
**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): June 10, 2022

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

(Former name or former address, if changed since last report)

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 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 8.01 Other Events.***Adjournment of Annual Meeting***

On June 10, 2022, Biocept, Inc. convened and adjourned its 2022 Annual Meeting of Stockholders (the “Annual Meeting”), without any business being conducted, due to lack of the requisite quorum being present. The Annual Meeting has been adjourned until 1:30 p.m. Pacific Time on Friday, July 8, 2022. The reconvened Annual Meeting will be held at the same virtual meeting link at www.proxydocs.com/BIOC.

Business Update

As previously announced on May 23, 2022 and discussed on our business update call on June 7, 2022, we are pursuing a re-focused business strategy. Our objective is to lead the emerging category of neurological tumor diagnostics with our CNSide™ cerebrospinal fluid (“CSF”) assay and become the provider of choice for biopharmaceutical companies developing therapies to treat cancer that has metastasized to the central nervous system. We estimate the initial annual market opportunity for CNSide to be \$1.2 billion in the United States and \$2.0 billion globally. Over time, we plan to explore the uses of CNSide for additional indications that could further expand the market opportunity, including, eventually, potentially other diseases beyond cancer that affect the central nervous system. In order to focus our resources on opportunities involving CSF, we plan to exit our blood-based oncology diagnostics business. This initiative is about 60% complete, and we expect it to be fully completed by the end of the third quarter of this year. We also plan to support our community with RT-PCR COVID-19 testing for as long as there is need and we can do so profitably.

We intend to generate evidence of clinical utility that will support CNSide reimbursement and adoption into patient care guidelines through our own and investigator-initiated clinical trials, while forming collaborations with biopharmaceutical companies that are developing treatments for central nervous system tumors or looking to expand indications of use for existing targeted therapies.

Preparations are underway for our company-sponsored FORESEE clinical trial, with enrollment expected to begin in the third quarter of this year. The FORESEE trial is expected to be a two-part multicenter prospective clinical trial that enrolls patients with breast cancer or non-small cell lung cancer who have suspected or confirmed leptomeningeal metastases. The trial is designed to compare CNSide with CSF cytology and radiology. The goal of the FORESEE trial is to further evaluate the performance of CNSide in monitoring response to treatment in a prospective clinical trial setting and to assess the impact of CNSide on treatment decisions made by physicians. This trial design is focused on demonstrating clinical utility, which is based on how and to what extent physicians find value in the detection of disease and how CNSide influences them in their decision-making. As we initiate and progress our planned FORESEE trial, we anticipate that some of the CNSide tests that would otherwise have been purchased commercially will be ordered for patients participating in the FORESEE trial, which would reduce commercial volume.

We also intend to solicit and fund select investigator-initiated trials, with the first such trial expected to begin before the end of 2022. These studies would target specific indications for use of CNSide, some of which may lead to expanded market opportunities. We plan to utilize the clinical evidence from these trials to create peer-reviewed publications demonstrating the valuable role CNSide can play in the care of patients with metastatic central nervous system cancers. We expect to submit the first peer-reviewed paper this year, with publication expected in the first quarter of 2023.

We also intend to seek to identify additional technologies, products and services we can in-license or acquire that can augment our offerings to neuro-oncologists.

Forward-Looking Statements

This report 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 “will,” “anticipate,” “expect,” “estimate,” “planned,” “objective,” “goal,” “believe,” “plan,” “potential,” “could,” or “intend” or the negative of these words or other variations on these words or comparable terminology. To the extent that statements in this report are not strictly historical, including, without limitation, statements regarding our new business strategy, our objectives, markets we may focus on and the size of market opportunities, potential new or expanded market opportunities, our ability to lead the emerging category of neurological tumor diagnostics and become the provider of choice for biopharmaceutical companies developing therapies to treat cancer that has metastasized to the central nervous system, our intention to generate evidence of clinical utility that will support CNSide reimbursement and adoption into patient care guidelines through our own and investigator-initiated clinical trials, our intention to form collaborations with biopharmaceutical companies that are developing treatments for central nervous system tumors or looking to expand indications of use for existing targeted therapies, our plan to continue providing RT-PCR COVID-19 testing, our plan to exit from our blood-based oncology diagnostics business and the timing thereof, our expected timing for commencing enrollment of the FORESEE trial and the design and objectives of that trial and other trials, our plans for investigator-initiated clinical trials including the timing thereof, our expectations regarding peer-reviewed publications, future commercial results, and the capabilities and performance of our CNSide assay, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. You are 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; we may be unable to increase sales of our current products, assays and services or successfully develop and commercialize other products, assays and services; we may be unable to execute our new business strategy; we may be unable to compete successfully with our competitors and increase or sustain our revenues; we may be unable to identify collaborators willing to work with us to conduct clinical utility studies, or the results of those or currently planned studies may not demonstrate that an assay provides clinically meaningful information and value or have the other benefits that we expect; Medicare and private payors may not provide coverage and reimbursement or may breach, rescind or modify their contracts or reimbursement policies or delay payments; our estimates regarding the sufficiency of our existing resources may not be accurate as the actual amount of funds that we will need will be determined by many factors, some of which are beyond our control; 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, 2022, filed with the Securities and Exchange Commission on May 23, 2022. The effects of such risks and uncertainties could cause actual results to differ materially from the forward-looking statements contained in this report. We do not plan to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this report except as required by law.

SIGNATURE

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: June 13, 2022

BIOCEPT, INC.

By: /s/ Samuel D. Riccitelli

Name: Samuel D. Riccitelli

Title: Interim President and Chief Executive Officer