

**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 16, 2021

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.)

9955 Mesa Rim Road, 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))

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 16, 2021, we issued a press release announcing our financial results for the three and six months ended June 30, 2021. 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 16, 2021.](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

Date: August 16, 2021

By: /s/ Timothy C. Kennedy
Timothy C. Kennedy
Chief Financial Officer, Chief Operations Officer and Corporate
Secretary

Biocept Reports Second Quarter 2021 Financial Results

- *Second quarter revenues of \$12.0 million driven by RT-PCR COVID-19 testing*
- *Continued sequential-quarter CNSide™ volume growth with customer base expanding to more than 30 leading U.S. academic institutions, including multiple repeat users*
- *Issued coverage with high-value payment by Medicare for the Target Selector™ breast cancer assay to detect the HER2 biomarker*
- *Received nearly 500,000 samples for COVID-19 RT-PCR testing since June 2020*

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

SAN DIEGO (August 16, 2021) – Biocept, Inc. (Nasdaq: BIOC), a leading provider of molecular diagnostic assays, products and services, reports financial results for the three and six months ended June 30, 2021 and provides a business update.

“We are reporting profitability for the first half of 2021 on revenues of nearly \$30 million driven by RT-PCR COVID-19 testing,” said Michael Nall, Biocept’s President and CEO. “Revenues of \$12.0 million for the quarter reflect the anticipated sequential quarter decline in COVID-19 testing as more Americans became vaccinated. That said, COVID-19 testing volume in the current quarter is presently running at a higher rate than second quarter levels largely due to the Delta variant with more than 50,000 samples received in the past month as we near the 500,000 sample milestone. We are prepared for increases in COVID-19 testing volume in the coming weeks as we begin receiving samples from California community college students returning to in-person classes.

“We are encouraged by the ongoing adoption of our paradigm-changing neuro-oncology CNSide assay, which provides physicians with a valuable tool to diagnose and manage patients with tumors that have metastasized to the central nervous system,” he added. “CNSide volume has grown each consecutive quarter since our beta launch in early 2020. We have now received orders from more than 30 leading U.S. academic institutions with the majority becoming repeat customers. Importantly, we have seen CNSide positively impact the life expectancy and the quality of life of patients who otherwise might be referred to hospice care.

“Finally, we are pleased with Medicare’s decision to provide coverage and high-value payment for our Target Selector breast cancer assay that detects the HER2 biomarker. Testing for the HER2 biomarker is among the most important sources of information when making treatment decisions for patients diagnosed with breast cancer and is among our most frequently ordered assay profiles,” concluded Mr. Nall.

Second Quarter 2021 and Recent Highlights

Commercial Developments and Agreements

Oncology

- Announced a positive coverage decision from Medicare and high-value reimbursement of \$2,435 for the Target Selector breast cancer assay to detect the HER2 biomarker from circulating tumor cells (CTCs) in liquid biopsy. The coverage decision became effective July 4, 2021.
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- Expanded the company's relationship with Quest Diagnostics to provide patients across the U.S. with access to the Target Selector NGS lung assay. Biocept anticipates that Quest's specialized oncology salesforce will begin marketing this Target Selector panel in the fourth quarter of 2021.
- Expanded the customer base for CNSide to more than 30 top U.S. academic institutions with the majority as repeat customers. CNSide is Biocept's cerebrospinal fluid assay that offers a timely and accurate method to diagnose patients with lung and breast cancer that has metastasized to the central nervous system, along with the ability to identify actionable biomarkers and assess a patient's response to therapy.

COVID-19

- Signed an agreement to make Biocept's COVID-19 testing available to the more than 2.1 million students, as well as faculty and staff of the California community colleges. The availability of COVID-19 testing is expected to provide information to help protect the safety of campus populations and reduce the spread of the SARS-CoV-2 virus as students return to campus.
- Coordinated with CLEARED4 to develop and implement a system to streamline testing protocols and track COVID-19 testing results. The system is intended to help Biocept customers, including California community colleges, ease the administrative burden of complying with complex health requirements.
- Received nearly 500,000 samples for COVID-19 RT-PCR testing at Biocept's high-complexity, CLIA-certified, CAP-accredited and BSL-2 safety level laboratory since the company began offering this test in June 2020. The lab is using Thermo Fisher Scientific's FDA-approved for EUA testing TaqPath™ molecular diagnostic platform and kit.

Corporate Developments

- Named Samuel Riccitelli as Chairman of the Board; Mr. Riccitelli joined the Biocept Board as a Director in October 2020.
- Expanded Board membership to nine with the appointments of Linda Rubinstein and Antonino Morales as Directors. Ms. Rubenstein and Mr. Morales bring extensive financial and leadership experience to support growth initiatives and advance the oncology diagnostics franchise.
- Named David Karlander as Senior Vice President of Commercial Operations with responsibility for all sales, marketing and reimbursement initiatives. He brings to Biocept more than 25 years of industry experience including building and managing major brands in diagnostics, devices and pharmaceuticals through all stages of commercialization.
- Biocept common stock was added to the Russell Microcap® Index, a broadly used performance benchmark for smaller growth stocks in the U.S. Membership in the Index is for one year with automatic inclusion in the appropriate growth and value style indexes.

Presentations

- Hosted a neuro-oncology [webinar](#) discussing CNSide for the diagnosis and management of cancer involving the central nervous system. The webinar featured a technology overview and leading neuro-oncologists from Northwestern University, Yale University and the Barrow Neurological Institute who reviewed case studies using the CNSide assay with subsequent favorable patient outcomes.

Intellectual Property

- Awarded a South Korean patent for the Primer-Switch technology, which detects rare mutations in circulating tumor DNA (ctDNA) using RT-PCR and associated analysis methods. Biocept's core technology and products are currently protected by 71 patents worldwide.

Second Quarter Financial Results

Net revenues for the second quarter of 2021 were \$12.0 million, compared with \$917,000 for the second quarter of 2020, with the increase primarily attributable to RT-PCR COVID-19 testing. Excluding a \$1.1 million increase in reserves for aged accounts receivables in the second quarter of 2021 that reduced net revenues, revenues were \$13.1 million and included \$12.1 million in RT-PCR COVID-19 test revenue, \$926,000 in oncology test revenue, \$33,000 in development services test revenue and \$34,000 in revenue for distributed products, Target Selector RUO kits, CEE-Sure® blood collection tubes and payments from Aegea for services associated with the development of a COVID-19 assay. Net 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.

Biocept accessioned 102,172 total samples and 101,982 commercial billable samples during the second quarter of 2021, compared with 1,306 total samples and 985 commercial billable samples during the second quarter of 2020. The increases were primarily attributable to COVID-19 testing.

Cost of revenues for the second quarter of 2021 was \$7.5 million, compared with \$2.5 million for the second quarter of 2020, with the increase primarily due to COVID-19-related collection kits and consumable expenses.

Research and development (R&D) expenses for the second quarter of 2021 were \$1.1 million, compared with \$1.6 million for the second quarter of 2020, with the decrease primarily attributable to lower facilities costs and cost of revenue allocations to R&D. General and administrative (G&A) expenses for the second quarter of 2021 were \$3.3 million, compared with \$1.9 million for the second quarter of 2020, with the increase primarily due to headcount additions and other expenses related to COVID-19 testing. Sales and marketing expenses for the second quarter of 2021 were \$1.9 million, compared with \$1.3 million for the second quarter of 2020, with the increase due to higher sales commissions on higher revenues.

The net loss attributable to common shareholders for the second quarter of 2021 was \$1.8 million including the \$1.1 million increase in reserves for aged accounts receivables, or \$0.14 per share on 13.5 million weighted average shares outstanding. This compares with a net loss attributable to common shareholders for the second quarter of 2020 of \$6.4 million, or \$0.51 per share on 12.7 million weighted-average shares outstanding.

Six Month Financial Results

Net revenues for the first six months of 2021 were \$29.8 million, compared with \$2.4 million for the first six months of 2020. Excluding the \$1.1 million increase in reserves for age accounts receivables which reduced net revenues, revenue for the first six months of 2021 the included \$30.7 million in commercial test revenue, \$73,000 in development services test revenue and \$95,000 in revenue for Target Selector RUO kits and CEE-Sure blood collection tubes and payments from Aegea for services associated with the development of a COVID-19 assay.

Operating expenses for the first six months of 2021 were \$28.9 million, and included cost of revenues of \$16.5 million, R&D expenses of \$2.2 million, G&A expenses of \$6.4 million and sales and marketing expenses of \$3.9 million. Operating income for the first six months of 2021 including the \$1.1 million increase in reserves for aged accounts receivables was \$772,000.

Net income for the first six months of 2021 was \$772,000, or \$0.06 per diluted share on 13.6 million shares weighted-average shares outstanding. This compares with a net loss for the first six months of 2020 of \$14.8 million, or \$1.44 per share on 10.3 million weighted-average shares outstanding.

Biocept reported cash and cash equivalents as of June 30, 2021 of \$19.5 million, compared with \$14.4 million as of December 31, 2020. During the three and six months ended June 30, 2021, the company raised net cash proceeds of \$3.9 million through the sale of common stock under its at-the-market (ATM) facility.

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 10157985. A replay of the webcast will be available for 90 days.

About Biocept

Biocept, Inc. develops and commercializes molecular diagnostic assays that provide physicians with clinically actionable information for treating and monitoring patients diagnosed with a variety of cancers. In addition to its broad portfolio of blood-based liquid biopsy assays, Biocept has developed the CNSide™ cerebrospinal fluid assay that detects cancer that has metastasized to the central nervous system. Biocept's patented Target Selector™ technology captures and quantitatively analyzes CSF tumor cells for tumor-associated molecular markers, using technology first developed for use in blood. Biocept also is leveraging its molecular diagnostic capabilities to offer nationwide COVID-19 RT-PCR testing to support public health efforts during this unprecedented pandemic. For more information, visit www.biocept.com. Follow Biocept on Facebook, LinkedIn and Twitter.

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 regarding the anticipated increases in COVID-19 testing volume, our anticipation that Quest's specialized oncology salesforce will begin marketing the Target Selector panel in the fourth quarter of 2021, the capabilities and performance of our CNSide assay and Target Selector technology, 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 risks and uncertainties, including risks and uncertainties associated with the continually evolving COVID-19 pandemic and the risk that our products and services may not perform as expected. These and other factors are described in greater detail under the "Risk Factors" heading of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, as filed with the Securities and Exchange Commission (SEC) on May 12, 2021, and under the "Risk Factors" heading of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, being filed with the SEC today. 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,	June 30,
	2020	2021
		(unaudited)
ASSETS		
Cash	\$ 14,367,942	\$ 19,451,189
Accounts receivable, net	14,144,911	12,595,694
Inventories, net	1,929,624	3,016,342
Prepaid expenses and other current assets	2,151,527	897,370
TOTAL CURRENT ASSETS	32,594,004	35,960,595
FIXED ASSETS, NET	2,317,616	2,078,464
LEASE RIGHT-OF-USE ASSETS	12,114,058	12,125,445
OTHER NON-CURRENT ASSETS	425,908	438,776
TOTAL ASSETS	\$ 47,451,586	\$ 50,603,280
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES, NET	\$ 12,494,253	\$ 9,654,472
NON-CURRENT LIABILITIES, NET	11,264,911	11,596,985
TOTAL LIABILITIES	23,759,164	21,251,457
SHAREHOLDERS' EQUITY	23,692,422	29,351,823
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 47,451,586	\$ 50,603,280

BIOCEPT, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME/(LOSS)

	For the three months ended June 30,		For the six months ended June 30,	
	2020 (unaudited)	2021 (unaudited)	2020 (unaudited)	2021 (unaudited)
NET REVENUES	\$ 917,471	\$ 12,047,166	\$ 2,364,020	\$ 29,803,356
COSTS AND EXPENSES				
Cost of revenues	\$ 2,517,902	\$ 7,461,819	\$ 5,464,760	\$ 16,467,675
Research and development expenses	1,588,716	1,137,614	2,901,392	2,180,339
General and administrative expenses	1,911,239	3,250,859	3,815,672	6,370,663
Sales and marketing expenses	1,333,271	1,944,661	2,798,386	3,867,933
Total costs and expenses	7,351,128	13,794,953	14,980,210	28,886,610
(LOSS)/INCOME FROM OPERATIONS	(6,433,657)	(1,747,787)	(12,616,190)	916,746
INTEREST AND OTHER INCOME/(EXPENSE), NET	(55,646)	(79,692)	(2,214,451)	(144,933)
(LOSS)/INCOME BEFORE INCOME TAXES	(6,489,303)	(1,827,479)	(14,830,641)	771,813
INCOME TAXES	—	—	—	—
NET (LOSS)/INCOME AND COMPREHENSIVE LOSS	\$ (6,489,303)	\$ (1,827,479)	\$ (14,830,641)	\$ 771,813
Deemed dividend related to warrants down round provision	—	—	(2,774)	—
NET (LOSS)/INCOME ATTRIBUTABLE TO COMMON SHAREHOLDERS	\$ (6,489,303)	\$ (1,827,479)	\$ (14,833,415)	\$ 771,813
NET (LOSS)/INCOME PER SHARE				
- Basic	\$ (0.51)	\$ (0.14)	\$ (1.44)	\$ 0.06
- Diluted	\$ (0.51)	\$ (0.14)	\$ (1.44)	\$ 0.06
WEIGHTED AVG NUMBER OF SHARES OUTSTANDING				
- Basic	12,717,372	13,462,329	10,308,681	13,431,340
- Diluted	12,717,372	13,462,329	10,308,681	13,646,789

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