Center of Excellence with the potential to jointly market services to the pharmaceutical industry.
- Entered into a commercial agreement with Highmark Health and the Allegheny Health Network, to evaluate the clinical utility and cost effectiveness of Target Selector™ in patients diagnosed with non-small cell lung cancer (NSCLC).
- Announced a collaboration with Providence St. Joseph Health, Southern California, and its wholly owned affiliates Providence Saint John's Health Center and the John Wayne Cancer Institute, to conduct a study to validate the use of cerebrospinal fluid with the Target Selector™ platform.
- Entered into a partnership with the Moores Cancer Center at UC San Diego Health to conduct two studies in patients with a variety of solid tumors to compare results from Target Selector™ with findings from computed tomography (CT) or positron emission tomography (PET) scans.
- Entered into an agreement with Agiomix FZ-LLC, a provider of genomics sample and bioinformatics services for research and clinical applications, to validate Target Selector™ technology. Subject to validation, Agiomix will purchase Biocept's RUO kits for use in its laboratory.

Industry Conferences and Study Results

- Announced the publication of case studies in the peer-reviewed journals *Clinics in Oncology* and *Oncology & Hematology Review* demonstrating the clinical utility of Target Selector™ in managing advanced NSCLC and metastatic breast cancer.
- Presented a poster at the 2019 American Association for Cancer Research Annual Meeting demonstrating the ability of the Target Selector™ liquid biopsy test to detect ESR1 mutations with high sensitivity.
- Presented two posters at the International Association for the Study of Lung Cancer's 19th World Conference on Lung Cancer featuring the ability of Target Selector™ technology platforms to detect and monitor actionable biomarkers in patients diagnosed with NSCLC.
- Presented two posters at the Fifth AACR-IASLC International Joint Conference, one featuring clinical data generated in collaboration with the University of Minnesota demonstrating the clinical utility of monitoring metastatic testicular cancer using Biocept's CTC assay technology, and the other highlighting data showing that incorporating Thermo Fisher Scientific's

QuantStudio 5 PCR Instrument into the Target Selector™ platform improves sensitivity and specificity for the detection of lung cancer biomarkers.

- Announced the publication of a letter to the editor in the peer-reviewed *Journal of Thoracic Oncology* outlining the ability of the Target Selector™ test to identify a *ROS1* gene rearrangement in a patient with lung cancer, confirming the results of a prior tissue biopsy.

Intellectual Property

- Issued patents in the U.S., Australia, seven European countries, China and Japan for assays to perform ctDNA analysis using real-time PCR, Sanger sequencing and next-generation sequencing encompassing Biocept's proprietary "switch-blocker" technology that enriches patient specimens, resulting in ultra-high sensitivity and specificity for the detection of cancer-associated mutations found in blood, tissue and other biological sources.
- Awarded patents in Australia, Canada and Japan covering the use of microchannels for the capture and detection of any target of interest, including proteins and nucleic acids, as well as the capture of cancer or other cells that can be used for molecular analysis in blood and other biological fluids.

Corporate

- Appointed Edwin C. Hendrick as Senior Vice President, Chief Commercial Officer. Hendrick brings more than 25 years of healthcare sales and commercial leadership experience including senior-level commercial and operational positions in clinical diagnostics.
- Retired our term debt facility with Oxford Finance eliminating approximately \$2.1 million in annualized cash expenditures.

Fourth Quarter Financial Results

Revenues for the fourth quarter of 2018 were \$860,000, and included approximately \$820,000 in commercial test revenues and approximately \$39,000 in development services test revenues. This compares with revenue of \$1.0 million for the fourth quarter of 2017, which included \$935,000 in commercial test revenues and \$61,000 in development services test revenues.

Biocept accessioned 1,043 total samples in the fourth quarter of 2018 compared with 1,057 total samples in the fourth quarter of 2017. Total accessions include billable samples and samples from research activities, assay validations and other non-billable sources. The Company accessioned 938 billable samples in the fourth quarter of 2018 compared with 982 billable samples in the fourth quarter of 2017.

Cost of revenues for the fourth quarters of 2018 and 2017 was unchanged at \$2.4 million.

Research and development (R&D) expenses for the fourth quarter of 2018 were \$1.3 million compared with \$0.9 million for the fourth quarter of 2017, with the increase due to a higher proportion of allocated laboratory costs associated with research and evaluation cases, costs associated with the development of new assays and automation of the CLIA laboratory, and costs related to the validation of the Thermo Fisher Scientific molecular oncology assay panel.

General and administrative (G&A) expenses for the fourth quarter of 2018 were \$1.6 million versus \$1.7 million for the fourth quarter of 2017, and sales and marketing expenses for the fourth quarter of 2018

were \$1.4 million versus \$1.6 million for the fourth quarter of 2017, with the declines due to the Company's initiatives to contain operating expenses.

The net loss for the fourth quarter of 2018 was \$6.0 million, or \$1.43 per share on 4.2 million weighted-average shares outstanding. This compares with a net loss for the fourth quarter of 2017 of \$5.7 million, or \$5.36 per share on 1.1 million weighted-average shares outstanding. In July 2018, we conducted a 1-for-30 reverse stock split of our outstanding common stock.

Full Year Financial Results

Net revenues recognized on an accrual basis were approximately \$3.2 million for the year ended December 31, 2018, compared with approximately \$3.8 million for the same period in 2017, a decrease of \$593,000, or 15%. As reported, net revenues were approximately \$3.2 million for the year ended December 31, 2018, compared with approximately \$5.1 million for the same period in 2017, a decrease of \$1.8 million, or 36%. All \$3.2 million of net revenues recognized during the year ended December 31, 2018, were recognized on an accrual basis, as compared to the same period in 2017 when approximately \$3.8 million of the \$5.1 million in net revenues were recognized on an accrual basis and approximately \$1.2 million of the net revenues were recognized upon the receipt of cash.

Biocept accessioned 4,252 total samples during 2018 compared with 5,051 total samples for 2017. The Company accessioned 3,896 billable samples during 2018 compared with 4,517 billable samples accessioned during 2017.

Cost of revenues for 2018 was \$10.1 million compared with \$9.3 million for 2017, with the increase primarily due to increases in depreciation expense, computer maintenance and equipment, software amortization, and allocated information technology and facility charges related to the implementation of our pathology partnership initiative.

R&D expenses for 2018 were \$4.5 million compared with \$3.4 million for the prior year, with the increase due to higher laboratory and personnel costs related to bringing new products to market.

G&A expenses for 2018 were \$7.1 million versus \$7.2 million for 2017, with the decrease due to lower stock-based compensation expenses and a decrease in facilities, depreciation, repairs and maintenance expenses.

Sales and marketing expenses for 2018 were \$5.9 million versus \$6.3 million for 2017, with the decrease due to lower personnel and travel costs, as well as a decrease in marketing materials, trade show and conference costs.

The net loss to common shareholders for 2018 was \$25.2 million, or \$9.01 per share on 2.8 million weighted-average shares outstanding. This compares with a net loss for 2017 of \$21.6 million, or \$23.58 per share on 917,000 weighted-average shares outstanding.

Cash and cash equivalents were \$3.4 million as of December 31, 2018, compared with \$2.1 million as of December 31, 2017. Since January 1, 2019, the Company has raised gross proceeds of \$18.5 million through equity offerings of common stock and warrants.

In the first quarter of this year we announced an initiative to reduce the use of cash. In July, we extinguished our term debt facility with Oxford Financial eliminating approximately \$2.1 million and in other categories an additional approximate \$1.2 million for a total reduction of approximately \$3.3 million in use of cash on an annualized basis. We also anticipate realizing additional reductions in use of cash in the near future from outsourcing our microfluidic channel manufacturing to a contract manufacturer. In addition, our current facility lease will expire in July 2020, and we anticipate that we will be able to realize further expense reductions in the future by obtaining a replacement facility lease with more favorable terms.

Conference Call and Webcast

Biocept will hold a conference call today at 4:30 p.m. Eastern time to discuss these results and answer questions. The conference call can be accessed by dialing (855) 656-0927 for domestic callers, (855) 669-9657 for Canadian callers or (412) 902-4109 for other international callers. A live webcast of the conference call will be available on the investor relations page of the company's website at <http://ir.biocept.com/events.cfm>. A replay of the webcast will be available for 90 days.

A replay of the call will be available for 48 hours following its conclusion and can be accessed by dialing (877) 344-7529 for domestic callers, (855) 669-9658 for Canadian callers or (412) 317-0088 for other international callers. Please use event passcode 10128915.

About Biocept

Biocept, Inc. is a molecular diagnostics company with commercialized assays for lung, breast, gastric, colorectal and prostate cancers, and melanoma. The Company uses its proprietary liquid biopsy technology to provide physicians with information for treating and monitoring patients diagnosed with cancer. The Company's patented Target Selector™ liquid biopsy technology platform captures and analyzes tumor-associated molecular markers in both circulating tumor cells (CTCs) and in plasma (ctDNA). With thousands of tests performed, the platform has demonstrated the ability to identify cancer mutations and alterations to inform physicians about a patient's disease and therapeutic options. For additional information, please visit www.biocept.com.

Forward-Looking Statements Disclaimer Statement

This news release contains forward-looking statements that are based upon current expectations or beliefs, as well as a number of assumptions about future events. Although we believe that the expectations reflected in the forward-looking statements and the assumptions upon which they are based are reasonable, we can give no assurance that such expectations and assumptions will prove to be correct. Forward-looking statements are generally identifiable by the use of words like "may," "will," "should," "could," "expect," "anticipate," "estimate," "believe," "intend" or "project," or the negative of these words or other variations on these words or comparable terminology. To the extent that statements in this news release are not strictly historical, including, without limitation, statements as to our ability to provide physicians with clinically actionable information to improve the outcomes of cancer patients, our ability to grow our business and drive adoption of our products, the number of billable samples we will have in the first quarter of 2019, whether our financial resources will allow us to implement our business strategy throughout the year, our ability to drive additional testing in non-U.S. territories, the success of our collaboration with Thermo Fisher Scientific and our ability to validate and commercially launch products as a result thereof, the success of our agreement with Agiomix, and our

ability to increase physician adoption of our liquid biopsy platform, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The reader is cautioned not to put undue reliance on these forward-looking statements, as these statements are subject to numerous risk factors as set forth in our Securities and Exchange Commission (SEC) filings. The effects of such risks and uncertainties could cause actual results to differ materially from the forward-looking statements contained in this news release. We do not plan to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this press release except as required by law. Readers are advised to review our filings with the SEC at <http://www.sec.gov>.

Investor Contact:

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BIOCEPT, INC.
CONDENSED BALANCE SHEETS

	December 31, <u>2017</u>	December 31, <u>2018</u> (unaudited)
ASSETS		
Cash	\$ 2,146,611	\$ 3,423,373
Accounts receivable, net	1,193,426	1,574,325
Inventories, net	498,702	587,222
Prepaid expenses and other current assets	416,600	425,961
TOTAL CURRENT ASSETS	<u>4,255,339</u>	<u>6,010,881</u>
FIXED ASSETS, NET	<u>3,123,567</u>	<u>2,739,422</u>
TOTAL ASSETS	<u><u>\$ 7,378,906</u></u>	<u><u>\$ 8,750,303</u></u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES, NET	\$ 4,661,345	\$ 4,609,647
NON-CURRENT LIABILITIES, NET	<u>1,421,527</u>	<u>1,098,137</u>
TOTAL LIABILITIES	<u>6,082,872</u>	<u>5,707,784</u>
SHAREHOLDERS' EQUITY	<u>1,296,034</u>	<u>3,042,519</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u><u>\$ 7,378,906</u></u>	<u><u>\$ 8,750,303</u></u>

BIOCEPT, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the three months ended December 31,		For the year ended December 31,	
	2017	2018	2017	2018
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
NET REVENUES	\$ 995,226	\$ 859,526	\$ 5,068,663	\$ 3,250,298
COSTS AND EXPENSES				
Cost of revenues	\$ 2,359,909	\$ 2,435,262	\$ 9,345,122	\$ 10,051,735
Research and development expenses	908,800	1,288,960	3,364,747	4,468,572
General and administrative expenses	1,650,097	1,632,670	7,189,529	7,074,024
Sales and marketing expenses	1,642,941	1,440,798	6,343,971	5,914,706
Total costs and expenses	6,561,747	6,797,690	26,243,369	27,509,037
LOSS FROM OPERATIONS	(5,566,521)	(5,938,164)	(21,174,706)	(24,258,739)
INTEREST AND OTHER INCOME/(EXPENSE), NET	(97,451)	(74,262)	(431,407)	(310,976)
LOSS BEFORE INCOME TAXES	(5,663,972)	(6,012,426)	(21,606,113)	(24,569,715)
INCOME TAXES	(2,601)	(1,147)	(7,624)	(1,886)
NET LOSS AND COMPREHENSIVE LOSS	\$ (5,666,573)	\$ (6,013,573)	\$ (21,613,737)	\$ (24,571,601)
Deemed dividend related to warrants down round provision	-	-	-	(636,370)
NET LOSS ATTRIBUTABLE TO COMMON SHAREHOLDERS	\$ (5,666,573)	\$ (6,013,573)	\$ (21,613,737)	\$ (25,207,971)
NET LOSS PER SHARE				
- Basic	\$ (5.36)	\$ (1.43)	\$ (23.58)	\$ (9.01)
- Diluted	\$ (5.36)	\$ (1.43)	\$ (23.58)	\$ (9.01)
WEIGHTED AVG NUMBER OF SHARES OUTSTANDING				
- Basic	1,058,055	4,209,221	916,599	2,798,243
- Diluted	1,058,055	4,209,221	916,599	2,798,243
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