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 29, 2021

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 March 29, 2021, we issued a press release announcing our financial results for the three months and year ended December 31, 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 March 29, 2021.

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: March 29, 2021

By: /s/ Timothy C. Kennedy

Name: Timothy C. Kennedy

Title: Chief Financial Officer, Chief Operations Officer and Corporate Secretary

EXHIBIT 99.1

Biocept Reports 2020 Fourth Quarter and Full Year Financial Results

Q4 features revenues of $18.5 million; 2020 revenues reach $27.5 million driven by COVID-19 testing

Introduces strategy to establish proprietary CSF assay as the standard of care in detecting cancer that has metastasized to the brain or central nervous system

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

SAN DIEGO (March 29, 2021) – Biocept, Inc. (Nasdaq: BIOC), a leading provider of molecular diagnostic assays, products and services, reports financial results for the three and 12 months ended December 31, 2020 and provides a business update.

"I'm exceptionally proud of the Biocept team for their enthusiasm and dedication in supporting the COVID-19 testing needs of our community while advancing our oncology business for a strong post-pandemic future," said Michael Nall, President and CEO of Biocept. "Our COVID-19 testing has provided valuable information to our clients, which has helped contain viral spread. We received about 140,000 samples for COVID-19 testing during the fourth quarter and, even with the relocation of our corporate headquarters and CLIA laboratory, our team provided the vast majority of COVID-19 test results to health providers within 48 hours of receiving the sample.

"Our financial results for the fourth quarter reflect our team's success with revenues reaching $18.5 million, resulting in our first-ever profitable quarter," he added. "Our ability to generate higher revenues in recent quarters due to COVID-19 testing significantly reduced our cash burn in 2020, while we continued to provide excellent service for our oncology and COVID-19 customers.

"The focus of our oncology business going forward is clearly on our neuro-oncology strategy and cerebrospinal fluid (CSF) assay," he added. "This assay uniquely addresses a high unmet clinical need by identifying metastatic progression of cancer to the central nervous system and brain. Approximately 10% to 30% of patients diagnosed with cancer, depending on tumor type, will ultimately experience spread of their disease to the central nervous system. Pilot studies have shown our CSF assay to be significantly more sensitive than conventional CSF cytology, the current standard of care, in detecting lung and breast cancer that has metastasized to the brain or central nervous system. Our CSF assay has the added advantages of identifying actionable molecular targets that provide physicians with valuable information in making treatment decisions, as well as providing quantitative information for monitoring treatment response and disease progression.

"Initial acceptance by neuro-oncology early -adopters has been highly encouraging as physicians from nearly two dozen leading academic institutions have ordered our assay with many becoming repeat users. Given the advantages of this offering, we have engaged a group of neuro-oncology thought-leaders from leading institutions to work with us in developing a strategy to establish our assay as the standard of care in diagnosing cancer with central nervous system involvement under National Comprehensive Cancer Network (NCCN) guidelines. Key among these actions is gathering clinical data in support of our testing. Later this year, we expect to start our Four C registry trial, which is designed to provide clinical validation of the performance of our assay against CSF cytology in predicting clinical outcomes in patients with suspected brain and central nervous system metastases," Mr. Nall concluded.

2020 and Recent Highlights

Corporate Developments

- Named Michael C. Dugan, MD as Chief Medical Officer and Medical Director with responsibilities for overseeing medical policy decision-making and the operations of Biocept's CLIA-certified, CAP-accredited, high-complexity molecular laboratory. Dr. Dugan is highly respected in the molecular diagnostics industry and has served in leading medical positions at Exact Sciences, Quest Diagnostics Nichols Institute and Roche Molecular Systems.
- Appointed Samuel D. Riccitelli to the Biocept Board of Directors. Mr. Riccitelli has more than 35 years of experience in the healthcare industry, including extensive experience in the molecular diagnostics industry, having served in executive-level positions and on the Boards of multiple publicly traded companies.
- Relocated Biocept's corporate offices and laboratory to a new 39,000- square- foot facility in San Diego. The move aligns with the Company's strategy of supporting growth while reducing overhead expense, and was completed with minimal impact to customers and saves approximately 20% annually in rental expense.
- Raised net proceeds of $27.3 million in 2020 including the exercise of warrants.

Clinical Study

- Announced plans for the Four C registry study, a non-interventional trial evaluating the performance of Biocept's CSF assay compared with clinical imaging, CSF cytology and clinical evaluation in patients with suspected leptomeningeal disease (LMD). The study is expected to enroll 200 patients with the objective of providing clinical validation for the Company's assay compared with CSF cytology in predicting clinical outcomes.

Commercial Launches, Developments and Agreements

Oncology

- Announced the commercial availability of the Target Selector™ assay to evaluate CSF for the presence of circulating tumor cells (CTCs) and biomarkers, which may be indicators of brain metastases, in patients with advanced lung and breast cancer. The validation study for the CSF assay was conducted in collaboration with Providence St. Joseph Health, Southern California, and its wholly owned affiliates Providence St. John's Health Center and John Wayne Cancer Institute.
- Announced a positive coverage decision by Highmark, America's fourth-largest Blue Cross Blue Shield affiliate, for Target Selector™ liquid biopsy assays for use in the diagnosis and treatment of patients with non-small cell lung cancer (NSCLC). The coverage determination follows two years of evaluation by the Allegheny Health Network Cancer Institute of Biocept's liquid biopsy assays to more rapidly assess the molecular status of patients with NSCLC, enabling oncologists to select the most appropriate therapy while also reducing the overall cost of care.
- Established a collaboration with Protean BioDiagnostics to research the ability of the Target Selector™ assay to determine EGFR status in NSCLC in an independent pathology laboratory setting. Protean BioDiagnostics also expects to validate the analytical performance of a laboratory developed test (LDT) based on Biocept's EGFR assay test kit in accordance with the requirements of the College of American Pathologists (CAP) validation process.
- 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.

- Signed laboratory services agreements with four California-based independent physician associations (IPAs) to provide Target Selector™ liquid biopsy testing services.
- 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. The 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.
- Expanded the 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.

COVID-19

- Received more than 300,000 samples for COVID-19 RT-PCR testing at Biocept's high-complexity, CLIA-certified, CAP-accredited and BSL-2 safety level laboratory since beginning testing in 2020. The lab is using Thermo Fisher Scientific's FDA-approved for EUA testing TaqPath™ molecular diagnostic platform and kit. The vast majority of results to date have been reported to healthcare providers within 48 hours of sample receipt.
- Expanded the agreement with MultiPlan, a healthcare cost management company offering payment integrity and network-based and analytics-based services, to include COVID-19 testing at a pre-negotiated price per test. More than 1 million healthcare providers participate in MultiPlan's networks and 60 million health plan members have access to its services.
- Signed a semi-exclusive agreement with a skilled nursing facility network with more than 50 sites in multiple states to provide COVID-19 testing to its residents and employees.
- Entered into development and supply agreements with Aegea Biotechnologies. The first agreement covered the development of a new, highly sensitive quantitative PCR-based COVID-19 assay utilizing the patented Switch-Blocker™ technology, which is also used in Biocept's Target Selector™ assays. After successful development of the assay, Biocept and Aegea entered into a supply agreement under which Aegea is supplying the COVID-19 assay kit for validation in Biocept's lab. Following validation, Biocept intends to commercialize an LDT. The test is designed for quantitative monitoring of RNA viral load in order to better assist healthcare providers in screening and managing patients.

Industry Conference Presentations and Publication

- Presented data from a pilot study showing the Target Selector™ molecular assay kit using Biocept's Switch-Blocker™ technology detected mutations in up to 50% of tissue biopsy specimens from patients diagnosed with NSCLC that were deemed quantity not sufficient for NGS analysis at the Molecular Med Tri-Con Virtual Conference.
- Presented results from a small, prospective study comparing Biocept's CSF testing to conventional CSF cytology in patients with NSCLC and LMD metastasis at the "Hot Topic: Liquid Biopsy" meeting of the International Association for the Study of Lung Cancer. Study results indicate that Biocept's CSF testing may play an important role in providing valuable information to neuro-oncologists in making treatment decisions for patients with lung cancer metastases to the brain and spinal cord.
- Presented results from a study using the Company's CSF assay to analyze CSF samples of patients with primary lung or breast cancer with either brain metastasis or LMD at the Society for Neuro-Oncology's SNO2020 Virtual Conference.
- Presented data affirming the ability of the Target Selector™ platform to identify potentially actionable mutations in the CSF 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.

- Presented results from a prospective study showing Target Selector™ was highly accurate in monitoring HER2 alterations in patients with metastatic breast cancer at the virtual 2020 San Antonio Breast Cancer Symposium® (SABC®). The results were featured in a poster presentation by Vered Stearns, MD, professor of oncology, breast cancer research chair in oncology, and director of the Women's Malignancies Disease Group at Johns Hopkins University School of Medicine/Johns Hopkins Sidney Kimmel Cancer Center.
- Clinical data were published in the *Journal of Clinical Pathology* that further validate Biocept's Target Selector™ qPCR Assay using Switch-Blocker™ technology to identify cancer-related mutations in liquid biopsy samples. Study results showed a very high concordance between the Company's liquid biopsy testing and tissue biopsy, and best-in-class detection of alterations down to a single mutant copy in both analytical and clinical settings.

Intellectual Property

- Awarded patents in the U.S., Japan, Australia and Brazil for Primer-Switch technology, which is useful for the detection of rare mutations, including cancer biomarkers, found in tissue, blood and CSF using ctDNA analysis through RT-PCR and associated analysis methods, including NGS.
- Awarded patents in the U.S., Canada and Hong Kong covering the enhanced detection of cancer cells. These patents expand the Company's IP estate for capturing and detecting rare cells of interest, including CTCs, to aid in the management of patients with cancer.
- Awarded a patent in Japan for the use of binding entities in combination with any solid surface to capture and detect any target of interest, including CTCs, from any sample type. This patent combines well with the Company's patented microchannel and cell-staining platforms, and provides opportunities for out-licensing technology with a focus on any target of interest, including single-cell analysis and other methodologies.
- Expanded the Company's global IP portfolio to 70 issued patents.

Regulatory Approval

- 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.

Fourth Quarter Financial Results

Revenues for the fourth quarter of 2020 were $18.5 million, compared with $1.8 million for the fourth quarter of 2019, with the increase attributable to RT-PCR COVID-19 testing. Revenues for the fourth quarter of 2020 included $18.3 million in commercial test revenue, inclusive of $17.6 million attributable to RT-PCR COVID-19 testing, and $32,000 in development services test revenue and $160,000 in revenue from distributed products, Target Selector™ RUO kits, CEE-Sure® blood collection tubes and payments from Aegea Biotechnologies for services associated with the development of a COVID-19 assay. Revenues for the fourth quarter of 2019 included $1.6 million in commercial test revenue, $87,000 in development services test revenue and $108,000 in revenue for Target Selector™ RUO kits, which were commercially launched in early 2019, and CEE-Sure® blood collection tubes.

Biocept accessioned 145,129 total samples during the fourth quarter of 2020, compared with 1,404 total samples during the fourth quarter of 2019. The Company accessioned 144,932 commercial billable samples during the

fourth quarter of 2020, compared with 1,159 commercial billable samples during the fourth quarter of 2019. The increase in total and billable samples was primarily attributable to COVID-19-related collection kits and consumable expenses.

Cost of revenues for the fourth quarter of 2020 was $10.0 million, compared with $2.9 million for the fourth quarter of 2019. Research and development (R&D) expenses for the fourth quarters of 2020 and 2019 were relatively flat at $1.2 million. General and administrative (G&A) expenses for the fourth quarter of 2020 were $3.1 million, compared with $1.9 million for the fourth quarter of 2019, with the increase primarily due to headcount additions to handle COVID-19-related activities as well as consulting expenses. Sales and marketing expenses for the fourth quarter of 2020 were $2.2 million, compared with $1.5 million for the fourth quarter of 2019, with the increase resulting from higher sales commissions due to higher revenues.

The fourth quarter of 2019 included a non-cash deemed dividend of $22,000 for the repricing of adjustable warrants. There was no comparable deemed dividend in the fourth quarter of 2020.

Net income attributable to common shareholders for the fourth quarter of 2020 was $1.9 million, or $0.14 per diluted share on 13.6 million weighted-average shares outstanding. This compares with a net loss attributable to common shareholders for the fourth quarter of 2019 of $5.7 million, or $1.97 per share on 2.9 million weighted-average shares outstanding. The change in outstanding share count reflects the 1-for-10 reverse split of common stock effected in September 2020.

Full Year Financial Results

Revenues for 2020 were $27.5 million, compared with $5.5 million for 2019. Revenues for 2020 included $26.9 million in commercial test revenue, inclusive of $23.3 million attributable to RT-PCR COVID-19 testing, and $177,000 in development services test revenue and $421,000 in revenue for Target Selector™ RUO kits, CEE-Sure blood collection tubes and payments from Aegea Biotechnologies for services associated with the development of a COVID-19 assay.

Operating expenses for 2020 were $42.9 million, and included cost of revenues of $21.3 million, R&D expenses of $5.2 million, G&A expenses of $10.0 million and sales and marketing expenses of $6.4 million. Operating expenses for 2019 were $28.6 million, and included cost of revenues of $11.0 million, R&D expenses of $4.7 million, G&A expenses of $7.0 million and sales and marketing expenses of $5.9 million.

The net loss for 2020 was $17.8 million, or $1.50 per share on 11.8 million weighted-average shares outstanding. This compares with a net loss for 2019 of $25.3 million, or $12.23 per share on 2.1 million weighted-average shares outstanding. The change in outstanding share count reflects the 1-for-10 reverse split of common stock effected in September 2020.

Biocept reported cash and cash equivalents as of December 31, 2020 of $14.4 million, compared with $9.3 million as of December 31, 2019.

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 10152872. 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, including metastatic tumors involving lung, breast and the central nervous system. Biocept's patented Target Selector™ technology platform captures and analyzes tumor-associated molecular markers in both circulating tumor cells (CTCs) and circulating tumor DNA (ctDNA) with higher sensitivity and specificity than most commercial assays. Additionally, Biocept is leveraging its molecular diagnostic capabilities to offer nationwide COVID-19 PCR testing to support public health efforts during this unprecedented pandemic. For additional 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 as to the ability of our assays to uniquely address a high unmet clinical need by identifying metastatic progression of cancer to the central nervous system and brain, our ability to establish our assays as the standard of care in diagnosing cancer with central nervous system involvement, the expected timing of our Four C registry trial and its ability to provide clinical validation of the performance of our assay against CSF cytology in predicting clinical outcomes in patients with suspected brain and central nervous system metastases, our ability to validate and commercialize COVID-19 assay kit co-developed with Aegea Biotechnologies, and our ability to provide physicians with clinically actionable information to improve the outcomes of cancer patients, 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	December 31, 2020 (unaudited)
ASSETS		
Cash	$ 9,301,406	$ 14,367,942
Accounts receivable, net	3,527,078	14,144,911
Inventories, net	767,986	1,929,624
Prepaid expenses and other current assets	296,127	2,151,527
TOTAL CURRENT ASSETS	13,892,597	32,594,004
FIXED ASSETS, NET	1,504,330	2,317,616
LEASE RIGHT-OF-USE ASSETS	2,335,717	12,114,058
OTHER NON-CURRENT ASSETS	—	425,908
TOTAL ASSETS	$ 17,732,644	$ 47,451,586
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES, NET	$ 5,558,812	$ 12,494,253
NON-CURRENT LIABILITIES, NET	973,189	11,264,911
TOTAL LIABILITIES	6,532,001	23,759,164
SHAREHOLDERS' EQUITY	11,200,643	23,692,422
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 17,732,644	$ 47,451,586

BIOCEPT, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the three months ended December 31,		For the year ended December 31,	
	2019 (unaudited)	2020 (unaudited)	2019	2020 (unaudited)
NET REVENUES	$ 1,783,742	$ 18,511,238	$ 5,528,566	$ 27,461,3
COSTS AND EXPENSES				
Cost of revenues	$ 2,872,098	$ 10,012,659	$ 10,977,520	$ 21,336,7
Research and development expenses	1,161,905	1,231,146	4,697,022	5,220,2
General and administrative expenses	1,911,593	3,134,073	6,970,120	9,973,0
Sales and marketing expenses	1,489,216	2,166,635	5,940,843	6,399,5
Total costs and expenses	7,434,812	16,544,513	28,585,505	42,929,6
(LOSS)/INCOME FROM OPERATIONS	(5,651,070)	1,966,725	(23,056,939)	(15,468,2
INTEREST AND OTHER INCOME/(EXPENSE), NET	(62,408)	(64,650)	(2,081,100)	(2,338,6
(LOSS)/INCOME BEFORE INCOME TAXES	(5,713,478)	1,902,075	(25,138,039)	(17,806,9
INCOME TAXES	—	—	—	
NET (LOSS)/INCOME AND COMPREHENSIVE LOSS	$ (5,713,478)	$ 1,902,075	$ (25,138,039)	$ (17,806,9
Deemed dividend related to warrants down round provision	(21,829)	-	(121,572)	(2,7
NET (LOSS)/INCOME ATTRIBUTABLE TO COMMON SHAREHOLDERS	$ (5,735,307)	$ 1,902,075	$ (25,259,611)	$ (17,809,6
NET (LOSS)/INCOME PER SHARE				
- Basic	$ (1.97)	$ 0.14	$ (12.23)	$ (1.
- Diluted	$ (1.97)	$ 0.14	$ (12.23)	$ (1.
WEIGHTED AVG NUMBER OF SHARES OUTSTANDING				
- Basic	2,912,859	13,396,824	2,066,086	11,845,2
- Diluted	2,912,859	13,604,025	2,066,086	11,845,2

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