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): August 12, 2020

BIOCEPT, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36284**	**80-0943522**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

5810 Nancy Ridge Drive, San Diego, CA	**92121**
(Address of principal executive offices)	**(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))

Securities registered pursuant to Section 12(b) of the Securities Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	BIOC	The Nasdaq Stock Market LLC

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 August 12, 2020, we issued a press release announcing our financial results for the three and six months ended June 30, 2020. 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 August 12, 2020.

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.

BIOCEPT, INC.

Dated: August 12, 2020

By: /s/ Timothy C. Kennedy

Name: Timothy C. Kennedy

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

EXHIBIT 99.1

Biocept Reports Second Quarter 2020 Financial Results

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

SAN DIEGO (August 12, 2020) – Biocept, Inc. (Nasdaq: BIOC), a leading provider of molecular technologies designed to provide physicians with clinically actionable information to improve the outcomes of patients, reports financial results for the three and six months ended June 30, 2020 and provides an update on its business progress.

"Due to our decision to initiate COVID-19 testing, overall commercial volume during the second quarter increased slightly versus the prior year, even with the impact of the pandemic," said Michael Nall, President and CEO of Biocept. "Commercial volume in our core oncology business was down 16% year-over-year, which is significantly better than the decline of up to 40% we anticipated in our second quarter forecast. We reached a low point in oncology testing early in the second quarter, with subsequent improvement as the quarter progressed. However, with the resurgence of the pandemic, physicians report that patient office visits have not returned to pre-COVID levels, which is continuing to affect our oncology testing volume. In addition to the launch of our COVID-19 testing service, our better-than-expected performance was driven in part by new assays that evaluate the cerebrospinal fluid of patients with breast or lung cancer suspected of brain or central nervous system metastases. Revenues for the quarter decreased 23% year-over-year, as a result of fewer patient visits to physician offices attributed to the concerns about COVID 19. That said, revenues for the first half of 2020 were up 7% over the prior year, driven by our strong first quarter performance before the full impact of the pandemic.

"For the immediate future, COVID-19 testing is an important part of our business and I'm pleased to report that we have received over 11,000 specimens to date," he added. "We have secured components to date for approximately 50,000 COVID-19 specimen collection kits to support current testing and expect to begin shipping our own COVID-19 specimen collection kits to our lab services customers later this year, which will contain our proprietary VEE-SURE™ viral transport media. These kits will be available for use in our lab or can be sold to other labs. We are excited about our recent development agreement with Aegea Biotechnologies to utilize Switch-Blocker™ technology to develop tests that could increase sensitivity in detecting SARS-CoV-2, the virus that causes COVID-19, and provide additional information on specific strain types.

"We are proud to support public health efforts by offering COVID-19 testing and plan to develop and offer these critical products and services for as long as they are needed," said Mr. Nall. "As a long-term strategy, we remain focused on oncology and believe we are well positioned to weather the pandemic as we continue to make progress on multiple aspects of our core business and build for a strong future. We are an established leader in liquid biopsy with our Target Selector™ assays, providing information that is critical to physician decision-making for their patients diagnosed with cancer. We expect that when the pandemic subsides, our commercial oncology volume will return to growth. We believe our recently strengthened balance sheet will support this strategy."

Second Quarter 2020 and Recent Highlights

Commercial Launches

- Launched COVID-19 testing and have received over 11,000 specimens to date. The vast majority of results to date have been reported to healthcare providers within 48 hours. The collection kits for RT-PCR SARS-CoV-2 testing have been assembled by Biocept with components sourced from another provider. Specimens are shipped overnight to Biocept's high-complexity, CLIA-certified, CAP-accredited and BSL-2 safety level laboratory. The lab is using Thermo Fisher Scientific's FDA-approved for EUA (Emergency Use Authorization) testing TaqPath™ molecular diagnostic platform and kit.
- Biocept is developing its own COVID-19 specimen collection kits for distribution to clients and expects those kits to be available later in 2020.
- Launched research-use-only (RUO) kits that allow molecular laboratories worldwide to detect oncogene mutations in tissue and liquid biopsies through the analysis of Formalin-Fixed Paraffin-Embedded (FFPE) tissue gained from surgical biopsies, as well as circulating tumor DNA (ctDNA) gained from blood. Our first RUO kit with the ability to use tissue and liquid biopsy samples is designed for the detection of EGFR mutations, which are among the most frequently evaluated biomarkers of lung cancer. RUO kits for other oncogene mutations are planned for future launches.
- Awarded CE-IVD Mark for the Target Selector™ molecular assay EGFR Kit. The CE Mark confirms that Target Selector™ kits meet the requirements of the European In-Vitro Diagnostic Devices Directive, and allows Biocept to commercialize these kits throughout the European Union and other geographies that recognize the CE Mark. Molecular assay kits detect key oncogene mutations through the analysis of both FFPE tissue and ctDNA. The EGFR pathway can include mutations that are among the most frequently evaluated biomarkers for lung cancer.
- Expanded menu of molecular assay kit offerings with the launch of a Target Selector™ kit to detect BRAF mutations. Similar to the EGFR kit, the BRAF RUO kit detects key oncogene mutations through the analysis of both FFPE tissue gained from surgical biopsies, as well as ctDNA gained from blood. The BRAF mutation is among the most frequently evaluated biomarkers across many solid tumors, including lung cancer and melanoma.

Development Agreement

- Entered into a development agreement with Aegea Biotechnologies to develop a new, highly sensitive, next-generation PCR-based COVID-19 assay utilizing the patented Switch-Blocker™ technology. The test is designed for improved analytical performance in order to better assist healthcare providers in screening and managing patients. The collaboration highlights the potential to apply the Switch-Blocker™ technology to molecular diagnostics in COVID-19 and other infectious diseases, in addition to oncology applications.

Commercial Agreements

- Entered into an agreement with reference-based pricing network Medical Cost Containment Professionals, LLC to process out-of-network claims for Target Selector™ liquid biopsy testing. Claims will be adjudicated through this network at pre-negotiated pricing in a timely manner, helping to accelerate collections while reducing the length of time receivables remain outstanding.
- Expanded Multiplan Health Insurance contract to now include Target Selector™ NGS panel for breast and lung cancer, as well as coverage for COVID-19 testing. Multiplan is an independent PPO network, with 4,500 acute care hospitals, 110,000 ancillary care facilities and 550,000 healthcare practitioners.
- Signed semi-exclusive agreement with skilled nursing facility network with over 50+ sites in multiple states to provide COVID-19 testing to residents and employees. Biocept is one of two laboratories selected.

Industry Conference Presentation

- Presented data affirming the ability of the Target Selector™ platform to identify potentially actionable mutations in the cerebrospinal fluid of patients whose cancer has metastasized to the central nervous system at the American Society for Clinical Oncology (ASCO) 2020 Virtual Scientific Program. The data were presented in a poster by the study's principal investigator Kevin Kalinsky, MD, MS, associate professor of medicine at Columbia University Vagelos College of Physicians and Surgeons, and an oncologist at New York-Presbyterian/Columbia University Irving Medical Center.

Intellectual Property

- Granted patents in Australia and Brazil for the Primer Switch technology, which is useful for ctDNA analysis using RT-PCR and associated methods, including next-generation sequencing (NGS).
- Awarded Canadian patent covering the enhanced detection of rare cells, including cancer cells, from a biological fluid sample such as blood or cerebrospinal fluid, expanding the Company's global patent estate to 40 for use in its molecular diagnostics business.

Corporate Developments

- Announced plans to relocate the Company's corporate offices and laboratory to a new 39,000 square foot facility in San Diego by the end of 2020. The move aligns with the strategy of supporting growth while reducing overhead expense, and is expected to be completed without disruption to workflow.
- Raised net proceeds of $9.6 million through a registered direct offering of common stock priced at-the-market.

Second Quarter Financial Results

Revenues for the second quarter of 2020 were $917,000, compared with $1.2 million for the second quarter of 2019, with the decrease attributable to the impact of the COVID-19 pandemic. Revenues for the second quarter of 2020 included $841,000 in commercial test revenue, $38,000 in development services test revenue and $38,000 in revenue for distributed products, Target Selector™ RUO kits and CEE-Sure® blood collection tubes. Revenues for the second quarter of 2019 included $1.1 million in commercial test revenue, $45,000 in development services test revenue and $28,000 from RUO kits and blood collection tubes.

Biocept accessioned 1,399 total samples during the second quarter of 2020, compared with 1,340 total samples during the second quarter of 2019. The Company accessioned 1,184 billable samples during the second quarter of 2020, compared with 1,211 billable samples during the second quarter of 2019. The decline in billable samples was attributable to the impact of the COVID-19 pandemic.

Cost of revenues for the second quarter of 2020 was $2.5 million, compared with $2.7 million for the second quarter of 2019, with the decrease primarily due to lower revenues attributable to the impact of the COVID-19 pandemic.

Research and development (R&D) expenses for the second quarter of 2020 were $1.6 million, compared with $1.1 million for the second quarter of 2019, with the increase primarily due to the launch of COVID-19 PCR testing, laboratory automation projects, and ongoing development and validation of liquid biopsy panels. General and administrative (G&A) expenses for the second quarter of 2020 were $1.9 million, compared with $1.7 million for the second quarter of 2019, with the increase due mainly to higher insurance costs, and higher legal fees primarily related to lease negotiations, warrant exercises and other matters. Sales and marketing expenses for the second quarter of 2020 were $1.3 million, compared with $1.6 million for the second quarter of 2019, with the decrease primarily attributable to lower sales and marketing activities due to pandemic-related travel restrictions.

Other expense, net for the second quarter of 2020 was $56,000, compared with $1.9 million for the second quarter of 2019, which included $1.8 million in warrant inducement expense.

The net loss attributable to common shareholders for the second quarter of 2020 was $6.5 million, or $0.05 per share on 127.2 million weighted-average shares outstanding. The net loss attributable to common shareholders for the second quarter of 2019 was $7.8 million, or $0.38 per share on 20.5 million weighted-average shares outstanding.

Six Month Financial Results

Revenues for the first six months of 2020 were $2.4 million, a 7% increase from $2.2 million for the first six months of 2019, and included $2.2 million in commercial test revenue, $99,000 in development services test revenue and $107,000 in revenue for Target Selector™ RUO kits and CEE-Sure blood collection tubes.

Operating expenses for the first six months of 2020 were $15.0 million, and included cost of revenues of $5.5 million, R&D expenses of $2.9 million, G&A expenses of $3.8 million and sales and marketing expenses of $2.8 million.

The net loss for the first six months of 2020 was $14.8 million, or $0.14 per share on 103.1 million weighted-average shares outstanding. This compares with a net loss for the first six months of 2019 of $13.8 million, or $0.83 per share on 16.7 million weighted-average shares outstanding.

Biocept reported cash and cash equivalents as of June 30, 2020 of $24.1 million, compared with $9.3 million as of December 31, 2019. The increase included approximately $27.3 million in net proceeds from three registered direct offerings in 2020, and exercise of overallotment of warrants from the December 2019 financing.

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 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 10145918. A replay of the webcast will be available for 90 days.

About Biocept

Biocept is a molecular diagnostics company with commercialized assays for lung, breast, gastric, colorectal and prostate cancers, and melanoma. Biocept uses its proprietary liquid biopsy technology to provide physicians with clinically actionable information for treating and monitoring patients diagnosed with cancer. Biocept's patented Target Selector™ liquid biopsy technology platform captures and analyzes tumor-associated molecular markers in both circulating tumor cells (CTCs) and in circulating tumor DNA (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. Additionally, Biocept is offering

nationwide COVID-19 polymerase chain reaction (PCR) testing to support public health efforts during this unprecedented pandemic. For more 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 perform COVID-19 testing and the likelihood of such test volume to be sustainable, our ability to provide and the timing of availability of our own COVID-19 specimen collection kits, the potential of our recent development agreement with Aegea Biotechnologies, including the potential to utilize Switch-Blocker™ technology to develop tests that could increase sensitivity in detecting SARS-CoV-2, and our ability to weather the COVID-19 pandemic and return commercial volume to normal levels and grow our business following the pandemic subsiding, 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/.

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BIOCEPT, INC.
CONDENSED BALANCE SHEETS

	December 31, 2019	June 30, 2020 (unaudited)
ASSETS		
Cash	$ 9,301,406	$ 24,053,269
Accounts receivable, net	3,527,078	3,179,217
Inventories, net	767,986	973,684
Prepaid expenses and other current assets	296,127	852,067
TOTAL CURRENT ASSETS	13,892,597	29,058,237
FIXED ASSETS, NET	1,504,330	1,336,726
LEASE RIGHT-OF-USE ASSETS	2,335,717	2,623,449
TOTAL ASSETS	$ 17,732,644	$ 33,018,412
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES, NET	$ 5,558,812	$ 5,631,559
NON-CURRENT LIABILITIES, NET	973,189	1,301,910
TOTAL LIABILITIES	6,532,001	6,933,469
SHAREHOLDERS' EQUITY	11,200,643	26,084,943
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 17,732,644	$ 33,018,412

BIOCEPT, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the three months ended June 30,		For the six months ended June 30,	
	2019 (unaudited)	2020 (unaudited)	2019 (unaudited)	2020 (unaudited)
NET REVENUES	$ 1,191,323	$ 917,471	$ 2,215,562	$ 2,364,020
COSTS AND EXPENSES				
Cost of revenues	$ 2,673,323	$ 2,517,902	$ 5,272,687	$ 5,464,760
Research and development expenses	1,148,280	1,588,716	2,371,571	2,901,392
General and administrative expenses	1,676,310	1,911,239	3,358,147	3,815,672
Sales and marketing expenses	1,614,732	1,333,271	2,989,292	2,798,386
Total costs and expenses	7,112,645	7,351,128	13,991,697	14,980,210
LOSS FROM OPERATIONS	(5,921,322)	(6,433,657)	(11,776,135)	(12,616,190)
WARRANT INDUCEMENT, INTEREST AND OTHER EXPENSE	(1,894,690)	(55,646)	(1,956,664)	(2,214,451)
LOSS BEFORE INCOME TAXES	(7,816,012)	(6,489,303)	(13,732,799)	(14,830,641)
INCOME TAXES	—	—	—	—
NET LOSS AND COMPREHENSIVE LOSS	$ (7,816,012)	$ (6,489,303)	$ (13,732,799)	$ (14,830,641)
Deemed dividend related to warrants down round provision	—	—	(99,743)	(2,774)
NET LOSS ATTRIBUTABLE TO COMMON SHAREHOLDERS	$ (7,816,012)	$ (6,489,303)	$ (13,832,542)	$ (14,833,415)
NET LOSS PER SHARE				
- Basic	$ (0.38)	$ (0.05)	$ (0.83)	$ (0.14)
- Diluted	$ (0.38)	$ (0.05)	$ (0.83)	$ (0.14)
WEIGHTED AVG NUMBER OF SHARES OUTSTANDING				
- Basic	20,466,224	127,173,744	16,670,184	103,086,834
- Diluted	20,466,224	127,173,744	16,670,184	103,086,834

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