UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE TRANSITION PERIOD FROM TO

Commission File Number: 001-36284

Biocept, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**80-0943522**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
9955 Mesa Rim Road, San Diego, California	**92121**
(Address of principal executive offices)	**(Zip Code)**

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

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

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definition of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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 7(a)(2)(B) of the Securities Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Stock Market on June 30, 2022, was $15,907,495.

The number of shares of Registrant's Common Stock outstanding as of April 13, 2023 was 17,777,185.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements included or incorporated by reference in this Annual Report other than statements of historical fact, are forward-looking statements. You can identify these and other forward-looking statements by the use of words such as "may," "will," "could," "anticipate," "expect," "intend," "believe," "continue" or the negative of such terms, or other comparable terminology. Forward-looking statements also include the assumptions underlying or relating to such statements. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under the caption "Risk Factors" in Part I, Item 1A and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of this Annual Report and elsewhere in this Annual Report. Moreover, we operate in an evolving environment. New risk factors and uncertainties emerge from time to time and it is not possible for us to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Readers are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements speak only as of the date on which they are made and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they are made except

as required by law. Readers should, however, review the factors and risks we describe in this Annual Report and in the reports we subsequently file from time to time with the Securities and Exchange Commission, or the SEC.

RISK FACTOR SUMMARY

Below is a summary of the material factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found in this Annual Report on Form 10-K under the heading "Risk Factors" and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the SEC before making investment decisions regarding our common stock.

- We are a molecular oncology diagnostics company with a history of net losses; we expect to incur net losses in the future, and we may never achieve sustained profitability.
- We need to raise additional capital to continue as a going concern.
- If we are unable to increase sales of our current products, assays and services or successfully develop and commercialize other products, assays and services, our revenues will be insufficient for us to achieve profitability.
- If we cannot develop products, assays and services to keep pace with rapid advances in technology, medicine and science, our operating results and competitive position could be harmed.
- If our sole laboratory facility becomes damaged or inoperable, or we are required to vacate the facility, our ability to sell and provide our products and diagnostic assays and pursue our research and development efforts may be jeopardized.
- We expect to continue to incur significant expenses to develop and market products and diagnostic assays, which could make it difficult for us to achieve and sustain profitability.
- Clinical utility studies are important in demonstrating to both customers and payors an assay's clinical relevance and value. If we are unable to identify collaborators willing to work with us to conduct clinical utility studies, or the results of those studies do not demonstrate that an assay provides clinically meaningful information and value, commercial adoption of such assay may be slow, which would negatively impact our business.
- The loss of key members of our executive management team could adversely affect our business.
- There is a scarcity of experienced professionals in our industry. If we are not able to retain and recruit personnel with the requisite skills, we may be unable to successfully execute our business strategy.
- Our failure to attract, hire and retain a sufficient number of qualified sales professionals would hamper our ability to increase demand for our products and diagnostic assays, to expand geographically and to successfully commercialize any other products or assays we may develop.
- We depend on third parties for the supply of samples and other biological materials that we use in our research and development efforts. If the costs of such samples and materials increase or our third-party suppliers terminate their relationship with us, our business may be materially harmed.
- We currently rely on third-party suppliers for our specimen collection tubes, or SCTs, shipping kits, and critical materials needed to perform our current assays, as well as our planned future products, assays and services, and any problems experienced by them could result in a delay or interruption of their supply to us.
- Our commercial success could be compromised if hospitals or other clients do not pay our invoices or if third-party payors, including managed care organizations and Medicare, do not provide coverage and reimbursement, breach, rescind or modify their contracts or reimbursement policies or delay payments for our current assays and our planned future assays.
- Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our common stock.
- We expect to depend on Medicare and a limited number of private payors for a significant portion of our revenues and if these or other payors stop providing reimbursement or decrease the amount of reimbursement for our current assays and our planned future assays, our revenues could decline.
- Because of certain Medicare billing policies, we may not receive complete reimbursement for assays provided to Medicare patients. Medicare reimbursement revenues are an important component of our business model, and

private payors sometimes look to Medicare determinations when making their own payment determinations; therefore, incomplete or inadequate reimbursement from Medicare would negatively affect our business.

- Long payment cycles of Medicare, Medicaid and/or other third-party payors, or other payment delays, could hurt our cash flows and increase our need for working capital.
- If we were required to conduct additional clinical studies or trials before continuing to offer assays that we have developed or may develop as laboratory developed tests, or LDTs, those studies or trials could lead to delays or failure to obtain necessary regulatory approval, which could cause significant delays in commercializing any future products and harm our ability to achieve sustained profitability.
- If we are unable to maintain effective proprietary rights for our products or services, we may not be able to compete effectively in our markets.
- If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired and our public reporting may be unreliable.
- General economic or business conditions may have a negative impact on our business.

PART I

Item 1. Business

Overview

We are a molecular oncology diagnostics company that develops and commercializes proprietary clinical diagnostic laboratory assays designed to identify rare tumor cells and cell-free tumor DNA from blood and cerebrospinal fluid, or CSF. The identification of tumor cells and cell-free tumor DNA in CSF has become our principal development focus following our early commercial expansion into CSF in 2020. This product was branded and trademarked as CNSide™ in April 2021.

The identification of circulating tumor cells, or CTCs, and circulating cell-free tumor DNA and RNA, or ctDNA and ctRNA, derived from solid tumors such as breast cancer, lung cancer and melanoma using a standard blood sample has been described as a "liquid biopsy." This term reflects the ease with which peripheral blood can be drawn compared to performing a surgical biopsy, but this technology is not limited to a peripheral blood approach.

In January 2020, we adapted and validated our proprietary blood-based liquid biopsy technology for commercial and clinical research use in CSF to identify tumor cells that have metastasized to the central nervous system, or CNS, in patients with advanced lung cancer or breast cancer. We have subsequently broadened the CNSide indications for use to include all carcinomas and melanomas. CNSide has been designed to improve the clinical management of patients with suspected metastatic cancer involving the CNS by enabling the quantitative analysis and molecular characterization of tumor cells and ctDNA and ctRNA in the CSF. Since then, we have worked extensively with leading neuro-oncologists and other cancer experts to further define and characterize the use of this unique assay.

The initial disease focus for CNSide is in leptomeningeal metastasis, or LM. LM is a condition in which the primary tumor develops a secondary malignant growth in leptomeningeal tissue; that is, two of the three membranes surrounding human brain and spinal cord. These membranes are also known specifically as the arachnoid and pia mater. Clinically, this tissue is almost always unobtainable for biopsy purposes and CSF sampling is required for these patients. CSF continuously flows between these membranes and is used clinically to diagnose leptomeningeal disease. The incidence of LM among patients with solid tumors has risen over the past several decades. Epidemiologic studies suggest that 3-8% of patients with solid tumors will develop LM. However, at autopsy, the frequency of LM averages twenty percent and is much higher in some tumor types. The most common solid tumors giving rise to LM are breast cancer, lung cancer, melanoma, and gastrointestinal malignancies. Currently the survivability of leptomeningeal disease in solid tumors in patients not receiving treatment is measured in weeks.

The gold standard for making the diagnosis of LM, is CSF cytology, which has a clinical sensitivity of approximately 50%. As a result, MRI imaging is heavily relied upon by oncologists but suffers from a limited specificity of approximately 77%. Additionally, previous attempts to create an MRI-based "scorecard" for leptomeningeal disease to assess treatment response/disease progression have had varied success.

Given the challenges associated with diagnosing LM and the need for biomarker information to guide therapeutic management, the opportunity for advanced technologies to benefit these patients became clear. This is the context under which CNSide has been developed, allowing it to potentially address significant unmet medical needs. We summarize the unmet needs for managing metastatic brain cancer patients as follows: Is there tumor (diagnosis)? Is there target (presence of a biomarker to aid treatment selection)? Is there trend (a response to therapy)?

The question "Is there tumor?" is essential for the diagnostic work-up of these patients. Tumor cells in the blood can be shed from either primary or metastatic tumors. They can be rapidly removed in the capillary beds of the spleen, liver, kidneys, lungs and other organs, so they are rarely found. Conversely, tumor cells in the CSF are the defining feature of leptomeningeal disease. To distinguish tumor cells derived from CSF and from blood we often refer to tumor cells in CSF as CSF tumor cells, rather than CTCs.

Regarding the second clinical question, "Is there target?" our CNSide assay provides a vehicle for several different diagnostic assay profiles which combined with our molecular test menu can identify tumor cell biomarkers that are intended to help physicians make decisions related to the evolution or course of metastatic tumor that may inform treatment decisions. Cancer cells typically acquire genetic alterations which differ from that of normal cells. Metastatic cancers often acquire additional genetic alterations which distinguish them from the primary tumor site. This marked genetic variation between areas of tumor

growth is termed “genetic heterogeneity,” and findings related to this were featured in our San Antonio Breast Cancer Symposium presentation in December 2021 illustrating the value of CNSide in identifying “genetic heterogeneity” of a targetable biomarker called HER2.

Finally, regarding the third clinical question, “Is there trend?” over the past three years, having tested CNSide in more than one thousand patients, we have gained considerable experience with detecting CSF tumor cells of patients that have been sampled multiple times over the course of their treatment. The association of quantitative CSF tumor cell counts with response to treatment has been noted in both lung and breast cancer, as well as other tumors examined. In August 2021, at the Society for Neuro-Oncology (SNO) Brain Metastases meeting, we presented data obtained from a single institution showing how serial monitoring of CSF tumor cells by CNSide was used to determine the response to treatment in patients with Non-Small Cell Lung Cancer having LM. In addition, in November 2021 at the SNO annual meeting, we presented the early findings of several patients with breast cancer having LM which had been followed with multiple CSF samples drawn at different time points throughout each patient's treatment. The downward progression of tumor cell counts has been noted by several treating physicians to correlate with response to treatment and resolution of symptoms. Serial monitoring of genetic alterations present in CSF tumor cells may create opportunities to change the therapy of certain patients throughout treatment. These observations presented in abstracts and poster presentations in 2021 and 2022 have informed our clinical study strategy which is the basis for our ongoing efforts to further explore these observations in a prospective clinical trial.

CNSide Description

CNSide encompasses a suite of cellular and molecular technologies intended to aid medical professionals in CSF analysis and CNS disease management in patients with solid tumors. We currently offer and conduct our commercialized diagnostic assays and offer our clinical trial services at our Clinical Laboratory Improvement Amendments of 1988 (CLIA) certified, College of American Pathologists (CAP) accredited and California state-licensed laboratory in San Diego, CA. These assays include cell capture and enumeration, immunocytochemistry, fluorescent in situ hybridization (FISH), and next generation sequencing (NGS).

CNSide offers several differentiating elements that make it a unique solution for oncologists, including:

- Dual-platform – CNSide offers both cellular and molecular assays under a single consistent protocol, enabling the maximum amount of information to be collected from a single specimen. This is crucial when working with a specimen that is challenging to obtain, such as CSF.
- CNSide CEE-Sure CSF specimen collection tube – This proprietary specimen collection tube enables up to 4-day shipping of CSF from patient care sites to our laboratories in ambient conditions while preserving both cells and nucleic acids for analysis.
- Unique cell capture – A flagship technology adapted from blood for use in CSF, the CNSide cell capture assay uses a cocktail of different cell surface antibodies directed at the tumor cell population of interest. These antibody cocktails facilitate the isolation, enumeration, and interrogation of tumor cells in specially configured microfluidic channels.
- Quantity and quality – By multiplexing immunocytochemical stains on a captured specimen, CNSide achieves the benefits of a quantitative assay (like flow cytometry) while at the same time maintaining the qualitative benefits of a still image. As such, it is possible to perform both a cell count and a morphologic study and use this information to layer additional assays into the microfluidic channel. Specifically, CNSide uses FISH to evaluate the cytogenetics of the captured population.

As of this filing date, CNSide has been used at 30 of the Nation’s 64 NCI designated cancer centers for a host of primary indications, including breast cancer, non-small cell lung cancer, small cell lung cancer, melanoma, esophageal cancer, gastric cancer, colorectal cancer, head and neck cancers, ovarian cancer, endometrial cancer, renal cancer, bladder cancer, prostate cancer, liver cancer, pancreatic cancer, neuroendocrine cancer, melanoma and others.

COVID-19 Pandemic Response Summary

In June 2020, to respond to a national public health emergency precipitated by the COVID-19 pandemic, we introduced molecular testing for SARS-CoV2, the virus responsible for COVID-19, using a United States Food and Drug Administration, or FDA, Emergency Use Authorization, or EUA, based "RT-PCR" method developed by Thermo-Fisher.

Since launch of our COVID-19 testing program, we performed more than 1,000,000 assays for patients and customers. We primarily marketed our COVID-19 testing services to skilled nursing facilities in the western United States and also to certain community colleges within California.

Our COVID-19 testing services were responsible for most of our revenues during the years ended December 31, 2022 and 2021. However, as a result of increased vaccination and immunization levels, as well as decreased COVID-19 hospitalizations, reported cases and mandatory COVID-19 testing, we experienced reduced demand for our COVID-19 testing services throughout 2022. We exited the COVID-19 testing business in February 2023.

Additional Oncology Testing Services

At our corporate headquarters facility located in San Diego, California, we operate a clinical laboratory that is CLIA-certified, CAP accredited and licensed by the California Department of Public Health. In this facility we also develop novel assays that are part of our project pipeline for future commercial launch and we manufacture our microfluidic channels and various reagents and products used in our testing processes. We also work closely with external manufacturers to outsource certain products such as specimen collection tubes and to manufacture items that we may, in the future, outsource to reduce costs and improve efficiency.

The assays we offer and intend to offer are classified as CLIA laboratory developed tests, or LDTs, under CLIA regulations. CLIA certification and state licensure in California and certain other states under the supervision of a qualified laboratory medical director is required before any clinical laboratory, including ours, may perform testing on human specimens for the purpose of obtaining information for the diagnosis, prevention, or treatment of disease or the assessment of health. In addition, we participate in and have received CAP accreditation, which includes rigorous bi-annual laboratory inspections and requires adherence to specific quality standards.

Commercial Strategy

Our primary sales strategy is to engage neuro-oncologists, oncologists and other physicians in the United States at private and group practices, hospitals, laboratories and cancer centers to educate them about our unique products and services. In addition, we market our clinical trial and research services to pharmaceutical and biopharmaceutical companies and clinical research organizations.

Our revenue generating efforts are focused in the following areas:

- providing laboratory services to neuro-oncologists, oncologists and other physicians or healthcare providers treating patients with neurological cancers who use the CNSide test result data we provide in order to determine the best treatment plan for their patients;
- providing laboratory services using both our cell capture and enumeration technology and ctDNA assays to help pharmaceutical and biopharmaceutical companies run clinical studies establishing the use of novel drug therapies used to treat cancer; and
- licensing our proprietary technology and selling our distributed products, including our SCTs and potential future assay kits, to partners in the United States and abroad.

We plan to grow our business by directly offering our CNSide testing services to neuro-oncologists, oncologists and other physicians or heath care providers who treat patients with cancer. Based on our product development data, as well as discussions with our key collaborators, we believe that our current and planned future assays, particularly those related to CSF, should provide important information and clinical value to physicians.

We believe our ability to rapidly translate insights about the utility of cytogenetic, immunocytochemical and molecular biomarkers to provide information to neuro-oncologists, oncologists and other physicians for treatment decisions in the clinical setting will improve patient treatment and management, and that these assays will become a key component of the standard of care for personalized cancer treatment.

Provider Agreements

In January 2017, we announced that we had secured an in-network provider agreement with Blue Cross Blue Shield of Texas, the largest provider of health benefits in Texas. In addition, we entered into a national master business agreement with the Blue Cross Blue Shield Association, a not-for-profit trade association that provides multiple services for its 38-member Blue Cross and Blue Shield health plan companies across the U.S., including forming national strategic vendor partnerships. We were selected by the Blue Cross Blue Shield Association based on a rigorous request-for-proposal progress. This agreement establishes pricing for our testing services through the Blue Cross Blue Shield Association's group purchasing organization, CareSource. The pricing offered by CareSource group purchasing organization is available to those Blue Cross and Blue Shield member health plans that have, or may seek, in-network agreements with us.

In July 2022, we signed a new, updated agreement with the BCBS Association, establishing pricing for CNSide, the company's Cerebrospinal Fluid Cell Based Assay through their group purchasing organization, Care Source. In September 2022, we executed a new agreement with BCBS of Michigan, the first major BCBS plan to cover and reimburse for CNSide. The Blue Care Network is the largest HMO in Michigan. In January 2023, we finalized an agreement with Blue Shield of California, serving 4.5 million health plan members and more than 65,000 physicians across the State of California, as well as 340 hospitals statewide.

In June 2017, we entered into a participating provider agreement with MediNcrease Health Plans, LLC and a preferred provider agreement with Scripps Health Plan Services, Inc., both establishing pricing for our Target Selector liquid biopsy testing service.

In December 2017, we signed an agreement with Wellmark, Inc., or Wellmark, the largest health insurer in Iowa and South Dakota. The agreement marked our third Blue Cross Blue Shield contract and enabled patients diagnosed with cancer to access our proprietary testing services in-network under their Wellmark health plan.

In August 2018, we entered into a quality initiative program with Highmark and Alleghany Health Network as a result of the Caresource Workgroup. The focus is to improve access to molecular testing to members with a diagnosis of lung cancer.
In July 2019, we announced that we entered into a Laboratory Services Provider Agreement with Beacon Laboratory Benefit Solutions, Inc., a nationally recognized premier provider of laboratory benefit management technology solutions to health and managed care companies in the United States.

In February 2020, we announced that we entered into an agreement with a California-based independent physician association, or IPA, to provide our testing services to physicians and patients in their network.

In June 2020, we announced that we entered into a managed care provider agreement with Medical Cost Containment Professional LLC, or MCCP, to process out-of-network claims for our Target Selector liquid biopsy testing. MCCP is a reference-based pricing insurance network that includes more than 150,000 providers nationwide.

In September 2020, we announced that Highmark, America's fourth largest Blue Cross Blue Shield affiliate, has made a positive coverage determination that our Target Selector liquid biopsy assay has been accepted for medical coverage for use in the diagnosis and treatment of patients with NSCLC. In addition, we announced that we entered into an agreement with Health Net Federal Services LLC to be an in-network provider for Target Selector (Target Selector brand has subsequently been replaced by CNSide in the case of CSF-based liquid biopsies) liquid biopsy oncology platform testing for cancer patients in the TRICARE West, or TriWest, region network. TriWest provides healthcare services to approximately 3 million members of the U.S. military and their families.

In December 2020, we announced entering into laboratory services agreements with two Southern California regional IPAs providing physicians and patients in-network access to our testing services. Both IPAs are headquartered in San Diego and combined they serve more than 70,000 covered lives in the Southern California region.

In March 2022, we entered into a contract with the CA Department of Health Care Services to participate in the State's Medi-Cal Program for low-income people.

In October 2022, we executed an amended agreement with MultiPlan, Inc., a healthcare cost management solutions company with over 700 payor organizations within their network throughout the country. The amended agreement now includes CNSide, our Cerebrospinal Fluid Tumor Cell Based Assay at a premium rate of reimbursement. This agreement offers our company access to all 10 of the nation's top 10 healthcare payors (by market share).

We are currently contracted with 12 preferred provider organizations and networks, including two national third party payor groups, seven large commercial health plans, and six regional independent physician associations.

Market Overview

Cancer Market Overview

Despite many advances in the treatment of cancer, it remains one of the greatest areas of unmet medical need. According to the American Cancer Society, the incidence of new cancer cases reported in United States was 1.9 million in 2021, with 608,570 people dying from cancer. Additionally, the prevalence of people living with cancer in the U.S. was 16,627,949 in 2019 according to the National Cancer Institute. These cancer patients are served by over 13,000 oncologists who are engaged in patient care as of 2022 according to the American Society for Clinical Oncology.

Brain tumors represent a diverse repertoire of malignancies that remain notoriously difficult to treat as manifested by the unfortunate fact that survival beyond two years remains rare. Cancer in the CNS typically arises from either within the brain tissue itself (primary brain cancer) or from cancer cells that have broken off and spread from other primary sites (i.e., metastatic CNS cancer). Brain metastases are responsible for nearly 90% of all brain malignancies.

Metastatic Brain Cancer Overview

Cancer metastasis accounts for 90% of all solid tumor cancer mortality (Taftaf, R. et al. Nature Communications 12, 4867 2021). Metastasis of cancers to the CNS (brain and spinal cord) constitutes a major complication of malignant disease, is associated with significant clinical symptoms and poor outcomes, and presents significant clinical challenges to physicians responsible for the care of these patients. The increasing frequency of metastatic brain cancer is thought to be rising due to longer survival resulting from better cancer diagnosis, improved cancer screening methods, and more effective treatments (Karimi et al. Nature Vol 614 2023).

Wen et al (ONCOLOGY 13(7):961, 1999) estimated that brain metastases will develop in 10% to 30% of adults and 6% to 10% of children with cancer. Most frequently, CNS metastasis occurs in tumors of the lung, breast, and melanoma, but also tumors of the gastro-esophageal junction, pancreas, biliary system, ovaries and head and neck, amongst many others. Certain subtypes of these solid tumors, such as triple negative breast cancer, HER2 positive breast cancer, small cell lung cancer, EGFR mutated non-small cell lung cancer and invasive BRAF positive melanoma are most likely to reach the CNS typically causing significant morbidity and subsequent mortality within a short period of time.

Several types of brain metastasis occur, most typically involving the brain parenchyma and forming a solid lesion that is visible on radiologic studies such as MRI. Other sites of metastasis such as in the leptomeninges, a membranous lining around the brain and spinal cord, are more subtle and difficult to diagnose. Leptomeningeal disease is usually diagnosed with a combination of clinical evaluation (symptoms), radiology (MRI or CT) and CSF cytology (examination of CSF under the microscope by a pathologist).

A recently completed large scale, quantitative market research project commissioned by us and conducted by a third-party organization concluded that the total addressable market for the CNSide assay is estimated to be $1.2 billion annually in the United States, with a $415.0 million opportunity in LM, and $744.0 million in parenchymal brain metastasis. This research included a survey of 150 randomly sampled U.S.-based medical oncologists as well as an exhaustive literature review to orthogonally assess the number of patients for whom CNSide would be clinically appropriate. From this effort, we estimated the total worldwide addressable market for CNSide is in excess of $2.0 billion, annually.

Procedural approach to metastatic cancers in the CNS

Our CNSide assay can be performed on a CSF sample obtained either by "lumbar puncture" or via an intraventricular catheter inserted into one of the lateral ventricles of the brain. These catheters are commonly known as an Ommaya reservoir.

With easy access to the CSF from an Ommaya reservoir, these samples may be obtained many times over the course of a patient's treatment for LM. Innovative methods of treating LM have significantly improved expected survival for many of these patients with survival of a year or more often achieved in patients who would otherwise die within a few weeks if untreated. These may be performed at various times over the course of a patient's life with cancer to help manage these patients.

Clinical need for CNSide

The challenge of diagnosing LM, selecting an appropriate treatment, and establishing treatment response all can benefit from the identification of tumor cells and other biomarkers. Clinical urgency may also require the evaluation of CSF to avoid the need for surgical biopsy. It is often necessary to perform repeated sampling of the CSF to establish a diagnosis of metastases due to the use of less sensitive, conventional techniques such as cytology. At the time of progression or recurrence there may be insufficient time and/or an urgent or precarious clinical status which does not favor a surgical approach to obtain diagnostic material. Additionally, many studies have shown that cancers frequently mutate during the course of treatment as cancer progresses, so genomic information from the initial tumor tissue may not be able to best inform later treatment decisions at the time of metastasis. We believe CNSide can be particularly advantageous when the patient has advanced disease and brain metastasis but is not a good candidate for surgery or other invasive diagnostic methods such as stereotactic biopsy.

Our Business Strategy

Our suite of CNSide testing services enables us to provide neuro-oncologists, oncologists and other physicians and health care providers that treat cancer with a means to profile and characterize the genomic alterations of their patients' CNS tumors by analyzing tumor cells and ctDNA found in CSF obtained by lumbar puncture or through an Ommaya reservoir, avoiding the need for surgical tissue biopsy or other more inconvenient or invasive methods. Our assays are designed to address three principal clinical questions:

Is there tumor? We believe that our technology, which provides information on the presence of tumor cells in the CSF can be used to diagnose the progression of disease, in particular, tumor cells in the CSF can be used to confirm suspected CNS metastasis of carcinomas and melanomas.

Is there target? Our technology can be used to assess molecular biomarkers in CSF tumor cells or ctDNA, that can provide information to physicians to help guide the selection of more effective targeted therapies where available.

Is there trend? Our CSF tumor cell assays can be used to follow the response to therapy, by providing a more sensitive and quantitative measure of tumor burden than other methods such as CSF cytology or radiologic imaging.

Our goal is to become the standard of care for cancer patients with advanced disease and suspected CNS metastasis. Our approach is to develop and commercialize CSF tumor cell and ctDNA assays and services that enable us to offer actionable information from a CSF sample for a range of tumor types so that oncologists can make treatment decisions which improve patient care. To achieve this, we intend to:

- Develop and commercialize a portfolio of proprietary CSF tumor cell enumeration, cellular characterization, and molecular assays that enable physicians to personalize cancer treatment. Our biomarker assays are designed to provide a more complete profile of a patient's disease and offer enhanced sensitivity and specificity compared to the current standard of care, based on our initial studies.
- Drive the development of clinical evidence to validate the claim that CNSide addresses the significant unmet medical needs of patients suffering from metastatic CNS cancer. Initially, this includes publications and presentations at national meetings where the clinicians and scientists that manage these patients gather annually. We have presented 11 such abstracts as of December 31, 2022 at meetings such as the Society of Neurooncologists (SNO), the American Academy of Neurology (AAN) and other leading academic gatherings. We expect that these initial abstracts will lead to peer-reviewed publication submissions during calendar year 2023. The resulting peer-reviewed papers would be the first such evidence in the peer-reviewed clinical literature supporting use of CNSide in these indications. Our ultimate near-term aim is to conduct prospective clinical trials that demonstrate the clinical utility of CNSide in managing LM patients. To this end, we have initiated the FORESEE clinical study (NCT#

05414123). The FORESEE trial is a multi-center prospective clinical trial that has now successfully enrolled its first patient. With the help of a leading oncology Clinical Research Organization, we have established the infrastructure for the trial, have opened two sites (one in Los Angeles and one in Dallas) and are now in the process of opening at least three additional clinical sites where patients with breast or non-small cell lung cancer (NSCLC) who have suspicious or confirmed LM will be enrolled. The FORESEE trial's primary outcome measure will assess the impact of CNSide on treatment decisions. Assuming the results of the trial are favorable, we intend to pursue the inclusion of CNSide in the standard National Comprehensive Cancer Network (NCCN) guideline for diagnosis and monitoring of LM disease.

- Scale our sales and marketing capabilities in line with our clinical evidence development. At December 31, 2022, we had four sales representatives. In early January 2023, we implemented a restructuring plan in an effort to preserve our cash resources that resulted in a reduction in our workforce. This reduction in force eliminated our field-based sales force. Once we have adequate resources to do so, we will need to hire and develop a field-based sales force to educate physicians directly on the benefits of our assays and the clinical data supporting them. In addition, we are actively seeking commercial partnerships that can increase our market reach.
- Develop and expand our collaborations with leading university hospitals and research centers. We have collaborated with key thought leaders, physicians and clinical researchers across the country, including those at Sarah Cannon Research Institute, University of Colorado, Northwestern University Lurie Cancer Center, Stanford University, Penn State University, University of California, San Diego, St John's Cancer Institute at Santa Monica (formerly John Wayne Cancer Institute), Columbia University, Emory University, Johns Hopkins Medical Institute, University of Texas Southwestern Medical Center, Yale University, Ohio State University, Vanderbilt University, Georgetown University, Dana Farber Cancer Center, MD Anderson Cancer Center, and many others. Our collaborations enable us to conduct Institutional Review Board approved clinical studies, test new technologies, validate the effectiveness and utility of our planned future assays in a clinical setting and provide us access to clinically well-characterized and highly annotated patient data. These samples and data accelerate our validation process and facilitate the testing and refinement of our planned new assays.
- Become an enabling technology to neuro-oncology directed targeted therapies. Biopharmaceutical companies will increasingly focus on the personalized cancer diagnostic as the prevalence of molecularly targeted neuro-oncology therapies approved by the FDA increases, thus necessitating the need for companion diagnostics. As targeted therapies move into their next phase, the market is beginning to see next generation cancer drugs such as AstraZeneca's Tagrisso® (Osimertinib) approved for CNS indications. With these drugs, because of tumor heterogeneity, the molecular status of the tumor might change from the original tissue biopsy, so the patient must undergo a re-biopsy procedure so the current molecular profile of the patient can be assessed. In many cases, re-biopsy is not medically feasible and CSF-based assays that identify molecular targets may offer a more cost effective and safer alternative in this application. Another area of interest for the pharmaceutical industry is in immuno-oncology. Immunotherapies help the body counter the cancer cell's ability to evade the immune system. Several protein-based tests have been developed in tissue to work as complimentary or companion diagnostics to these new and promising drugs, but the use of these tests will be limited in CNS as a result of limitations with tissue biopsies in the CNS. Our solution is to test for these proteins with a CSF liquid biopsy-based test rather than relying on tissue biopsies.
- Continue to enhance our current and planned future CNSide assays and reduce the costs associated with providing them through internal research and development and partnering with leading technology developers and reagent suppliers. We intend to work closely with select key technology developers and suppliers to further automate the optical interpretation of our current assays and our planned additional CSF tumor assays, including enumeration, immunocytochemical biomarker staining and FISH. We utilize an automation system that significantly reduces the hands-on time of our cytogenetic technologists for microfluidic channel analysis while increasing the uniformity of the data we generate. This system is also expected to provide the ability to evaluate multiple fluorescent signals of different wavelengths simultaneously for multiplexed analysis, further enhancing efficiency.
- We envision building a valuable business franchise with our novel CNS-based diagnostic services by 1) aiding physicians who treat neurological cancers to better diagnose and manage their patients, 2) becoming the standard of care for numerous CNS cancer indications, and 3) ultimately leveraging these capabilities to enable better diagnosis, therapy selection, and therapy monitoring in other challenging cancers and diseases of the CNS.

Our Competitive Advantages

We believe that the competitive advantages of our molecular assays, including our assays which are still under development, would include the following.

- *Our current CNSide assays enable, and we anticipate our planned future CSF based assays will enable, detailed analysis of a patient's cancer utilizing a CSF sample, facilitating testing at any time, including when a biopsy is not available or inconclusive, offering real-time monitoring of the cancer and the response of the cancer therapy, and allowing medical oncologists, neuro-oncologists, radiation oncologists, surgical oncologists, pulmonologists, urologists, integrative oncologists, and pathologists and other physicians to select timely modifications to treatment regimens.* Because the tumor cells and ctDNA, we analyze are derived from the primary tumor or its metastases, they function as surrogates for the tumor, with the advantage of being readily accessible in a standard CSF sample. This is especially important in situations where a biopsy is not available or advised. The simplicity of obtaining a standard CSF sample permits repeat testing in a monitoring mode to detect recurrence or progression and to offer information on treatment modifications based on a current assessment of the cancer's properties. A significant advantage to using our services is the availability of our proprietary CEE-SureÔ CSF specimen collection and transport tube (SCT). The CEE-Sure tube enables 4-day, ambient condition shipping of CSF while maintaining cellular and ctDNA integrity for follow-on analysis. This is the enabling technology that provides us the ability to interrogate both tumor cell and ctDNA biomarker targets. We believe we are the only company with a validated CSF specimen collection and shipping container for this purpose.
- *Our current CNSide assays provide, and we anticipate our planned future assays will each provide, more information than competitors' existing tests, as a result of being able to provide biomarker results for both ctDNA and CSF tumor cells.* We anticipate that such additional biomarker information will better enable a physician to develop a personalized patient treatment plan. By including biomarker information in our analysis, in addition to tumor cell enumeration, our current assays and our planned future assays are designed to provide a more complete profile of a patient's disease than other existing cell-based or ctDNA only assays. We intend for our assays to contain actionable information to assist physicians in selecting appropriate therapies for individual patients.
- *Our current CNSide set of services and our planned future assays are designed to detect and characterize tumor cells in CSF better than other existing tests such as CSF cytology and to be applicable to, or quickly modifiable for, a wide range of cancer types.* Our antibody capture cocktail includes antibodies targeting not only the traditional epithelial CTC capture antigen, or EpCAM, utilized in the CellSearch® system and in other platforms, but also other epithelial antigens as well as mesenchymal and cancer stem cell antigens, indicative of cells having undergone the epithelial-to-mesenchymal transition. These cells may be more relevant for metastasis. Our detection methods include cellular staining for cytokeratin and other protein biomarkers with a broader range of applications than existing CTC tests. We believe that through our enhanced capture and staining, more tumor cells in CSF will be identified than by the CSF cytology alone, resulting in fewer non-informative cases and more information for physicians.
- *Our current and planned cell capture and ctDNA assays will be flexible and readily configurable to accommodate new biomarkers with clinical relevance as they are identified.* In theory, our platforms permit essentially any analysis that is currently performed on tumor tissue to be performed on CSF tumor cells, including immunocytochemical staining, FISH and molecular analysis. As new therapies are approved, and to the extent that they are targeted therapies for which knowledge of a particular gene amplification event, mutation or presence, absence or modification, such as phosphorylation, of a protein are indicative of likely response or resistance to that therapy, we will be able to include them in our assays with minimal changes. This is attractive to pharmaceutical and biotechnology companies that are developing such therapies or seeking ways to make their clinical trials more efficient, as this flexibility enables them to focus on patients more likely to respond to a particular therapy and demonstrate a benefit from that therapy.
- *Collaborative relationships with physicians including key opinion leaders at several nationally recognized health and research institutions and other leading strategic partners and accounts.* We have worked closely with dozens of physicians on various collaborative projects in different cancer types including breast, NSCLC, prostate, colorectal, ovarian, bladder and endometrial. These projects provide us access to leading researchers, clinicians and key opinion leaders, access to valuable patient samples and insight into clinical applications for our assays. Some of these projects have resulted in publications in leading journals, such as Cancer Discovery and Cancer Medicine, which enhances our standing in the oncology community and supports our marketing efforts.

Our Assays, Products and Services

Assays, Products and Services

We currently offer and conduct our commercialized diagnostic assays and offer our clinical trial services at our CLIA-certified, CAP-accredited and California state-licensed laboratory in San Diego, CA. We have commercialized our CNSide assays for detecting and characterizing many different carcinomas (including breast cancer, NSCLC, SCLC, gastric cancer, colorectal cancer, prostate cancer, pancreaticobiliary cancer, and ovarian cancer) and melanoma.

These assays utilize our dual cellular and ctDNA technology platforms and provide biomarker analysis from a patient's CSF sample.

Our current assays and clinical trial services include:

- *CSF tumor cell and ctDNA.* After completing testing, we or our partners provide our customers with an easy-to-understand report that describes the results of the analyses performed, which is designed to help medical oncologists, neuro-oncologists, surgical oncologists, radiation oncologists, urologists, pulmonologists, pathologists and other physicians make better decisions about the treatment of their patients. We introduced a CNSide specific report in 2021 and have improved this to include a serial report feature. Serial reporting enables clinicians to follow tumor cell count trends that assist with their assessment of treatment response.
- *Clinical Trial Services.* We plan to utilize our clinical laboratory and translational research capabilities to provide clinical trial and research services to pharmaceutical companies, biopharmaceutical companies and clinical research organizations to improve the efficiency and economic viability of their clinical studies. Our clinical studies and translational research services could leverage our knowledge of capturing CSF tumor cells and assaying CSF ctDNA and our ability to develop and implement new cytogenetic, immunocytochemical and molecular diagnostic assays. Our current assays can, and our other planned cancer diagnostic assays and biomarker assays are anticipated to be able to, help optimize clinical trial patient selection and/or monitor cancer drivers during the course of treatment or disease progression. Demonstration of clinical utility of our assays would more easily enable these tests to be adopted in standard clinical practice, helping physicians select the most appropriate therapy for their patients.

We analytically validated PD-L1 testing utilizing our cell capture and enumeration technology in 2016. PD-L1 is a biomarker that is informative for immuno-oncology therapies currently marketed for lung cancer and melanoma, as well as therapies in development for other tumor types. We collaborated with David Rimm, M.D., Ph.D., a pathologist at Yale Medical School and a scientific advisor to us, on the analytical development of this assay.

We intend to continue to commercialize CNS focused cancer diagnostic assays in the United States as LDTs performed in our CLIA-certified, CAP-accredited, and state-licensed laboratory. We plan to evaluate potential opportunities for the commercialization of our products in other countries.

In 2019, we announced the launch of the NGS lung cancer panel and the NGS breast cancer panel using the Thermo Fisher Oncomine platform. These two NGS panels are important offerings within our CNSide suite of services. We intend to gain payment for these assays with Palmetto GBA, LLC, or Palmetto, which is contracted with Centers for Medicare & Medicaid Services, or CMS, to administer the Molecular Diagnostic Services, or MolDX, to vet new technologies and assays. This means that we must demonstrate to them that our tests are reasonable and necessary for the care of patients diagnosed with LM subsequent to a diagnosis of primary NSCLC or breast cancer. This is a major step in gaining reimbursement for a proprietary test, and is a necessary step to establish coding and pricing for these services. Once that has been achieved, Noridian Healthcare Solutions, LLC, or Noridian, the Medicare carrier for our region, must review and accept the recommendation for payment from Palmetto. If they agree with the recommendation from Palmetto MolDX, then Noridian will adopt the payment and reimbursement recommendation or develop their own, and we can then receive payment from Medicare for our NGS panels. We intend to use the same MolDX pathway to gain reimbursement from CMS for the other portions of the CNSide suite of services that are not currently reimbursed – namely the cell capture and enumeration aspect of CNSide.

In April 2021, we announced the full commercial launch of our branded CNSide cerebrospinal fluid assay to address unmet needs of patients with metastatic brain cancer. The CNSide cerebrospinal fluid assay is designed to detect and manage treatment of metastatic cancers involving the CNS.

In June 2021, we announced a collaboration with Quest Diagnostics, or Quest to provide laboratory testing services to Quest patients using our Target Selector NGS-based liquid biopsy targeted lung cancer panel. Quest is the leading provider of diagnostic information services, including advanced diagnostics. Quest launched the test on December 15, 2021. We ended this relationship in January 2023 due to lack of orders from Quest.

In July 2021, we received a positive final Local Coverage Determination that expands Medicare coverage for use of our Target Selector assay to identify the HER2 biomarker from circulating tumor cells. This coverage determination from the CMS MolDX Program was effective July 4, 2021 and continues to be an important part of the CNSide suite of services.

Pharmaceutical, Research and Health Economic Collaborations

In October 2020, we announced results from a prospective study at the International Association for the Study of Lung Cancer (IASLC) comparing our CNSide testing service to conventional cytology in patients with NSCLC and LM showing that our CNSide testing may provide a more robust method for detecting lung cancer metastasis in CSF than the current standard of cytology analysis.

In November 2020 at the SNO annual meeting, we announced results of a study analyzing CSF samples in patients with primary lung or breast cancer with either brain or LM disease. The findings indicate that our CNSide assays are a viable and sensitive platform for CSF tumor cell detection and molecular analysis compared to the current standard of care, CSF cytology, which is typically used to establish or confirm LM disease when radiological imaging findings are suspicious or equivocal.

In December 2020, we announced results from a prospective study showing our tumor cell capture and enumeration technology - a key component of our CNSide suite of services - was highly accurate in monitoring HER2 alterations from blood specimens in patients with metastatic breast cancer. The results were featured in a poster presentation at the virtual 2020 SABCS.

In August 2021, in conjunction with the University of Utah, data was presented at the Society for Neuro-oncology (SNO) Brain Metastasis conference related to the use of CNSide on 15 unique non-small cell lung cancer cases.

In November 2021, in conjunction with Northwestern Medicine, Yale School of Medicine, the University of Texas Southwestern, and Barrow Neurological institute, data was presented at the SNO annual meeting in Boston on the experience of using CNSide for longitudinal therapy response monitoring in four unique breast cancer patients.

In December 2021, in a spotlight poster presentation at the SABCS, we presented our experience with genetic heterogeneity of HER2 in CSF tumor cells compared to that in the primary tumor evaluated in patients with breast cancer that had metastasized to the CNS.

In February 2022, at the Molecular TriConference for Precision Medicine in San Diego, we presented a brief summary of our collective experience evaluating CSF tumor cells for purposes of evaluating metastatic cancer involving the CNS to determine targets for therapy and quantify the response to treatment over time.

In April 2022, in conjunction with Saint John’s Health Center and Pacific Neuroscience Institute, data was presented at American Academy of Neurology annual meeting in Seattle on 64 patient specimens from five unique patients comparing tumor cell identification on CSF cytology vs. CNSide throughout the course of treatment.

In June 2022, Columbia University of Irving Medical Center published a prospective study among advanced or metastatic breast cancer patients in Clinical Breast Cancer and concluded that CNSide may be a viable platform to detect tumor cells in the CSF with use as a potential diagnostic for LM disease, reporting a sensitivity of 100% and a specificity of 83%.

In June 2022 we announced a collaboration with Plus Therapeutics for a multi-year agreement to employ Biocept’s CSF assay CNSide in Plus Therapeutics’ ReSPECT-LM Phase 1/2a dose-escalation clinical trial of Rhenium-186 NanoLiposome (186RNL) for the treatment of patients with leptomeningeal disease (LM).

In November 2022, in conjunction with 10 leading medical institutions, data was presented at the SNO annual meeting in Tampa regarding the genetic heterogeneity of HER2 amplification between the primary site and metastatic cells to the CNS, concluding that 38% of patients that were previously categorized as HER2 negative or equivocal demonstrated a population of HER2 amplified cells in their CSF specimen.

In November 2022, in conjunction with Saint John’s Health Center and Pacific Neuroscience Institute, data was presented at the SNO annual meeting on the cell capture of a primary brain tumor and a pineal tumor using a modified CNSide protocol. We intend to expand our services for CNSide testing to include additional tumor types that may benefit from CSF testing. These include tumors for which biopsy and/or resection is severely limited by anatomic location, such as those tumors seen arising in the midline of the brain, as well as tumors for which diffuse CSF involvement warrants a significant change in medical management, such as medulloblastoma and ependymoma.

Laboratory Testing

From our CLIA-certified laboratory in San Diego, California, we provide test results from our current and planned CNSide assays to medical oncologists, neuro-oncologists, surgical oncologists, radiation oncologists, urologists, pulmonologists, pathologists and other physicians in community hospitals, cancer centers, group practices and offices. At the federal level, clinical laboratories, such as ours, must be certified under CLIA in order for us to perform testing on human specimens. Our laboratory is also accredited by CAP, which is one of six accreditation organizations approved by CMS under CLIA. Our clinical laboratory is located in California and we hold the requisite license from the California Department of Public Health to operate our laboratory. In addition, we hold licenses issued by the states of Maryland, Pennsylvania and Rhode Island to test specimens from patients in those states or received from ordering physicians from those states. In addition, our clinical reference laboratory is required to be licensed on a product-specific basis by New York as an out of state laboratory and our products, as LDTs, must be approved by the New York State Department of Health before they are offered in New York. As part of this process, the State of New York requires validation of our assays. We currently do not have the necessary New York license, but we are in the process of addressing the requirements for licensure in New York. Our lab director holds a New York Certificate of Qualification applicable to the evaluation of tumor biomarkers.

Clinical Study Biomarker Testing Services

Industry research has revealed that many promising drugs have produced disappointing results in clinical trials. For example, a study by Princess Margaret Hospital in Toronto estimated that over a five-year study period 85% of the new therapies for solid tumors which were tested in early clinical trials in the United States, Europe and Japan failed, and that of those that survive through to Phase III trials, only a third will be approved. Given such a high failure rate of oncology drugs in clinical development, combined with constrained budgets for pharmaceutical and biopharmaceutical companies, there is a significant need for drug developers to utilize molecular diagnostics to help decrease these failure rates. For specific molecular-targeted therapeutics, the identification of appropriate biomarkers may help to optimize clinical trial patient selection and success rates by helping clinicians identify patients that are most likely to benefit from a therapy based on their individual genetic profile.

In addition to testing for physicians and their patients, we offer CNSide testing services to help increase the efficiency and economic viability of biomarker analysis pertinent to clinical trials conducted by pharmaceutical and biopharmaceutical companies and clinical research organizations focused on cancers of the CNS. Our testing services are aimed at developing customizable assays and techniques utilizing CSF cell capture and enumeration and ctDNA technologies to provide sensitive, real-time characterization of an individual patient’s tumors using a CSF sample. These assays may be useful as, and ultimately developed into, companion diagnostics associated with a specific therapeutic. Additionally, through our services, we may gain further insights into biomarkers for disease progression and drug resistance, as well as those associated with current drug development efforts, which we can incorporate into assays. To date we have one CNSide biopharmaceutical collaboration, with Plus Therapeutics.

Assay Development Process

Our CNSide suite of services were, and our planned additional tumor cell capture and enumeration and molecular assays are being, developed and validated in conjunction with leading academic and clinical research centers to ensure that the needs of the clinical community are being met with the latest research on key biomarkers that affect patient care. We utilize a research and validation process to help ensure that we are providing diagnostic, prognostic and predictive information that is clinically relevant and accurate. The timeframe for this process from design through development and market launch is dependent upon, among other things, the biomarkers in question having been discovered and validated before we incorporate them in an assay, the specific clinical claims we plan to pursue, and the availability of high-quality samples for validation. Our development protocol calls for us to monitor and review the process in four stages as detailed below:

- **Stage 1, Research**. We review known, validated biomarkers, preferably associated with a specific therapeutic or other high value treatment decision, and discuss with clinical collaborators and key thought leaders to characterize the opportunity, the specific clinical setting and the product profile of the candidate assay.
- **Stage 2, Assay Development**. We design the assay, which typically has two parts: efficient capture of tumor cells and/or isolation of ctDNA from the targeted cancer type and development of the biomarker assays that will be included. For example, the first part may involve modification of the antibody capture cocktail and the second could include development of specific mutation assays or testing of FISH probes. Assay development utilizes

contrived analytical samples, normal control specimens and ultimately clinical samples to assure performance. The assay development process includes defining the performance characteristics of the assay as well as developing standard protocols for our CLIA-certified, CAP accredited, and state-licensed laboratory, where the assay will ultimately be performed. This assessment includes such features as accuracy, precision (inter-assay, intra-assay, inter-operator, inter-instrument, etc.), sensitivity, and specificity.

- **Stage 3, Clinical Validation**. When the assay is performing as desired it undergoes a rigorous validation process which includes both analytical and clinical validation. Clinical accuracy is performed and validated against an orthogonal reference for that biomarker, which is typically tumor tissue analysis. Depending on the tumor type and specimen requirement, samples are collected from patients through collaborators, or in the case of molecular assays, from commercial sample banks, where clinical information on the patients, including outcomes, is already available. We create standard operating procedures, quality assurance and quality control measures to ensure reproducibility and high standards of quality.
- **Stage 4, Availability for Commercialization**. Upon the completion of clinical validation and before launch, we take several steps to prepare an assay for marketing as an LDT. We create standard operating procedures and quality assurance and quality control measures to ensure repeatability and high standards of quality. We train both our commercial and laboratory staff on the interpretation and use of the data. Licenses and approvals for our laboratory to perform or use LDTs have been obtained from the appropriate regulatory authorities, such as CMS, which oversees CLIA, and different state regulatory bodies.

We currently offer 14 CNSide panels that are available for clinical use that have completed all four stages of the development protocol. Other assays for both CSF tumor cells and CSF molecular testing are in earlier stages of development.

We may be required to seek FDA clearance or approval to expand the commercial use of assays to other laboratories and testing sites in the United States. We may also need to complete additional activities to submit each of these assays for regulatory clearance or approval before commercialization in each of the international markets where introduction is planned.

If the FDA finalizes its current draft guidance on a risk-based framework for regulation of LDTs, our process would also need to allow for obtaining FDA review, clearance or approval, as applicable, which would add delay, expense and risk to our current assay development process. In November 2016, the FDA put the process to review and issue this guidance on hold and has not yet provided further information as to when the process will move forward.

Translational/Clinical Research

In the course of our research and validation studies, we have processed and analyzed thousands of normal control and cancer patient samples. Tumor cells captured by Biocept's proprietary cell capture and enumeration system can be analyzed directly within the microfluidic channel, removing the need to re-deposit cells on a slide and thereby minimizing cell loss or damage. Furthermore, given the transparency of our microfluidic channel, captured cells can be immediately analyzed on a microscope. Together, these two important features allow for a very efficient process that is well suited for a LDT performed in a CLIA laboratory. The post-capture analyses directed towards evaluation of biomarkers, are particularly important and valuable to physicians and patients since they focus on actionable information related to therapy selection. We have performed several clinical research studies in collaboration with The University of Texas MD Anderson Cancer Center investigators involving various tumor types, including breast, ovarian, endometrial, lung, colorectal, bladder and prostate cancers during the development of our proprietary technology.

Clinical utility studies, which demonstrate the specific clinical setting in which a particular CNSide assay is used, and how to use the information generated for medical, specifically treatment-related, decision making is a key part of our strategy and research and development plan. Data resulting from such studies is critical not only in the sales and marketing process, but also for reimbursement, as many health plans and government payors now ask for peer-reviewed publications describing such studies and results before agreeing to coverage of a specific novel assay. This was a primary impetus for our investments in our FORESEE clinical study to evaluate the clinical utility of CNSide.

Sales and Marketing

On December 31, 2022, our sales organization consisted of 4 field sales personnel allocated to strategic geographies around the country that have high concentrations of cancer patients. In early January 2023 we announced a reduction in force that eliminated our field-based selling organization in an effort to conserve our cash resources. Once we have adequate resources to do so, we will need to hire and develop a field-based selling organization. Our sales and marketing efforts will be based on a five-part marketing strategy:

- work with neuro-oncologists, radiation oncologists, surgical oncologists, other physicians and group practices to educate them on the advantages and opportunities that CSF tumor cell and ctDNA assays provide for better information, allowing them to select the most appropriate therapy for their patients, and how and when these assays are most effectively used;
- build relationships with key opinion leaders in oncology, specifically in the cancer types for which we are offering or plan to offer assays, to educate and support oncologists and neuro-oncologists;
- collaborate with leading research universities and institutions that enable the validation of our new assays, as well as the generation of clinical utility data;
- partner with biopharmaceutical and pharmaceutical companies for clinical trial work focusing on CSF tumor cell and ctDNA testing and analysis; and
- add value for the payor community by delivering clinically actionable information and providing a cost-effective alternative to access clinically actionable information using a simple blood or CSF-based test.

We will also take advantage of customary marketing channels commonly used by the diagnostic and pharmaceutical industries, such as medical meetings, broad-based publication of our scientific and clinical data, and the internet. In addition, we provide easy-to-access information to our customers through our website and a data portal for physicians who wish to access test results electronically. Our customers value secure and easily accessible information in order to quickly review their patients' information and begin developing a treatment protocol.

Outside the United States

Outside the United States, where a central laboratory business model is less developed, we will evaluate opportunities with our existing and other partners for the conversion and/or development of our current and planned CSF tumor cell and ctDNA assays into test systems or IVDs, and related strategies to develop and serve such regional oncology markets. We also plan to sell our clinical trial services to biopharmaceutical companies and research organizations outside the United States.

We plan to cooperate with partners on accessing markets internationally. We plan for this to be accomplished either through partnerships with local groups and distributors or the development of test kits.

Competition

As a cancer diagnostics company focused on current and planned CNSide assays from standard patient CSF samples, we rely extensively on our ability to combine novel technology and biomarker information with high-quality, state-of-the art clinical laboratory testing. We believe that we compete principally on the basis of:

- our ability to utilize standard CSF samples, enabling frequent testing of patients through the course of their disease as well as, without a tissue biopsy, thereby reducing cost and trauma, saving time, and providing real-time information on the status of the tumor;
- our ability to include biomarker information in our analysis, in addition to CSF tumor cell enumeration, thereby providing a more complete profile of a patient's disease than existing standard of care cytology testing, radiological examinations and evaluation of patient signs and symptoms This clinically actionable information can assist physicians in selecting more personalized treatment plans for individual patients;
- our current and planned future CNSide service offerings' ability to capture and detect a broader range of tumor cell phenotypes than existing tests, and potentially at earlier stages of disease, resulting in fewer non-informative cases and more information for physicians. For example, our antibody capture cocktail targets not only EpCAM

but also other epithelial antigens as well as mesenchymal and cancer stem cell antigens, indicative of cells having undergone the epithelial-to-mesenchymal transition. These cells may be more relevant for metastasis;

- our ability to rapidly integrate new biomarkers, either validated in academic laboratories or of interest to pharmaceutical and biopharmaceutical companies in the context of their new therapies, into our current and planned future assays, facilitating the expansion of actionable information for medical oncologists, neuro-oncologists, surgical oncologists, radiation oncologists, urologists, pulmonologists, pathologists and other physicians; and
- our research and clinical collaborations with key academic and clinical study groups, which enhance our research and development resources and, by enhancing our standing in the oncology community, support our marketing efforts.

We believe that we compete favorably with respect to these factors that our continued success depends on our ability to:

- expand and enhance our current and planned CNSide service offerings to provide clinically meaningful information in additional cancers;
- work with clinicians to design and implement clinical studies that demonstrate the clinical utility of our products;
- continue to innovate and maintain scientifically advanced technology including development and regulatory approvals;
- successfully market and sell assays;
- continue to comply with regulatory guidelines and obtain appropriate regulatory approvals in the United States and abroad as applicable;
- continue to validate our pipeline of assays;
- conduct or collaborate with clinical utility studies to demonstrate the application and medical value of our assays;
- continue to seek to obtain positive coverage and reimbursement decisions from Medicare and private third-party payors;
- continue to enter into sales and marketing partnerships;
- maintain existing and enter into new research and clinical collaborations with key academic and clinical study groups;
- continue to attract and retain skilled scientific, clinical, laboratory, sales and marketing personnel;
- continue to participate in and gain clinical trial work through biopharma partnerships;
- receive payment for the testing we provide for patients;
- obtain patents or other protection for our technologies, assays and services; and
- obtain and maintain our clinical reference laboratory accreditations and licenses.

Our principal competition comes from established molecular diagnostic clinical testing services and products, used by medical oncologists, neuro-oncologists, surgical oncologists, radiation oncologists, urologists, pulmonologists, pathologists and other physicians, which are based on tumor tissue analysis. It may be difficult to change established clinical practices and behavior of medical oncologists, neuro-oncologists, surgical oncologists, radiation oncologists, urologists, pulmonologists, pathologists, and other physicians to get them to adopt the use of our CNSide suite of services, in their practices in conjunction with or instead of molecular diagnostic tests from tissue biopsies or other conventional methodologies including the current standard of care of cytology, radiological examination, and clinical evaluation of patient signs and symptoms.

CNSide services for CNS oncology applications represent a new area of science and medicine and we cannot predict what products or assays others will develop that may compete with or provide results similar or superior to the results we are able to achieve with the products or assays we develop.

We face competition from specialty oncology diagnostic companies that are conducting research and development to develop proprietary CTC or ctDNA based assays and assay test panels for use in genomic profiling and monitoring solid tumor cancers.

Competitors developing ctDNA based assays and assay panels include but are not limited to companies such as Guardant Health, Foundation Medicine, Tempus Laboratories, NeoGenomics, Invitae, Natera, Inivata and Biodesix. EPIC Sciences, Menarini Silicon Biosystems, Biofluidica and Angle PLC offer CTC-based assays. These companies, in addition to operating research and development laboratories, have established CLIA-certified testing laboratories and have developed LDTs that they market directly to oncologists and pathologists. A few of these companies, like Guardant Health and Foundation Medicine, have achieved FDA clearance for their proprietary laboratory tests.

There are a number of national and regional specialty diagnostic companies, such as Caris Life Sciences and CSI, which are focused on the oncology diagnostic market, who while not currently offering CTC or ctDNA assays are selling to oncologists and pathologists and could develop or offer ctDNA or CTC or assays. In addition, large laboratory services companies such as Quest and LabCorp which provide a broad array of cancer diagnostic assays and testing services could also offer CTC or ctDNA based clinical testing services.

There is currently limited competition for our CSF-based tumor cell capture and enumeration and ctDNA assays. There are no known specialty oncology diagnostic companies or large laboratory services companies that offer CSF-based tumor cell capture and enumeration and ctDNA tests for neuro-oncology applications as a standard commercial clinical testing service. A few academic based pathology labs such as Memorial Sloan Kettering Cancer Center offer CSF-based testing mainly for research purposes.

There are a number of companies which are focused on the oncology diagnostic market, who while not currently offering CTC or ctDNA assays are selling to the medical oncologists and pathologists and could develop or offer CTC or ctDNA assays focused on cancers of the CNS. Large laboratory services companies such as Quest and LabCorp provide more generalized cancer diagnostic assays and testing but could also offer a CTC or ctDNA assay service. Companies like Abbott, Danaher and others could develop equipment or reagents in the future as well. Currently, companies like Streck, Roche and Exact Sciences offer SCTs, and in the future, companies like Covidien, Beckton Dickinson, Thermo Fisher, and other large medical device companies may develop SCTs as well.

There are a number of life science technology companies that are focused on the oncology diagnostic market, such as Thermo Fisher Scientific, Illumina, Abbott Molecular, Bio-Rad, Sysmex, Qiagen, and Roche Diagnostics, that are selling equipment and reagents kits for ctDNA assays and assay panels. These companies compete with our ctDNA assay kit products and SCTs. Menarini Silicon Biosystems sells equipment and reagents kits for CTC assays. These companies market their products to specialty laboratories that offer testing for oncology applications, including national reference laboratories, regional laboratories and pathology laboratories that are part of academic medical centers and hospital systems. These laboratories may purchase these products and developed ctDNA and CTC based laboratory developed tests that are marketed to medical oncologists and pathologists that compete with our lab services.

Some of our present and potential competitors have widespread brand recognition and substantially greater financial and technical resources and development, production and marketing capabilities than we do. Others may develop lower-priced, less complex assays that payors, medical oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists and other physicians could view as functionally equivalent to our current or planned future assays, which could force us to lower the list price of our assays and impact our operating margins and our ability to achieve and maintain profitability. In addition, technological innovations that result in the creation of enhanced products or diagnostic tools that are more sensitive or specific or offer more content than our tests may enable other clinical laboratories, hospitals, physicians or medical providers to provide specialized products or diagnostic assays similar to ours in a more patient-friendly, efficient or cost-effective manner than is currently possible. If we cannot compete successfully against current or future competitors, we may be unable to increase or create market acceptance for sales of our current or planned future products or assays, which could prevent us from increasing or sustaining our revenues or achieving or sustaining profitability.

We expect that biopharmaceutical companies will increasingly focus resources on development of targeted oncology therapies that may require a companion diagnostic test approved by the FDA. We may face increasing competition from companies that offer CTC or ctDNA assays or products that are approved by the FDA as an IVD for companion diagnostic uses.

Additionally, projects related to cancer diagnostics and particularly genomics have received increased government funding, both in the United States and internationally. As more information regarding cancer genomics becomes available to the public, we anticipate that more products aimed at identifying targeted treatment options will be developed and that these products may compete with ours. In addition, competitors may develop their own versions of our current or planned future products or assays

in countries where we did not apply for patents or where our patents have not issued and compete with us in those countries, including encouraging the use of their product or assay by physicians or patients in other countries.

Third-Party Suppliers and Manufacturers

Some of the components used in our current or planned future products are currently sourced from a supplier for which alternative suppliers exist, but we have not validated the products of such alternative suppliers, and substitutes for these components might not be able to be obtained easily or may require substantial design or manufacturing modifications. Any significant problem experienced by any one of our suppliers may result in a delay or interruption in the supply of components to us until that supplier cures the problem or an alternative source of the component is located and qualified. Any delay or interruption would likely lead to a delay or interruption in our manufacturing operations. The inclusion of substitute components must meet our product specifications and could require us to qualify the new supplier with the appropriate government regulatory authorities.

Patents and Technology

The proprietary nature of, and protection for, our products, services, processes, and know-how are important to our business. Our success depends in part on our ability to protect the proprietary nature of our products, services, technology, and know-how, to operate without infringing on the proprietary rights of others, and to prevent others from infringing our proprietary rights. We seek patent protection in the United States and internationally for our products, services and other technology. Our policy is to patent or in-license the technology, inventions and improvements that we consider important to the development of our business.

We also rely on trade secrets, know-how, and continuing innovation to develop and maintain our competitive position. We cannot be certain that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents granted to us in the future will be commercially useful in protecting our technology.

Our success depends on an intellectual property portfolio that supports our future revenue streams and erects barriers to our competitors. We are maintaining and building our patent portfolio through filing new patent applications, prosecuting existing applications, and licensing and acquiring new patents and patent applications.

We have been issued patents with broad claims covering our CEE-Sure SCT, antibody cocktail approach, microchannel device, CTC detection methodologies, and ctDNA analysis. In addition to issued patents in the U.S., we have patents for our proprietary microchannel device in China, Europe, Hong Kong, Canada and Japan, and for our antibody cocktail in Australia, Europe, Canada, China, Hong Kong and Japan. Our patent estate continues to evolve, and in addition to the broad patent estate around our CTC platform, solidifying our proprietary enrichment methodology for detecting ctDNA with very high sensitivity. Our CTC platform patents were filed from 2005 through 2012, and we expect to have patent protection into the 2030s. Our CTC patents and applications cover not only cancer as a target, but also prenatal and other rare cells of interest. Recently granted patents in the U.S. cover the capture of any target of interest on any solid surface using our antibody capture approach. The patent for our proprietary SCTs expires in 2031, and the patents for our ctDNA technology expire in the early 2030s.

As of March 1, 2023, we owned 61 issued patents and have 4 patent applications pending. Of these, 14 were issued U.S. patents and three were pending patent applications in the U.S., and one was a pending PCT application, while 47 were issued patents in non-U.S. territories.

Operations and Production Facilities

Our research and development laboratory, our CLIA-certified, CAP accredited, and state-licensed diagnostic testing laboratory, and our manufacturing facility are located in our San Diego, California headquarters. The laboratories employ commercial state-of-the-art equipment as well as custom-made components specific to our CTC process that are generated in-house. The manufacturing facility used for the production of our microfluidic channels is a Class 10,000 suite in which polydimethylsiloxane, or PDMS, is formed into the base of our proprietary microfluidic channels in a molding process. A glass cover slip suitable for optical analysis is added to seal the channels and make them watertight. Plasma activation is utilized to bond the PDMS with other functional groups typically leaving an amine functional group for binding. The inside of the microfluidic channels is subsequently chemically derivatized to enable the attachment of binding elements that strongly bind

to antibody-tagged (fluorescently conjugated) CTCs or CSF tumor cells. Because the microfluidic channels have micrometer dimensions, and we are seeking individual cells in a blood sample to interact with the surface of the microfluidic channel, dust particles and other microscopic debris that could clog the channel need to be avoided. Humidity is also a factor that affects binding capability especially in the plasma activation step.

The process of performing our assays is straightforward. When a health care professional takes a standard venous blood sample or a CSF specimen from a lumbar puncture or Ommaya reservoir from a patient for CTC, CSF tumor cell, or ctDNA testing, he or she will place the sample in our SCTs, complete a requisition form, and package the specimen in our shipping kit for direct shipment to us. Once we receive the specimen at our laboratory and we enter all pertinent information about the specimen into our clinical laboratory information system, our laboratory technologists prepare the specimen for processing and analysis. Laboratory technologists, including clinical laboratory technologists and clinical laboratory scientists then conduct the analysis, including enumeration of tumor cells and biomarker analysis such as FISH. Usage of fluorescent tags enables colored imaging in this process to increase the biomarker analysis capability. The data, including images and the processed cells, are sent to our in-house or contracted pathologists or a commercialization partner's pathologists who are experienced in the analysis and evaluation requested by the referring oncologist or pathologist.

After analysis, our in-house or contracted pathologists or a commercialization partner's pathologists use laboratory information systems to prepare a comprehensive report, which may include selected relevant images associated with the specimen. Our Internet reporting portal allows a referring oncologist or pathologist to access his or her patient's test results in real time in a secure manner that we believe to be compliant with the Health Insurance Portability and Accountability Act, or HIPAA, and other applicable standards. The reports are generated in industry standard .pdf formats which allows for high-definition color images to be reproduced clearly. We send the results to the ordering physician and bill the payor using third-party medical billing software.

Quality Management Program

We have established a Quality Management Program for our research, development and CLIA certified testing laboratories. This program is designed to help ensure accurate and timely test results, to produce consistent high-quality testing services, as well as procedures which allow for the continual improvement of established and new operations. Our Quality Management Program foundation is built upon a rigorous documentation program which allows transparent quality assurance and performance improvement plans, necessary to ensure the highest quality of diagnostic testing services. This program is designed to satisfy the requirements of local and state licensures, as well as those for accreditation by CAP. The CAP accreditation program involves unannounced on-site inspections of our laboratories. CAP is an independent, non-governmental organization of board-certified pathologists that accredits laboratories nationwide on a voluntary basis and that has been recognized by the CMS as an accreditation organization to inspect laboratories to determine adherence to CLIA standards.

We are committed to providing reliable and accurate diagnostic testing to our customers. Accurate specimen sample management, timely communication of test results, and strict adherence to patient privacy policies are a critical core competency of our company. We monitor and improve our performance through our internal audit program, which investigates any abhorrent results, continually track performance indicators, perform internal proficiency testing and host external quality audits, primarily conducted by CAP.

In addition to the compulsory proficiency programs and external inspections required by CMS and other regulatory agencies, we have developed a variety of internal systems and procedures to emphasize, monitor and continuously improve the quality of our operations. We maintain internal quality controls by routinely processing specimens with known diagnoses in parallel with patient specimens. We also have an internally administered proficiency program for specimen testing.

Third-Party Payor Reimbursement

Revenues from our clinical laboratory testing are derived from several different sources. Depending on the billing arrangement, instructions of the ordering physician and applicable law, parties that reimburse us for our services include:

- third-party payors that provide coverage to the patient, such as an insurance company, a managed care organization or a governmental payor program;
- physicians or other authorized parties, such as hospitals or independent laboratories, that order the testing service or otherwise refer the services to us;

- patients in cases where the patient has no insurance, has insurance that partially covers and reimburses the testing, or owes a co-payment, co-insurance or deductible amount;
- collaboration partners; or
- biopharmaceutical companies, universities or researchers for clinical trial work.

We are reimbursed for two categories of testing, anatomic pathology, which includes cell staining such as immunocytochemical staining, or ICC, FISH, and immunofluorescence, and molecular pathology, which includes mutation analysis. Reimbursement under the Medicare program for the diagnostic services that we offer is based on either the Medicare Physician Fee Schedule, or PFS, or the Medicare Clinical Laboratory Fee Schedule, or CLFS, each of which is subject to geographic adjustments and is updated annually. Medical services provided to Medicare beneficiaries that require a degree of physician supervision, judgment or other physician involvement, such as pathology services, are generally reimbursed under the PFS, whereas clinical diagnostic laboratory tests are generally reimbursed under the CLFS. Some of the services that we provide are genetic and molecular testing, which are reimbursed as clinical diagnostic laboratory tests.

The cell capture and enumeration portion of our CNSide suite of services currently receives little to no reimbursement, depending on the payor and circumstances. We intend to gain payment for this aspect of CNSide with Palmetto GBA, LLC, or Palmetto, which is contracted with Centers for Medicare & Medicaid Services, or CMS, to administer the Molecular Diagnostic Services, or MolDX, to vet new technologies and assays. This means that we must demonstrate to them that our tests are reasonable and necessary for the care of patients diagnosed with LM subsequent to a diagnosis of primary NSCLC or breast cancer. This is a major step in gaining reimbursement for a proprietary test, and we and is a necessary step to establish coding and pricing for these services. Once that has been achieved, Noridian Healthcare Solutions, LLC, or Noridian, the Medicare carrier for our region, must review and accept the recommendation for payment from Palmetto. If they agree with the recommendation from Palmetto MolDX, then Noridian will adopt the payment and reimbursement recommendation or develop their own, and we can then receive payment from Medicare for our proprietary cell capture and enumeration technology.

Regardless of the applicable fee schedule, Medicare payment amounts are established for each Current Procedural Terminology, or CPT, code. In addition, under the CLFS, Medicare also sets a cap on the amount that it will pay for any individual assay. This cap, usually referred to as the National Limitation Amount, is set at a percentage of the median of all the contractor fee schedule amounts for each billing code.

Medicare also has policies that may limit when we can bill directly for our services and when we must instead bill another provider, such as a hospital. When the testing that we perform is done on a specimen that was collected while the patient was in the hospital, as either an inpatient or outpatient, we may be required to bill the hospital for clinical laboratory services and for the technical component of pathology services. Which party is to be billed depends primarily on whether the service was ordered at least 14 days after the patient's discharge from the hospital. Complying with these requirements is complex and time-consuming and may affect our ability to collect for our services. In addition, hospitals may refuse to pay our invoices or may demand pricing that negatively affects our profit margin. While we await MolDX reimbursement approval for certain aspects of our CNSide suite of services, we may require our hospital clients to sign lab service agreements with us so we may bill the hospital directly for portions of our CNSide service offerings which are not currently reimbursed.

Medicare generally requires a beneficiary to pay a 20% co-insurance amount for most services billed under the PFS. Medicare covers the remaining 80% in such circumstances. There is currently no patient co-payment or co-insurance amount applicable to testing billed under the CLFS. Patients often have supplemental insurance policies that cover the co-insurance amount for physician services.

Medicare has coverage policies that can be national or regional in scope. Coverage means that assay is approved as a benefit for Medicare beneficiaries. If there is no coverage, neither the supplier nor any other party, such as a reference laboratory, may receive reimbursement from Medicare for the service. There is currently no national coverage policy regarding the tumor cell capture and enumeration portion of our testing. Because our laboratory is in California, the regional Medicare Administrative Contractor, or MAC, for California is the relevant MAC for all our testing. The previous MAC for California, Palmetto, which is contracted with CMS to administer the MolDX program that sets guidelines for coding, coverage and reimbursement of molecular diagnostic assays, adopted a negative coverage policy for CTC enumeration in blood. The current MAC for California, Noridian Healthcare Solutions, LLC, is adopting the coverage policies from Palmetto. Therefore, the enumeration portion of our testing is not currently covered, and we will receive no payment from Medicare for this portion of the service unless and until the coverage policy is changed. We continue to receive orders for our traditional enumeration testing, which

counts disease burden, and therefore the enumeration testing receives no payment from Medicare based upon the existing coverage decision. The Tumor Cell enumeration counts disease burden, and although oncologists find the information valuable, it does not currently meet many of the medical necessity requirements of Medicare and the payors. We intend to pursue payment for the capture portion of our CNSide technology.

Reimbursement rates paid by private third-party payors can vary based on whether we are considered to be an "in-network" provider, a participating provider, a covered provider, an "out-of-network" provider or a non-participating provider. These definitions can vary among payors, but we are generally considered an "out-of-network" or non-participating provider by most private third-party payors. An in-network provider usually has a contract with the payor or benefits provider. This contract governs, among other things, service-level agreements and reimbursement rates. In certain instances, an insurance company may negotiate an in-network rate for our testing. An in-network provider may have rates that are lower per assay than those that are out-of-network, and that rate can vary widely. The rate varies based on the payor, the testing type and often the specifics of the patient's insurance plan. If a laboratory agrees to contract as an in-network provider, it generally expects to receive quicker payment and access to additional covered patients.

Billing and Billing Codes for Third-Party Payor Reimbursement

CPT codes are the main billing code set used by physicians, hospitals, laboratories and other health care professionals to report separately payable clinical laboratory and pathology services for reimbursement purposes. The CPT coding system is maintained and updated on an annual basis by the American Medical Association. We believe there are existing codes that describe nearly all the steps in our testing process. We currently use a combination of codes to bill for our testing and analysis.

In order to ensure our coding is compliant, we have engaged industry experts to provide guidance on the proper coding of our assays. These experts include consultants at Senergene Solutions, LLC, Codemap, LLC and ADVI Health, LLC. However, coding can be complex, and payors may require differing codes for a given assay to effect payment. Changes in coding and reimbursement could adversely impact our revenues going forward, or payors could request that we reimburse them for payments we have already received. There can be no guarantees that Medicare and other payors will establish new positive or adequate coverage policies or reimbursement rates, or not change existing positive coverage policies, in the future.

We are moving forward with plans to obtain reimbursement coverage for the capture components of our CNSide assays. For other tests, we are able to utilize existing CPT codes from the PFS and CLFS. For these established CPT codes (for example, the codes for molecular testing, FISH and ICC), positive coverage determinations have been adopted as part of national Medicare policy or under applicable Local Coverage Determinations. Specific codes for our assays, however, do not assure an adequate coverage policy or reimbursement rate. Please see the section entitled "Legislative and Regulatory Changes Impacting Clinical Laboratory Tests" for further discussion of certain legislative and regulatory changes to these billing codes and the anticipated impact on our business.

Coverage and Reimbursement for our Current Assays and our Planned Future Assays

Our Medicare Administrative Contractor has issued a negative coverage determination for the enumeration component of all CTC assays. We have received reimbursement for the enumeration component of our assays from some private payors, including major private third-party payors, based on submission of standard CPT codes. FISH, ICC and Molecular Testing CPT codes are the subject of positive coverage national or local Medicare determinations. We believe these codes can be used to bill for the analysis components of our current and planned future CSF tumor cell assays, however, CMS, Palmetto or Noridian could adopt specific negative coverage policies for CSF tumor cells or ctDNA analysis in the future.

Additionally, on March 16, 2018 CMS issued a final determination decision memo for Next-Generation Sequencing, or NGS, tests for Medicare Beneficiaries with Advanced Cancer (CAG-00450N). Under this final determination, NGS tests that gain FDA approval or clearance as a companion diagnostic will receive coverage, and the final determination of coverage for NGS tests that are LDTs will be left up to the local MAC. Currently, only two of our CLIA validated assays are NGS-based; however, we plan to offer additional NGS assays in the future. To gain coverage for those assays, we will need to apply to Palmetto, which is the MAC that evaluates and recommends payment coverage or denial for molecular testing in our jurisdiction.

We believe, based on research showing that approximately 54% of new cancers occur in persons age 65 and older and that almost all Americans age 65 and older are enrolled in Medicare that a substantial portion of the patients for whom we would expect to perform cancer diagnostic assays will have Medicare as their primary medical insurance. We cannot assure you that, even if our current and our planned future assays are otherwise successful, reimbursement for the currently Medicare-covered

portions of our current and our planned future assays would, without Medicare reimbursement for the enumeration portion, produce sufficient revenues to enable us to reach profitability and achieve our other commercial objectives.

Where there is a private or governmental third-party payor coverage policy in place, we bill the payor and the patient in accordance with the established policy. Where there is no coverage policy in place, we pursue reimbursement on a case-by-case basis. Our efforts in obtaining reimbursement based on individual claims, including pursuing appeals or reconsiderations of claims denials, could take a substantial amount of time, and bills may not be paid for many months, if at all. Furthermore, if a third-party payor denies coverage after final appeal, payment may not be received at all. We are working to decrease risks of nonpayment by implementing a revenue cycle management system.

We cannot predict whether, or under what circumstances, payors will reimburse for all components of our assays. Payment amounts can also vary across individual policies. Full or partial denial of coverage by payors, or reimbursement at inadequate levels, would have a material adverse impact on our business and on market acceptance of our assays.

Legislative and Regulatory Changes Impacting Clinical Laboratory Tests

From time to time, Congress has revised the Medicare statute and the formulas it establishes for both the CLFS, and the PFS. Annually, CMS releases the payment amounts under the Medicare fee schedules. The rates are important because they not only determine our reimbursement under Medicare, but those payment amounts are also often used as a basis for payment amounts set by other governmental and private third-party payors. For example, state Medicaid programs are prohibited from paying more than the Medicare fee schedule limit for clinical laboratory services furnished to Medicaid recipients.

In accordance with Section 1833 (h)(2)(A)(i) of the Social Security Act, the annual update to the CLFS for calendar year 2022 is 5.4% (see 42 CFR405.509(b)(1)). With respect to our diagnostic services for which we expect to be reimbursed under PFS, CMS issues a Final Rule on an annual basis. Since 2015, the PFS Final Rules have included both increases and decreases in certain relative value units and geographic adjustment factors used to determine reimbursement for a number of codes used in our current assays and our planned future assays. These codes describe services that we must perform in connection with our assays and we bill for these codes in connection with the services that we provide.

Additionally, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, enacted in March 2010, made a number of substantial changes in the way health care is financed by both governmental and private insurers.

Although some of these provisions may negatively impact payment rates for clinical laboratory tests, the ACA also extended coverage to over 30 million previously uninsured people, which resulted in an increase in the demand for certain diagnostic assays. There have been executive, judicial and congressional challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden Administration will impact the ACA.

Moreover, other legislative changes have been proposed and adopted since the ACA was enacted. The Protecting Access to Medicare Act of 2014, or PAMA, was signed to law, which, among other things, significantly altered the current payment methodology under the CLFS. Under the law, applicable clinical laboratories must report laboratory test payment data for each Medicare-covered clinical diagnostic laboratory test that it furnishes during the specified time period. The reported data must include the payment rate (reflecting all discounts, rebates, coupons and other price concessions) and the volume of each test that was paid by each private payor (including health insurance issuers, group health plans, Medicare Advantage plans and

Medicaid managed care organizations). Effective January 1, 2018, the Medicare payment rate for each clinical diagnostic laboratory test is equal to the weighted median amount for the test from the most recent data collection period. The payment rate applies to laboratory tests furnished by a hospital laboratory if the test is separately paid under the hospital outpatient prospective payment system. PAMA's reporting obligations began in 2017 and occur every three years thereafter (or annually in the case of advanced diagnostic laboratory tests). Reporting of payment data under PAMA for clinical diagnostic laboratory tests has been delayed on numerous occasions. Based on current law, between January 1, 2024 and March 31, 2024, applicable laboratories will be required to report on data collected during January 1, 2019 and June 30, 2019. This data will be utilized to determine 2025 to 2026 CLFS rates. In addition, CMS updated the statutory phase-in provisions such that the rates for clinical diagnostic laboratory tests in 2020 could not be reduced by more than 10% of the rates for 2019. Pursuant to the CARES Act, the statutory phase-in of payment reductions has been extended through 2024, with a 0% reduction cap for 2021-2023 and a 15% reduction cap for 2024 through 2026. The PAMA rate changes did not materially affect our payments beginning in 2018; however, we cannot predict how this may affect future payment in coming years. Also, under PAMA, CMS is required to adopt temporary billing codes to identify new tests and new advanced diagnostic laboratory tests that have been cleared or approved by the FDA. For an existing test that is cleared or approved by the FDA and for which Medicare payment is made as of April 1, 2014, CMS is required to assign a unique billing code if one has not already been assigned by the agency. In addition to assigning the code, CMS is required to publicly report payment for the tests. Further, under PAMA, CMS is required to adopt temporary billing codes to identify new tests and new advanced diagnostic laboratory tests that have been cleared or approved by the FDA.

Additionally, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers and suppliers of up to 2% per fiscal year, starting in 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2031 unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. In addition, the Middle-Class Tax Relief and Job Creation Act of 2012, or MCTRJCA, mandated an additional change in Medicare reimbursement for clinical laboratory tests. Congress is considering additional health reform measures as part of other reform initiatives.

On March 22, 2022, CMS ceased the HRSA COVID-19 Uninsured Program (UIP), which provided federal COVID-19 relief funding for uninsured individuals to receive testing and treatment for COVID-19.

Further, with respect to the Medicare program, Congress has proposed on several occasions to impose a 20% coinsurance charge on patients for clinical laboratory tests reimbursed under the CLFS, which would require us to bill patients for these amounts. Because of the relatively low reimbursement for many clinical laboratory tests, in the event that Congress were to ever enact such legislation, the cost of billing and collecting for these services would often exceed the amount actually received from the patient and effectively increase our costs of billing and collecting.

Some of our Medicare claims may be subject to policies issued by Palmetto and Noridian Healthcare Solutions, our former and current MACs for California, respectively. Palmetto has issued a Local Coverage Determination, whereby Palmetto will not cover many molecular diagnostic assays, such as the enumeration component of our current assays, unless the test is expressly included in a National Coverage Determination issued by CMS or a Local Coverage Determination or coverage article issued by Palmetto. Currently, laboratories may submit coverage determination requests to Palmetto for consideration and apply for a unique billing code for each assay (which is a separate process from the coverage determination). In the event that a non-coverage determination is issued, the laboratory must wait six months following the determination to submit a new request. Palmetto currently has a negative coverage determination for the enumeration component of CTC assays, but there is no such negative coverage determination for the analysis component of such CTC assays. Denial (or continuation of denial) of coverage for the enumeration component of our current and anticipated tumor cell assays by Palmetto or its successor MAC, Noridian Healthcare Solutions, which adopts coverage policies set by the MolDX program, or reimbursement at inadequate levels, would have a material adverse impact on our business and on market acceptance of our current assays and our planned future assays. Noridian Healthcare Solutions intends to follow, for CTC assays, the positive or negative coverage determinations which from time-to-time Palmetto makes as well as any coverage policy changes set by the MolDX program. On November 27, 2013, Palmetto denied our request for coverage for the enumeration/detection portion of our testing. We have not received any other indications to suggest that the negative coverage determination will be reversed. The Tumor Cell enumeration counts disease burden, and although oncologists find the information valuable, it does not currently meet many of the medical necessity requirements of Medicare and the payors. We intend to pursue payment for the capture portion of our CNSide technology.

Additionally, the Centers for Disease Control and Prevention, CMS and the Office of Civil Rights issued a final rule in February 2014 to amend both the HIPAA and CLIA regulations. The final rule amended the HIPAA privacy rule to remove the CLIA laboratory exceptions, and as a result, HIPAA-covered laboratories are now required to provide individuals, upon request, with access to their completed test reports. Similarly, the final rule amended CLIA to state that CLIA laboratories and CLIA-exempt laboratories may provide copies of the patient's completed rest reports that, using the laboratory's authentication process, can be identified as belonging to that patient.

Governmental Regulations

Clinical Laboratory Improvement Amendments of 1988 and State Regulation

As a provider of laboratory testing on human specimens for the purpose of diagnosis, prevention, or treatment, we are required to hold certain federal, state and local licenses, certifications and permits to conduct our business. In 1988, Congress enacted CLIA, which established quality standards for all laboratories providing testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. Our laboratory holds a CLIA certificate of accreditation from CAP, and is in good standing. As to state laws, we are required to meet certain laboratory licensing and other requirements. Our laboratory holds the required licenses from the applicable state agencies in which we operate. For more information on state licensing requirements, see the sections entitled see the section entitled "Governmental Regulations—California State Laboratory Licensing" and "Governmental Regulations—Other States' Laboratory Licensing."

Under CLIA, a laboratory is defined as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of, or assessment of health of human beings. CLIA also requires that we hold a certificate applicable to the complexity of the categories of testing we perform and that we comply with certain standards. CLIA further regulates virtually all clinical laboratories by requiring they comply with various operational, personnel, facilities administration, quality and proficiency testing requirements intended to ensure that their clinical laboratory testing services are accurate, reliable and timely. CLIA certification is also a prerequisite to be eligible to be reimbursed for services provided to state and federal health care program beneficiaries. CLIA is user-fee funded. Therefore, all costs of administering the program must be covered by the regulated facilities, including certification and survey costs.

We are subject to survey and inspection every two years to assess compliance with program standards and may be subject to additional unannounced inspections. Laboratories performing high-complexity testing are required to meet more stringent requirements than laboratories performing less complex tests. In addition, a laboratory like ours that is certified as "high complexity" under CLIA may obtain analyte-specific reagents, which are used to develop laboratory developed tests, or LDTs.

In addition to CLIA requirements, we must comply with the standards set by CAP, which accredits our laboratory. Under CMS requirements, accreditation by CAP is sufficient to satisfy the requirements of CLIA. Therefore, because we are accredited by CAP, we are deemed to also comply with CLIA. CLIA also provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and certain states have implemented their own more stringent laboratory regulatory schemes.

Federal, State and Foreign Fraud and Abuse Laws

A variety of federal and state laws prohibit fraud and abuse regarding the preparation and submissions of claims for services as well as avoiding unlawful inducements in our relations with those who may refer patients to our laboratory. These laws are interpreted broadly and enforced aggressively by various state and federal agencies, including CMS, the Department of Justice, the Office of Inspector General for the U.S. Department of Health and Human Services, or HHS, and various state agencies. In addition, the Medicare and Medicaid programs increasingly use a variety of contractors to review claims data and to identify improper payments as well as fraud and abuse. These contractors include Recovery Audit Contractors, Medicaid Integrity Contractors and Zone Program Integrity Contractors. In addition, CMS conducts Comprehensive Error Rate Testing audits, the purpose of which is to detect improper Medicare payments. In addition, many private insurers as well as other managed care organizations have their own internal auditing programs to ensure against any false claims being submitted. Any overpayments identified must be repaid unless a favorable decision is obtained on appeal. In some cases, these overpayments can be used as the basis for an extrapolation, by which the error rate is applied to a larger universe of claims, and which can result in even higher repayments.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, receiving, or providing remuneration, directly or indirectly, to induce or in return for either the referral of an individual, or the

furnishing, recommending, or arranging for the purchase, lease or order of any health care item or service reimbursable, in whole or in part, under a federal health care program. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, credit arrangements, payments of cash, ownership interests and providing anything at less than its fair market value. Recognizing that the federal Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the health care industry, the Office of Inspector General for HHS has issued a series of regulatory "safe harbors." These safe harbor regulations set forth certain requirements that, if met, will assure immunity from prosecution under the federal Anti-Kickback Statute. Although full compliance with these provisions protects against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued. For further discussion of the impact of federal and state health care fraud and abuse laws and regulations on our business, see the section entitled "Risk Factors—Regulatory Risks Relating to Our Business." We are subject to federal and state health care fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.

In addition, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created new federal civil and criminal penalties, regarding health care fraud and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing or attempting to execute a scheme to defraud any health care benefit program, including private third-party payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from federal health care programs, such as the Medicare and Medicaid programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from federal health care programs.

Another development affecting the health care industry is the increased enforcement of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "*qui tam*" provisions. The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government. The *qui tam* provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government and permit such individuals to share in any amounts paid by the entity to the government in fines or settlement. In addition, various states have enacted false claim laws analogous to the federal False Claims Act, and some of these state laws apply where a claim is submitted to any third-party payor. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus significant civil monetary penalties.

Further, the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA's reach extends beyond federal health care programs to include private insurance (i.e., it is an "all payor" statute). The full scope of such law is uncertain and is subject to a variety of interpretations.

Additionally, the civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. However, at this time, such reporting requirements do not extend to clinical laboratories such as ours.

Also, many states have laws similar to those listed above that may be broader in scope and may apply regardless of payor.

Additionally, in Europe various countries have adopted anti-bribery laws providing for severe consequences, in the form of criminal penalties and/or significant fines for individuals and/or companies committing a bribery offence. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation. For instance, in the United Kingdom, under the Bribery Act 2010, a bribery occurs when a person offers, gives or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions

or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the Bribery Act 2010. Under the new regime, an individual found in violation of the Bribery Act 2010 faces imprisonment of up to 10 years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

Despite our implementation of a robust healthcare compliance program, we may be subject, from time to time, to inspections, investigations, and other enforcement actions by governmental authorities. If we are found not to be in compliance with applicable laws or regulations, the applicable governmental authority can impose significant civil, criminal and administrative penalties, such as fines, delay, suspend, or revoke regulatory approvals, institute proceedings to recoupment of monies, impose marketing or operating restrictions, enjoin future violations, imprisonment, exclusion from government funded healthcare programs such as Medicare and Medicaid, integrity oversight and reporting obligations, and assess similar significant penalties against our officers or employees.

Physician Self-Referral Prohibitions

Under a federal law directed at "self-referral," commonly known as the "Stark Law", there are prohibitions, with certain exceptions, on Medicare and Medicaid payments for laboratory tests referred by physicians who personally, or through a family member, have a "financial relationship"—including an investment or ownership interest or a compensation arrangement—with the clinical laboratory performing the tests. Several Stark Law exceptions are relevant to arrangements involving clinical laboratories, including: (1) fair market value compensation for the provision of items or services; (2) payments by physicians to a laboratory for clinical laboratory services; (3) certain space and equipment rental arrangements that satisfy certain requirements, (4) personal services arrangements that satisfy certain requirements; and (v) ownership in certain publicly traded companies. The laboratory cannot submit claims to the Medicare Part B program for services furnished in violation of the Stark Law, and Medicaid reimbursements may be at risk as well. Penalties for violating the Stark Law include significant civil, criminal and administrative penalties, such as the return of funds received for all prohibited referrals, fines, civil monetary penalties exclusion from the federal health care programs integrity oversight and reporting obligations, and imprisonment. Many states have comparable laws that are not limited to Medicare and Medicaid referrals.

Corporate Practice of Medicine

A number of states, including California, do not allow business corporations to employ physicians to provide professional services to patients. This prohibition against the "corporate practice of medicine" is aimed at preventing corporations such as us from exercising control over the medical judgments or decisions of physicians in treating patients. The state licensure statutes and regulations and agency and court decisions that enumerate the specific corporate practice rules vary considerably from state to state and are enforced by both the courts and regulatory authorities, each with broad discretion. If regulatory authorities or other parties in any jurisdiction successfully assert that we are engaged in the unauthorized corporate practice of medicine, we could be required to restructure our contractual and other arrangements. In addition, violation of these laws may result in significant civil, criminal and administrative penalties, such as sanctions imposed against us and/or the professional through licensure proceedings, and exclusion from state and federal health care programs. However, it is important to note that laboratories may contract with physicians to act as medical directors for their company as long as none of the compensation is for professional services rendered to patients.

Direct Billing Laws and Other State Law Restrictions on Billing for Laboratory Services

Laws and regulations in certain states prohibit laboratories from billing physicians or other purchasers directly for testing that they order. Some of those laws and regulations apply only to anatomic pathology services while others extend to other types of testing. Some states may allow laboratories to bill physicians directly but may prohibit the physician (and, in some cases, other purchasers) from charging more than the purchase price for the services (or may allow only for the recovery of acquisition costs) or may require disclosure of certain information on the invoice. In some cases, and if not prohibited by law or regulation, we may bill physicians, hospitals and other laboratories directly for the services that they order. An increase in the number of states that impose similar restrictions could adversely affect us by encouraging physicians to perform laboratory services in-house or by causing physicians to refer services to other laboratories that are not subject to the same restrictions.

CMS promulgated in 2009, a revision to the regulation that prohibits the mark up of purchased diagnostic services 42 C.F.R. §414.50 (the "Anti-Markup Rule"). The Anti-Markup Rule prohibits a physician or other supplier from marking up the price paid for the technical or professional component of a diagnostic test that was ordered by the billing physician or supplier and which was performed by a physician who does not share a practice with the billing physician or supplier. The billing physician

is prohibited from billing the Medicare program an amount greater than the lesser of: (i) the performing supplier's net charge to the billing physician; (ii) the billing physician's actual charge; or (iii) the fee schedule amount for the test that would be allowed if the performing supplier billed directly.

Physician Licensing

A number of the states where specimens originate require that the physician interpreting those specimens for a primary diagnostic purpose be licensed by that particular state. Physicians who fail to comply with these licensure requirements could face fines or other penalties for practicing medicine without a license and we could be required to pay those fines on behalf of our pathologists or subject to liability under the federal False Claims Act and similar state laws if we bill for services furnished by unlicensed pathologists. We do not believe that the services our pathologists perform in overseeing CLIA laboratory operations or releasing results generated by our laboratory on behalf of referring physicians from other states who diagnose and treat patients with cancer under their care constitutes the practice of medicine in any state in which our pathologists are not licensed. Our physicians are licensed in the state of California where our CLIA laboratory is located and are engaged in the practice of laboratory medicine in California per requirements established by the California Department of Health Laboratory Field Services Office and evaluated by the College of American Pathologists, or CAP, which is a principal accrediting organization for laboratories around the world.

In addition, many states also prohibit the splitting or sharing of fees between physicians and non-physician entities. We do not believe that our contractual arrangements with physicians, physician group practices or hospitals will subject us to claims under such regulations. However, changes in the laws may necessitate modifications in our relationships with our clients.

California State Laboratory Licensing

Our laboratory is licensed and in good standing under the State of California Department of Public Health standards. Our current licenses permit us to receive specimens obtained in California.

California state laws and regulations also establish standards for the day-to-day operations of clinical laboratories, including physical facility requirements and equipment, quality control and proficiency testing requirements. If we are found to be out of compliance with California statutory or regulatory standards, we may be subject to suspension, restriction or revocation of our laboratory license or assessed civil money penalties. The operator of a noncompliant laboratory may also be found guilty of a misdemeanor under California law. A finding of noncompliance, therefore, may result in harm to our business.

Other States' Laboratory Licensing

Several states require the licensure of out-of-state laboratories that accept specimens from those states. We hold licenses from the states of Maryland, Pennsylvania and Rhode Island to test specimens from patients in those states or received from ordering physicians in those states. We are currently in the process of addressing the requirements for licensure in New York. We have engaged and have been in recurring communication with the New York State Department Of Health and we have now received their permission to provide CNSide in the state of New York, beyond the traditional 50-specimen limit, while we complete the licensing and permit process with them.

From time to time, other states may require out of state laboratories to obtain licensure in order to accept specimens from such states. If we identify any other state with such requirements or if we are contacted by any other state advising us of such requirements, we intend to follow instructions from the state regulators as to how we should comply with such requirements.

U.S. Food and Drug Administration

We perform our laboratory tests as LDTs. Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required laboratories that offer LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). In recent years, however, the FDA has stated it intends to end its policy of enforcement discretion and regulate certain LDTs as medical devices. To this end, on October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)", respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The FDA has indicated that it does not intend to modify its policy

of enforcement discretion until the draft guidance documents are finalized. In January 2017, the FDA announced that final guidance on the oversight of LDTs would allow for further public discussion. On January 13, 2017, the FDA issued a "Discussion Paper on Laboratory Developed Tests (LDTs)," which states that the material in the document does not represent a final version of the LDT draft guidance documents that were published in 2014 or position of the FDA; rather, the document is a method to encourage additional dialogue. The timing of when, if at all, the draft guidance documents will be finalized is unclear, and even then, the new regulatory requirements are proposed to be phased-in consistent with the schedule set forth in the guidance. Nevertheless, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time. LDTs with the same intended use as a cleared or approved companion diagnostic are defined in FDA's draft guidance as "high-risk LDTs (Class III medical devices)" for which premarket review would be first to occur.

Failure to comply with applicable FDA regulatory requirements may trigger a range of enforcement actions by the FDA including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of production, and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity.

Other Regulatory Requirements

Our laboratory is subject to federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste, including chemical, biological agents and compounds, blood and bone marrow samples and other human tissue. Typically, we use outside vendors who are contractually obligated to comply with applicable laws and regulations to dispose of such waste. These vendors are licensed or otherwise qualified to handle and dispose of such waste.

The Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for health care employers, including requirements to develop and implement programs to protect workers from exposure to blood-borne pathogens by preventing or minimizing any exposure through needle stick or similar penetrating injuries.

Compliance Program

The health care industry is highly regulated and scrutinized with respect to fraud, abusive billing practices and improper financial relationships between health care companies and their referral sources. The Office of the Inspector General of HHS, or OIG, has published compliance guidance, including the Compliance Program Guidance for Clinical Laboratories in August of 1998, and advisory opinions. The Company has implemented a robust Compliance Program, which is overseen by our Board of Directors. Its objective is to ensure compliance with the myriad of federal and state laws, regulations and governmental guidance applicable to our business. Our program consists of training/education of employees and monitoring and auditing Company practices. The Board of Directors has formed a Compliance Committee of the Board, which meets regularly to discuss all compliance-related issues that may affect the Company. The Company reviews its policies and procedures as new regulations and interpretations come to light to comply with applicable regulations. The Chief Compliance Officer reports directly to the Board of Directors.

Hotline

As part of its Compliance Program, the Company provides a hotline for employees who wish to anonymously or confidentially report suspected violations of our codes of conduct, policies/procedures, or laws and regulations. Employees are strongly encouraged to report any suspected violation if they do not feel the problem can be appropriately addressed through the normal chain of command. The hotline does not replace other resources available to our employees, including supervisors, managers and human resources staff, but is an alternative channel available. The hotline forwards all reports to the Chief Compliance Officer who is responsible for investigating, reporting to the Compliance Committee, and documenting the disposition of each report. The Chief Compliance Officer forwards any calls pertaining to the financial statements or financial issues to the Chairman of the Audit Committee. The Company does not allow any retaliation against an employee who reports a compliance related issue in good faith.

Confidentiality and Security of Personal Health Information

The Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA"), contains provisions that protect individually identifiable health information from unauthorized use or disclosure by "covered entities," such as certain healthcare providers, health plans, and healthcare clearinghouses and their respective "business associates," as well as their covered subcontractors, that perform services for them, which involve the creation, receipt, use, maintenance, transmission or

disclosure of, individually identifiable health information for or on behalf of a covered entity. The Office for Civil Rights of HHS, the agency responsible for enforcing HIPAA, has published regulations to address the privacy, or the Privacy Rule, and security, or the Security Rule, of protected health information, or PHI. The Company is a covered entity under HIPAA and has adopted policies and procedures to comply with the Privacy Rule and the Security Rule and HIPAA. The health care facilities and providers that refer specimens to the Company are also bound by HIPAA. HIPAA also requires that all providers who transmit claims for health care goods or services electronically utilize standard transaction and data sets and use standardized national provider identification codes. The Company endeavors to comply with HIPAA regulations, utilizes standard transaction data sets, and has obtained and implemented national provider identifiers, or NPIs, as the standard unique health identifier in filing and processing health care claims and other transactions.

The American Recovery and Reinvestment Act, or ARRA, enacted the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, which extends the scope of HIPAA to permit enforcement against business associates for a violation, establishes new requirements to notify the Office for Civil Rights of a breach of PHI, and allows the Attorneys General of the states to bring actions to enforce violations of HIPAA. Rules implementing various aspects of HIPAA are continuing to be promulgated. With respect to these rules, CMS requires all HIPAA-covered entities such as the Company to conduct electronic claim submissions and related electronic transactions under the HIPAA transaction standard called Version 5010.

In addition to the HIPAA Privacy Rule and Security Rule described above, the Company is subject to state laws regarding the handling and disclosure of patient records and patient health information. The HIPAA Privacy Rule and Security Rule regulations do not supersede state laws that may be more stringent; therefore, we are required to comply with both federal privacy and security regulations and varying state privacy and security laws and regulations. These laws vary widely. Penalties for violation include sanctions against a laboratory's licensure as well as civil or criminal penalties. Additionally, private individuals may have a right of action against the Company for a violation of a state's privacy laws. We endeavor to comply with current state laws regarding the confidentiality of health information and will continue to monitor new or changing state laws.

Employees

As of March 31, 2023 we had a total of 50 full-time employees, four of whom are engaged in full-time research and development activities and four of whom hold doctorate degrees, as well as two temporary employees. None of our employees are represented by a labor union.

Available Information

Our website address is www.biocept.com. We post links to our website to the following filings as soon as reasonably practicable after they are electronically filed with or furnished to the SEC: annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, and any amendments to those reports filed or furnished pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended. All such filings are available through our website free of charge. The SEC also maintains an internet site at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

Company Information

Our principal executive offices and our laboratory operations are located at 9955 Mesa Rim Road, San Diego, California 92121. Our telephone number is (858) 320-8200 and our website address is www.biocept.com. The information contained in, or that can be accessed through, our website is not incorporated into and is not part of this annual report. We were incorporated in California on May 12, 1997 and reincorporated as a Delaware corporation on July 30, 2013.

Item 1A. Risk Factors

An investment in our securities involves a high degree of risk. You should consider carefully the risks described below, together with all of the other information included in this Annual Report, as well as in our other filings with the SEC, in evaluating our business. If any of the following risks actually occur, our business, financial condition, operating results and future prospects could be materially and adversely affected. In that case, the trading price of our common stock may decline and you might lose all or part of your investment. The risks described below are not the only ones we face. Additional risks that we currently do not know about or that we currently believe to be immaterial may also impair our business, financial condition, operating

results and prospects. Certain statements below are forward-looking statements. For additional information, see the information included under the heading "Special Note Regarding Forward-Looking Statements."

Risks Relating to Our Financial Condition and Capital Requirements

We are a molecular oncology diagnostics company with a history of net losses; we expect to incur net losses in the future, and we may never achieve sustained profitability.

We have historically incurred substantial net losses, including a net loss of approximately $32.1 million for the year ended December 31, 2022. We experienced reduced demand for our COVID-19 testing services and stopped offering these services in February 2023. We will continue to incur net losses and negative cash flows from operations for the foreseeable future. At December 31, 2022, our accumulated deficit was approximately $298.4 million.

We expect our losses to continue as a result of costs relating to our laboratory operations as well as sales and marketing costs and research and development expenses. These losses have had, and will continue to have, an adverse effect on our working capital, total assets and stockholders' equity. Because of the numerous risks and uncertainties associated with our commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations and cash flows.

We need to raise additional capital to continue as a going concern.

We expect to continue to incur losses for the foreseeable future and will have to raise additional capital to fund our planned operations and to meet our long-term business objectives. We currently expect that our existing resources will only be sufficient to fund our planned operations and expenditures into the third quarter of 2023. Management intends to continue its efforts to contain costs and to raise additional capital until we can generate sufficient cash from commercial sales to support operations, if ever. Until we can generate significant cash from operations, including product and assay revenues, we expect to continue to fund our operations with the proceeds from offerings of our equity securities or debt, or transactions involving product development, technology licensing or collaboration. We can provide no assurances that any sources of a sufficient amount of financing will be available to us on favorable terms, if at all. General market conditions resulting from high inflation, high interest rates, global supply chain issues, the Russia-Ukraine conflict, COVID-19, bank failures, general economic uncertainty and other macroeconomic factors, as well as market conditions affecting companies in the life sciences industry in general, may make it difficult for us to obtain financing from the capital markets on attractive terms, or at all. Failure to raise additional capital in sufficient amounts when needed would significantly impact our ability to continue as a going concern. The actual amount of funds that we will need and the timing of any such investment will be determined by many factors, some of which are beyond our control. To fund our current and planned operations in the short- and long-term, we may seek to raise additional capital through public or private equity offerings, debt financings, borrowings or strategic partnerships coupled with an investment in our company or a combination thereof. If we raise additional funds through the issuance of convertible debt securities, or other debt securities, these securities could be secured and could have rights senior to those of our common stock. In addition, any new debt incurred by us could impose covenants that restrict our operations. The issuance of any new equity securities will also dilute the interest of our current stockholders. Given the risks associated with our business, including our unprofitable operating history and our ability or inability to develop additional assays, and the current volatility in the equity markets, additional capital may not be available when needed on acceptable terms, or at all. There is no assurance that we will be able to raise adequate funds when needed or on favorable terms. If adequate funds are not available when needed, we will need to delay, scale back or discontinue one or more product development programs, curtail our commercialization activities, significantly reduce expenses (through reductions in our workforce or otherwise), sell assets (potentially at a discount to their fair value or carrying value), enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop or commercialize independently, pursue an acquisition of our company at a price that may result in a significant loss on investment to our stockholders, file for bankruptcy, seek other protection from creditors, or liquidate all of our assets.

We expect to continue to incur significant expenses to develop and market products and diagnostic assays, which could make it difficult for us to achieve and sustain profitability.

In recent years, we have incurred significant costs in connection with the development of our products and diagnostic assays. For the years ended December 31, 2022 and 2021, our research and development expenses were $6.2 million and $5.0 million, respectively, and our sales and marketing expenses were $7.1 million and $8.3 million, respectively. We expect our expenses to be significantly more than our revenues for the foreseeable future and increase as we conduct studies of our current products, assays and services and our planned future products, assays and services, establish our sales and marketing organization, drive adoption of and reimbursement for our products and diagnostic assays and develop new products, assays and services. As a result, we will need to generate significant revenues in order to achieve sustained profitability.

We may undertake internal restructuring activities in the future that could result in disruptions to our business or otherwise materially harm our results of operations or financial condition.

From time to time we may undertake internal restructuring activities as we continue to evaluate and attempt to optimize our cost and operating structure in light of developments in our financial condition, business strategy and long-term operating plans. For example, we completed a reduction in our workforce in the first quarter of 2023, including our entire field-based salesforce. Subject to obtaining sufficient funding, we plan to hire and develop a field-based sales organization in the future as part of our long-term business strategy.

Any restructuring activities we undertake in the future may result in write-offs or other restructuring charges. There can be no assurance that any restructuring activities that we have undertaken or undertake in the future will achieve the cost savings, operating efficiencies or other benefits that we may initially expect. Restructuring activities may also result in a loss of continuity, accumulated knowledge and inefficiency during transitional periods and thereafter. In addition, internal restructurings can require a significant amount of time and focus from management and other employees, which may divert attention from commercial operations. If any internal restructuring activities we have undertaken or undertake in the future fail to achieve some or all of the expected benefits therefrom, our business, results of operations and financial condition could be materially and adversely affected.

Risks Relating to Our Business and Strategy

If we are unable to increase sales of our current products, assays and services or successfully develop and commercialize other products, assays and services, our revenues will be insufficient for us to achieve profitability.

We currently derive substantially all our revenues from sales of diagnostic assays. We began offering our assays through our Clinical Laboratory Improvement Amendments of 1988, or CLIA, certified CAP accredited, and state-licensed laboratory in 2014. Additionally, the sale of our proprietary SCTs commenced in June 2018, which allow for the intact transport of liquid biopsy samples for research use only, or RUO, from regions around the world. We are in varying stages of research and development for other products and diagnostic assays that we may offer. If we are unable to increase sales of our existing products and diagnostic assays or successfully develop and commercialize other products and diagnostic assays, we will not produce sufficient revenues to become profitable.

If we are unable to execute our sales and marketing strategy for our products and diagnostic assays and are unable to gain acceptance in the market, we may be unable to generate sufficient revenue to sustain our business.

We are an early-stage molecular oncology diagnostics company and have engaged in only limited sales and marketing activities for the diagnostic assays we currently offer through our CLIA-certified, CAP accredited, and state-licensed laboratory. Except for net income generated in the first quarter of 2021 as a result of our COVID-19 testing business, which we discontinued in February 2023, our revenue has been insufficient to fund operations.

Although we believe that our current assays and our planned future assays, our molecular kits as well as our blood and viral collection tube product, represent a promising commercial opportunity, our products or assays may never gain significant acceptance in the marketplace and therefore may never generate substantial revenue or profits for us. We will need to establish a market for our products and diagnostic assays and build that market through physician education, awareness programs and the publication of clinical trial results. Gaining acceptance in medical communities requires, among other things, publications in leading peer-reviewed journals of results from studies using our current products, assays and services and/or our planned future products, assays and services. The process of publication in leading medical journals is subject to a peer review process and peer reviewers may not consider the results of our studies sufficiently novel or worthy of publication. Failure to have our

studies published in peer-reviewed journals would limit the adoption of our current products, assays and services and our planned future products, assays and services.

Our ability to successfully market the products and diagnostic assays that we have developed, and may develop in the future, will depend on numerous factors, including:

- the success of our FORESEE clinical study to evaluate the clinical utility of CNSide in LM patients, and our ability to conduct clinical utility studies of CNSide or other assays in collaboration with key thought leaders to demonstrate their use and value in important medical decisions such as treatment selection;
- whether CNSide is included in NCCN treatment guidelines;
- whether private health insurers, government health programs and other third-party payors will adopt liquid biopsy-based assays, including CNSide, in their guidelines, or cover such diagnostic assays and, if so, whether they will adequately reimburse us.
- whether our partners vigorously support our offerings;
- whether healthcare providers believe such diagnostic assays provide clinical utility;
- whether the medical community accepts that such diagnostic assays are sufficiently sensitive and specific to be meaningful in-patient care and treatment decisions;
- our ability to continually source raw materials, SCTs, shipping kits and other products that we sell or consume in our manufacturing process that are of sufficient quality and supply;
- our ability to successfully hire and develop a field-based sales force in the future, and the success of any such sales force; and
- our ability to fund sales and marketing activities.

Failure to achieve widespread market acceptance of our current products, assays and services, as well as our planned future products, assays and services, would materially harm our business, financial condition and results of operations.

If we cannot develop products, assays and services to keep pace with rapid advances in technology, medicine and science, our operating results and competitive position could be harmed.

In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. Several new cancer drugs have been approved, and a number of new drugs in clinical development may increase patient survival time. There have also been advances in methods used to identify patients likely to benefit from these drugs based on analysis of biomarkers. We must continuously develop new products and diagnostic assays and enhance any existing products, assays and services to keep pace with evolving standards of care. Our current products, assays and services and our planned future products, assays and services could become obsolete unless we continually innovate and expand them to demonstrate benefit in the diagnosis, monitoring or prognosis of patients with neurological metastatic cancer. New cancer therapies typically have only a few years of clinical data associated with them, which limits our ability to develop products and diagnostic assays based on, for example, biomarker analysis related to the appearance or development of resistance to those therapies. If we cannot adequately demonstrate the applicability of our current products, assays and services and our planned future products, assays and services to new treatments, by incorporating important biomarker analysis, sales of our products, assays and services could decline, which would have a material adverse effect on our business, financial condition and results of operations.

If our current products, assays and services and our planned future products, assays and services do not continue to perform as expected, our operating results, reputation and business will suffer.

Our success depends on the market's confidence that we can continue to provide reliable, high-quality products and assay results. We believe that our customers are likely to be particularly sensitive to product or assay defects and errors. As a result, the failure of our current or planned future products or assays to perform as expected, including with respect to our ability to maintain the sensitivity, specificity, concordance or reproducibility of such assays, would significantly impair our reputation and the public image of our products and cancer assays, and we may be subject to legal claims arising from any defects or errors. This could also impact our ability to get paid or the amount we are paid.

If our sole laboratory facility becomes damaged or inoperable, or we are required to vacate the facility, our ability to sell and provide our products and diagnostic assays and pursue our research and development efforts may be jeopardized.

We currently derive our revenues from our diagnostic assays conducted in our CLIA-certified, CAP accredited, and state-licensed laboratory. We do not have any clinical reference laboratory facilities other than our facility in San Diego, California. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including fire, earthquake, flooding and power outages, which may render it difficult or impossible for us to sell our products or perform our diagnostic assays for some period of time. The inability to sell our current or planned future products, or to perform our current assays and our planned future assays, or the backlog of assays that could develop if our facility is inoperable for even a short period of time, may result in the loss of customers or harm to our reputation or relationships with scientific or clinical collaborators, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our facilities and the equipment we use to perform our research and development work could be costly and time-consuming to repair or replace.

The San Diego area periodically experiences serious fires and power outages and is considered to lie in an area with earthquake risk.

Additionally, a key component of our research and development process involves using biological samples as the basis for our diagnostic assay development. In some cases, these samples are difficult to obtain. If the parts of our current or future laboratory facility where we store these biological samples were damaged or compromised, our ability to pursue our research and development projects, as well as our reputation, could be jeopardized. We carry insurance for damage to our property and the disruption of our business, but this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

Further, if our current or future CLIA-certified, CAP accredited, and state-licensed laboratory becomes inoperable or unqualified in any way we may not be able to license or transfer our technology to another facility with the necessary qualifications, including state licensure and CLIA certification, under the scope of which our current assays and our planned future assays could be performed. Even if we find a facility with such qualifications to perform our assays, it may not be available to us on commercially reasonable terms.

Our business is subject to risks arising from pandemic and epidemic diseases

A pandemic or other public health epidemic, poses the risk that we or our employees, contractors, suppliers, courier delivery services and other partners may be prevented from conducting business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. The continued spread of an infectious disease and the measures taken by state and local governments could disrupt the supply chain of material needed for our assays, interrupt our ability to receive samples, impair our ability to perform or deliver the results from our tests, impede patient movement or interrupt healthcare services causing a decrease in test volumes, delay coverage decisions from Medicare and third party payors, delay ongoing and planned clinical trials involving our tests and have a material adverse effect on our business, financial condition and results of operations. The COVID-19 pandemic previously resulted in a number of restrictions to reduce the spread of the disease, including executive orders in California, and several other state and local orders across the country, which, among other things, directed individuals to shelter at their places of residence, directed schools, businesses and governmental agencies to cease non-essential operations at physical locations, prohibited certain non-essential gatherings, and ordered cessation of non-essential travel. The effects of state and local stay-at-home orders may disrupt our business and delay our development programs and regulatory timelines and negatively impact our commercial activities, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations due to a resurgence of COVID-19 or another health epidemic or pandemic could negatively impact our business, operating results and financial condition.

If we cannot compete successfully with our competitors, we may be unable to increase or sustain our revenues or achieve and sustain profitability.

Our principal competition comes from established molecular diagnostic clinical testing services and products, used by medical oncologists, neuro-oncologists, surgical oncologists, radiation oncologists, pulmonologists, pathologists and other physicians, which are based on tumor tissue analysis. It may be difficult to change established clinical practices and behavior of medical

oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists and other physicians to get them to adopt the use of our CSF-based tumor cell and ctDNA assays, in their practices in conjunction with current standard of care.

Liquid biopsy molecular tests based on tumor cell and ctDNA assays for oncology applications represent a new area of science and medicine and we cannot predict what products or assays others will develop that may compete with or provide results similar or superior to the results we are able to achieve with the products or assays we develop.

We face competition from specialty oncology diagnostic companies that are conducting research and development to develop proprietary CTC or ctDNA based assays and assay test panels for use in genomic profiling and monitoring solid tumor cancers. Competitors developing ctDNA based assays and assay panels include but are not limited to companies such as Guardant Health, Foundation Medicine, Tempus Laboratories, NeoGenomics, Invitae, Natera, Inivata and Biodesix. EPIC Sciences, Menarini Silicon Biosystems and Angle PLC offer CTC-based assays. These companies, in addition to operating research and development laboratories, have established CLIA-certified testing laboratories and have developed LDT (lab developed tests) that they market directly to oncologists and pathologists. A few of these companies, like Guardant Health, have achieved FDA clearance for their proprietary laboratory tests.

There are several national and regional specialty diagnostic companies, such as Caris Life Sciences and CSI, which are focused on the oncology diagnostic market, who while not currently offering CTC or ctDNA assays are selling to oncologists and pathologists and could develop or offer ctDNA or CTC or assays. In addition, large laboratory services companies such as Quest and LabCorp which provide a broad array of cancer diagnostic assays and testing services could also offer CTC or ctDNA based clinical testing services.

Another new area of science and medicine is tumor cell and ctDNA assays performed from CSF samples for neuro-oncology applications and there is currently limited competition for our CSF-based tumor cell and ctDNA assays. There are no known specialty oncology diagnostic companies or large laboratory services companies that offer CSF-based tumor cell and ctDNA tests for neuro-oncology applications as a standard commercial clinical testing service. A few academic based pathology labs such as Memorial Sloan Kettering Cancer Center offer CSF-based testing mainly for research and internal purposes.

Companies like Abbott, Danaher and others could develop equipment or reagents in the future as well. Currently, companies like Streck, Roche and Exact Sciences offer SCTs, and in the future, companies like Covidien, Beckton Dickinson, Thermo Fisher, and other large medical device companies may develop SCTs as well.

There are a number of life science technology companies that are focused on the oncology diagnostic market, such as Thermo Fisher Scientific, Illumina, Abbott Molecular, Bio-Rad, Sysmex, Qiagen, and Roche Diagnostics, that are selling equipment and reagents kits for ctDNA assays and assay panels. These companies compete with our ctDNA assay kit products and SCTs. Menarini Silicon Biosystems sells equipment and reagents kits for CTC assays. These companies market their products to specialty laboratories that offer molecular based testing for oncology applications, including national reference laboratory, regional laboratories and pathology laboratories that are part of academic medical centers and hospital systems. These laboratories may purchase these products and developed ctDNA and CTC based laboratory developed tests that are marketed to medical oncologists and pathologists that compete with our lab services.

Some of our present and potential competitors have widespread brand recognition and substantially greater financial and technical resources and development, production and marketing capabilities than we do. Others may develop lower-priced, less complex assays that payors, medical oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists and other physicians could view as functionally equivalent to our current or planned future assays, which could force us to lower the list price of our assays and impact our operating margins and our ability to achieve and maintain profitability. In addition, technological innovations that result in the creation of enhanced products or diagnostic tools that are more sensitive or specific or offer more content than ours may enable other clinical laboratories, hospitals, physicians or medical providers to provide specialized products or diagnostic assays similar to ours in a more patient-friendly, efficient or cost-effective manner than is currently possible. If we cannot compete successfully against current or future competitors, we may be unable to increase or create market acceptance and sales of our current or planned future products or assays, which could prevent us from increasing or sustaining our revenues or achieving or sustaining profitability.

We expect that biopharmaceutical companies will increasingly focus resources on development of targeted oncology therapies that may require a companion diagnostics test approved by the FDA. Biocept may face increasing competition from

companies that offer CTC or ctDNA assays or products that are approved by the FDA as an IVD for companion diagnostic uses.

Additionally, projects related to cancer diagnostics and particularly genomics have received increased government funding, both in the United States and internationally. As more information regarding cancer genomics becomes available to the public, we anticipate that more products aimed at identifying targeted treatment options will be developed and that these products may compete with ours. In addition, competitors may develop their own versions of our current or planned future products or assays in countries where we did not apply for patents or where our patents have not issued and compete with us in those countries, including encouraging the use of their product or assay by physicians or patients in other countries.

If medical oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists and other physicians decide not to order our current or planned future assays, or if laboratory supply distributors or their customers decide not to order our current or planned future products, we may be unable to generate sufficient revenue to sustain our business.

To generate demand for our current products, assays and services and our planned future products, assays and services, we will need to hire and develop a field-based sales organization to educate medical oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists, and other physicians and other health care professionals, as well as laboratory and medical equipment suppliers, on the clinical utility, benefits and value of the products, assays and services we provide through published papers, presentations at scientific conferences, educational programs and one-on-one education sessions by members of our sales force. In addition, we need to educate medical oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists and other physicians of our ability to obtain and maintain coverage and adequate reimbursement from third-party payors. We will need to hire additional commercial, scientific, technical and other personnel to support this process. Unless an adequate number of medical practitioners order our current assays and our planned future assays, or unless an adequate number of laboratory supply distributors order our current and planned future products, we will likely be unable to create demand in sufficient volume for us to achieve sustained profitability.

Clinical utility studies are important in demonstrating to both customers and payors an assay's clinical relevance and value. If we are unable to identify collaborators willing to work with us to conduct clinical utility studies, or the results of those studies do not demonstrate that an assay provides clinically meaningful information and value, commercial adoption of such assay may be slow, which would negatively impact our business.

Clinical utility studies, including the FORESEE trial for CNSide, show when and how to use a clinical test or assay and describe the particular clinical situations or settings in which it can be applied and the expected results. Clinical utility studies also show the impact of the test or assay results on patient care and management. Clinical utility studies are typically performed with collaborating oncologists or other physicians at medical centers and hospitals, analogous to a clinical trial, and generally result in peer-reviewed publications. Sales and marketing representatives use these publications to demonstrate to customers how to use a clinical test or assay, as well as why they should use it. These publications are also used with payors to obtain coverage for a test or assay, helping to assure there is appropriate reimbursement.

We need to conduct additional studies for our assays, increase assay adoption in the marketplace and obtain coverage and adequate reimbursement. Should we not be able to perform these studies, or should their results not provide clinically meaningful data and value for medical oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists and other physicians, adoption of our assays could be impaired, and we may not be able to obtain coverage and adequate reimbursement for them.

The loss of key members of our executive management team could adversely affect our business.

Our success in implementing our business strategy depends largely on the skills, experience and performance of key members of our executive management team and others in key management positions. The collective efforts of each member of the executive team and others working with them as a team are critical to us as we continue to develop our technologies, products, services, assays and research and development and sales programs. As a result of the difficulty in locating qualified new management, the loss or incapacity of existing members of our executive management team could adversely affect our operations. If we were to lose one or more of these key employees, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies and implementing our business strategy. Our executive management team each have employment agreements, however, the existence of an employment agreement does not guarantee

retention of members of our executive management team and we may not be able to retain those individuals for the duration of or beyond the end of their respective terms. We do not maintain “key person” life insurance on any of our employees.

In addition, we rely on collaborators, consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our collaborators, consultants and advisors are generally employed by employers other than us and may have commitments under agreements with other entities that may limit their availability to us.

The loss of a key employee, the failure of a key employee to perform in his or her current position or our inability to attract and retain skilled employees could result in our inability to continue to grow our business or to implement our business strategy.

There is a scarcity of experienced professionals in our industry. If we are not able to retain and recruit personnel with the requisite technical skills, we may be unable to successfully execute our business strategy.

The specialized nature of our industry results in an inherent scarcity of experienced personnel in the field. Our future success depends upon our ability to attract and retain highly skilled personnel, including scientific, technical, commercial, business, regulatory and administrative personnel, necessary to support our anticipated growth, develop our business and perform certain contractual obligations. Given the scarcity of professionals with the scientific knowledge that we require and the competition for qualified personnel among life science businesses, we may not succeed in attracting or retaining the personnel we require to continue and grow our operations.

Our failure to obtain sufficient funding and to attract, hire and retain a sufficient number of qualified sales professionals would hamper our ability to increase demand for our products and diagnostic assays, to expand geographically and to successfully commercialize any other products or assays we may develop.

To succeed in selling our products and diagnostic assays and any other products or assays that we develop, we intend to hire and develop a U.S. based field-based sales organization in the future, subject to obtaining sufficient funding to do so. We will seek to recruit sales representatives with extensive experience in oncology and established relationships with medical oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists, oncology nurses, and other physicians and hospital personnel, as well as laboratory supply distributors. To achieve our marketing and sales goals, we will need to build and develop a sales and commercial infrastructure. Sales professionals with the necessary technical and business qualifications are in high demand, and there is a risk that we may be unable to attract, hire and retain the number of sales professionals with the right qualifications, scientific backgrounds and relationships with decision-makers at potential customers needed to achieve our sales goals. We expect to face competition from other companies in our industry, some of whom are much larger than us and who can pay greater compensation and benefits than we can, in seeking to attract and retain qualified sales and marketing employees. If we are unable to hire and retain qualified sales and marketing personnel, our business will suffer.

Our dependence on commercialization partners for sales of products, assays and services could limit our success in realizing revenue growth.

We may seek to grow our business through the use of commercialization partners for the sales, marketing and commercialization of our current products, assays and services, as well as our planned future products, assays and services, and to do so we must enter into agreements with these partners to sell, market or commercialize our products, assays and services. These agreements may contain exclusivity provisions and generally cannot be terminated without cause during the term of the agreement. We may need to attract additional partners to expand the markets in which we sell products or assays. These partners may not commit the necessary resources to market and sell our products and diagnostics assays to the level of our expectations, and we may be unable to locate suitable alternatives should we terminate our agreement with such partners or if such partners terminate their agreement with us.

If future commercialization partners do not perform adequately, or we are unable to locate commercialization partners, we may not realize revenue growth.

We depend on third parties for the supply of samples and other biological materials that we use in our research and development efforts. If the costs of such samples and materials increase or our third-party suppliers terminate their relationship with us, our business may be materially harmed.

We have relationships with suppliers and institutions that provide us with samples and other biological materials that we use in developing and validating our current assays and our planned future assays. If one or more suppliers terminate their relationship with us or are unable to meet our requirements for samples, we will need to identify other third parties to provide us with blood samples and biological materials, which could result in a delay in our research and development activities and negatively affect our business. In addition, as we grow, our research and academic institution collaborators may seek additional financial contributions from us, which may negatively affect our results of operations. To the extent that the third parties supplying us with samples or other biological materials are impacted by COVID-19 or another health epidemic or pandemic or supply chain issues, our costs and availability of such supplies may be impacted.

We currently rely on third-party suppliers for our SCTs, shipping kits, and critical materials needed to perform our current assays, as well as our planned future products, assays and services, and any problems experienced by them could result in a delay or interruption of their supply to us.

We currently purchase our SCTs and raw materials for our microfluidic channels and assay reagents under purchase orders and do not have long-term contracts with most of the suppliers of these materials. If suppliers were to delay or stop producing our SCTs, shipping kits, materials or reagents, or if the prices they charge us were to increase significantly, or if they elected not to sell to us, we would need to identify other suppliers. We could experience delays in obtaining SCTs and shipping kits, manufacturing the microfluidic channels, or performing assays while finding another acceptable supplier, which could impact our results of operations. The changes could also result in increased costs associated with qualifying the new SCTs, shipping kits, materials or reagents and in increased operating costs. Further, any prolonged disruption in a supplier's operations could have a significant negative impact on our ability to perform diagnostic assays in a timely manner and sell our products. If our third-party suppliers' operations are impacted by COVID-19 or another health epidemic or pandemic or supply chain issues, we may experience supply delays or interruptions.

Some of the components used in our current or planned future products are currently sourced from a supplier for which alternative suppliers exist but we have not validated the products of such alternative suppliers, and substitutes for these components might not be able to be obtained easily or may require substantial design or manufacturing modifications. Any significant problem experienced by any one of our suppliers may result in a delay or interruption in the supply of components to us until that supplier cures the problem or an alternative source of the component is located and qualified. Any delay or interruption would likely lead to a delay or interruption in our manufacturing operations or product sales. The inclusion of substitute components must meet our product specifications and could require us to qualify the new supplier with the appropriate government regulatory authorities.

If we were sued for product liability or professional liability, we could face substantial liabilities that exceed our resources.

The marketing, sale and use of our products and current assays, as well our planned future products, assays and services, could lead to the filing of product liability claims against us if someone alleges that our products or assays failed to perform as designed. We may also be subject to liability for errors in the assay results we provide to physicians or for a misunderstanding of, or inappropriate reliance upon, the information we provide. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend.

Our insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could damage our reputation, result in the recall of products or assays, or cause current partners to terminate existing agreements and potential partners to seek other partners, any of which could impact our results of operations.

If we use biological and hazardous materials in a manner that causes injury, we could be liable for damages.

Our activities currently require the controlled use of potentially harmful biological materials and chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability

could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject to, on an ongoing basis, federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant and could have a material adverse effect on our financial condition, results of operations and cash flows. In the event of an accident or if we otherwise fail to comply with applicable regulations, we could lose our permits or approvals or be held liable for damages or penalized with fines.

We may acquire other businesses or form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of businesses and assets. We also may pursue strategic alliances and joint ventures that leverage our core technology and industry experience to expand our offerings or distribution. We have no experience with acquiring other companies and limited experience with forming strategic alliances and joint ventures. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

To finance any acquisitions or joint ventures, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

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If we cannot support demand for our current products, assays and services, as well as our planned future products, assays and services, including successfully managing the evolution of our laboratory service, our business could suffer.

As our product and assay volume grows, we will need to increase our assay capacity, implement automation, increase our scale and related processing, customer service, billing, collection and systems process improvements and expand our internal quality assurance program and technology to support assays on a larger scale. Examples of challenges we may face include, but are not limited to, maintaining the same validated sensitivity in our assays for both CTC and ctDNA analysis as our assay volume increases. We will also need additional clinical laboratory scientists and other scientific and technical personnel to process these additional assays. Any increases in scale, related improvements and quality assurance may not be successfully implemented and appropriate personnel may not be available. As additional products, assays and services are commercialized, we may need to bring new equipment online, implement new systems, technology, controls and procedures and hire personnel with different qualifications. Failure to implement or maintain necessary procedures or to hire the necessary personnel could result in a higher cost of processing or an inability to meet market demand. We cannot assure you that we will be able to perform assays on a timely basis, or procure SCTs, shipping kits or other materials we sell, at a level consistent with demand, that our efforts to scale our commercial operations will not negatively affect the quality of our assay results, or that we will respond successfully to the growing complexity of our operations. If we encounter difficulty meeting market demand or quality standards for our current products, assays and services and our planned future products, assays and services, including with respect to our assays our ability to maintain the sensitivity, specificity, concordance and reproducibility of such assays, our reputation could be harmed, and our future prospects and business could suffer, which may have a material adverse effect on our financial condition, results of operations and cash flows.

Billing for our diagnostic assays is complex, and we must dedicate substantial time and resources to the billing process to be paid.

Billing for clinical laboratory assay services is complex, time-consuming and expensive. Depending on the billing arrangement and applicable law, we bill various payors, including Medicare, insurance companies and patients, all of which have different

billing requirements. We generally bill third-party payors for our diagnostic assays and pursue reimbursement on a case-by-case basis where pricing contracts are not in place. To the extent laws or contracts require us to bill patient co-payments or co-insurance, we must also comply with these requirements. We may also face increased risk in our collection efforts, including potential write-offs of doubtful accounts and long collection cycles, which could adversely affect our business, results of operations and financial condition.

Several factors make the billing process complex, including:

- differences between the list price for our assays and the reimbursement rates of payors;
- compliance with complex federal and state regulations related to billing Medicare;
- risk of government audits related to billing Medicare;
- disputes among payors as to which party is responsible for payment;
- differences in coverage and in information and billing requirements among payors, including the need for prior authorization and/or advanced notification;
- the effect of patient co-payments or co-insurance;
- changes to billing codes and/or coverage policies that apply to our assays;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

We use standard industry billing codes, known as Current Procedural Terminology, or CPT, codes, to bill for our diagnostic assays. These codes can change over time. When codes change, there is a risk of an error being made in the claim adjudication process. These errors can occur with claims submission, third-party transmission or in the processing of the claim by the payor. Claim adjudication errors may result in a delay in payment processing or a reduction in the amount of the payment received. Coding changes, therefore, may have an adverse effect on our revenues. There can be no assurance that payors will recognize these codes in a timely manner or that the process of transitioning to such a code and updating their billing systems and ours will not result in errors, delays in payments and a related increase in accounts receivable balances.

As we introduce new assays, we will need to add new codes to our billing process as well as our financial reporting systems. Failure or delays in effecting these changes in external billing and internal systems and processes could negatively affect our collection rates, revenue and cost of collecting.

Additionally, our billing activities require us to implement compliance procedures and oversight, train and monitor our employees, challenge coverage and payment denials, assist patients in appealing claims, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. Payors also conduct external audits to evaluate payments, which add further complexity to the billing process. If the payor makes an overpayment determination, there is a risk that we may be required to return some portion of prior payments we have received. These billing complexities, and the related uncertainty in obtaining payment for our assays, could negatively affect our revenue and cash flow, our ability to achieve profitability, and the consistency and comparability of our results of operations.

We rely on third-party billing provider software, and an in-house billing function, to transmit claims to payors, and any delay in transmitting claims could have an adverse effect on our revenue.

While we manage the overall processing of claims, we rely on third-party billing provider software to transmit the actual claims to payors based on the specific payor billing format. We have previously experienced delays in claims processing when our third-party provider made changes to its invoicing system. Additionally, coding for diagnostic assays may change, and such changes may cause short-term billing errors that may take significant time to resolve. If claims are not submitted to payors on a timely basis or are erroneously submitted, or if we are required to switch to a different software provider to handle claim submissions, we may experience delays in our ability to process these claims and receipt of payments from payors, or possibly denial of claims for lack of timely submission, which would have an adverse effect on our revenue and our business.

We may encounter manufacturing problems or delays that could result in lost revenue.

We currently manufacture our proprietary microfluidic channels at our San Diego facility and intend to continue to do so. We believe we currently have adequate manufacturing capacity for our microfluidic channels. If demand for our current products, assays and services and our planned future products, assays and services increases significantly, we will need to either expand our manufacturing capabilities or outsource to other manufacturers. If we or third-party manufacturers engaged by us fail to manufacture and deliver our microfluidic channels or certain reagents in a timely manner, our relationships with our customers could be seriously harmed. We cannot assure you that manufacturing, or quality control problems will not arise as we attempt to increase the production of our microfluidic channels or reagents or that we can increase our manufacturing capabilities and maintain quality control in a timely manner or at commercially reasonable costs. If we cannot manufacture our microfluidic channels consistently on a timely basis because of these or other factors, it could have a significant negative impact on our ability to perform assays and generate revenues. We may encounter supply chain constraints in obtaining the raw materials needed to manufacture our products for a variety of reasons, including events outside of our control such as COVID-19, or another health epidemic or pandemic and geopolitical events.

International expansion of our business would expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

As part of our long-term business strategy, we may pursue international expansion, including partnering with academic and commercial testing laboratories, and introducing our technology outside the United States as part of in vitro diagnostic, or IVD, test kits and/or testing systems utilizing our technologies. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain regulatory approvals for the sale or use of our current products or assays and our planned future products or assays in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing government payor systems, multiple payor-reimbursement regimes or self-pay systems;
- logistics and regulations associated with shipping blood samples, including infrastructure conditions and transportation delays;
- limits on our ability to penetrate international markets if our current products or assays and our planned future products or assays cannot be processed by an appropriately qualified local laboratory;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights, or lack of them in certain jurisdictions, forcing more reliance on our trade secrets, if available;
- natural disasters, political and economic instability, including wars, invasions, other military actions, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, by maintaining accurate information and control over sales activities and distributors' activities.

Any of these risks, if encountered, could significantly harm our future international expansion and operations and consequently, have a material adverse effect on our financial condition, results of operations and cash flows.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including, without limitation, regulatory investigations or actions, litigation, interruption to our operations, harm to our reputation, fines, penalties, liability, or a loss of revenues, customers or sales, or other adverse consequences.

In the ordinary course of our business, we may process proprietary, confidential and sensitive information, personal data (including health information), intellectual property, trade secrets, and other sensitive business information owned or controlled by ourselves or other parties (collectively, sensitive information).

Despite the implementation of security measures, we and the third parties upon whom we rely (including the Internet and related systems) face a variety of evolving threats related to sensitive information, including without limitation ransomware attacks, which could cause security incidents. Cyberattacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel misconduct or error, employee theft or misuse, sophisticated nation-state and nation-state supported actors. Some actors now engage and are expected to continue to engage in cyberattacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyberattacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products

We and the third parties upon whom we rely are subject to a variety of evolving threats, including but not limited to social engineering attacks (including through phishing attacks), software bugs, malicious code (such as viruses and worms), denial-of-service attacks (such as credential stuffing), ransomware attacks, supply chain attacks, malware installation (including as a result of advanced persistent threat intrusions), server malfunction, software or hardware failures, loss of data or other computer assets, adware, physical break-ins, fires, telecommunications or network failures, malicious human acts, natural disasters, or other similar issues. Ransomware attacks, including those from organized criminal threat actors, nation-states, and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, disruption of clinical trials, loss of sensitive information (including data related to clinical trials), loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the financial, operational and reputational impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments).

In addition, we rely upon third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including without limitation, assay processing, sample tracking, quality control, customer service and support, billing and reimbursement, research and development activities and our general and administrative activities. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive sensitive information with or from third parties. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. Similarly, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our platform, systems and networks or the systems and networks of third parties that support us and our services. Despite the security controls we have in place, such attacks are very difficult to avoid.

Any of the aforementioned threats and other similar attacks, disruptions or accidents could cause a security incident, which, in turn, could result in unauthorized access to, damage to, disablement or encryption of, use or misuse of, disclosure of, modification of, destruction of, or loss of our sensitive information, or disrupt our ability to provide our platform or our service providers' ability to support our services or develop or deliver our products. We may expend significant resources, fundamentally change our business activities and practices, or modify our operations in an effort to protect against security incidents and to mitigate, detect and address actual and potential vulnerabilities. Certain data privacy and security obligations may require us to implement and maintain specific, industry-standard or reasonable security measures to protect our information technology systems and sensitive information. Despite the precautionary measures we have taken to try to prevent a security incident, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Despite our efforts to identify and address vulnerabilities, if any, in our information technology systems, our efforts may not be successful. These vulnerabilities pose risk to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure of any security incident or the failure to comply with such requirements could lead to adverse consequences. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business, such as preventing us from processing assays; providing assay results to medical oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists, and other physicians; billing payors; processing reimbursement appeals; handling patient or physician inquiries; conducting research and development activities and managing the administrative aspects of our business.

Furthermore, if we or any third party upon whom we rely experience a security incident, or are perceived to have experienced a security incident, it could result in: government enforcement actions that could include investigations, fines, penalties, audits and inspections; additional reporting requirements and/or oversight; restrictions on processing personal data or sensitive information (which could impact our ability to conduct tests or develop our products); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business.

Furthermore, there can be no assurance that our contracts contain limitations of liability, and even where they do, such limitations may not be enforceable, adequate or otherwise protect us from liabilities or damages if we fail to comply with obligations related to security incidents. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

Regulatory and Reimbursement Risks Relating to Our Business

Healthcare policy changes, including recently enacted legislation reforming the U.S. health care system, may have a material adverse effect on our financial condition, results of operations and cash flows.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, enacted in March 2010, made a number of substantial changes in the way health care is financed by both governmental and private insurers.

Although some of these provisions may negatively impact payment rates for clinical laboratory tests, the ACA also extends coverage to over 30 million previously uninsured people, which resulted in an increase in the demand for our current assays and our planned future assays. There have been executive, judicial and congressional challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. The Protecting Access to Medicare Act of 2014, or PAMA, was signed to law, which, among other things, significantly altered the current payment methodology under the Medicare Clinical Laboratory Fee Schedule, or CLFS. Beginning in 2017 and every three years

thereafter (or annually in the case of advanced diagnostic laboratory tests), applicable clinical laboratories must report laboratory test payment data for each Medicare-covered clinical diagnostic laboratory test that it furnishes during the specified time period. The reported data must include the payment rate (reflecting all discounts, rebates, coupons and other price concessions) and the volume of each test that was paid by each private payor (including health insurance issuers, group health plans, Medicare Advantage plans and Medicaid managed care organizations). Effective January 1, 2018, the Medicare payment rate for each clinical diagnostic laboratory test is equal to the weighted median amount for the test from the most recent data collection period. The payment rate applies to laboratory tests furnished by a hospital laboratory if the test is separately paid under the hospital outpatient prospective payment system. The PAMA rate changes did not materially affect our payments beginning in 2018; however, we cannot predict how this may affect future payment in coming years. Reporting of payment data under PAMA for clinical diagnostic laboratory tests has been delayed on numerous occasions. Based on current law, between January 1, 2024 and March 31, 2024, applicable laboratories will be required to report on data collected during January 1, 2019 and June 30, 2019. This data will be utilized to determine 2025 to 2026 CLFS rates. In addition, CMS updated the statutory phase-in provisions such that the rates for clinical diagnostic laboratory tests in 2020 could not be reduced by more than 10% of the rates for 2019. Pursuant to the CARES Act, the statutory phase-in of the payment reductions has been extended through 2024, with a 0% reduction cap for 2021-2022 and a 15% reduction cap for 2024 through 2026.. It is unclear what impact new quality and payment programs or new pricing structures, such as those adopted under PAMA, may have on our business, financial condition, results of operations, or cash flows.

Also, under PAMA, CMS is required to adopt temporary billing codes to identify new tests and new advanced diagnostic laboratory tests that have been cleared or approved by the FDA. For an existing test that is cleared or approved by the FDA and for which Medicare payment is made as of April 1, 2014, CMS is required to assign a unique billing code if one has not already been assigned by the agency. In addition to assigning the code, CMS is required to publicly report payment for the tests. Further, under PAMA, CMS is required to adopt temporary billing codes to identify new tests and new advanced diagnostic laboratory tests that have been cleared or approved by the FDA. We cannot determine at this time the full impact of PAMA, including its implementing regulations, on our business, financial condition and results of operations.

Additionally, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers and suppliers of up to 2% per fiscal year, starting in 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2031 unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. The full impact on our business the sequester law is uncertain. In addition, the Middle-Class Tax Relief and Job Creation Act of 2012, or MCTRJCA, mandated an additional change in Medicare reimbursement for clinical laboratory tests. In addition, Congress is considering additional health reform measures as part of other reform initiatives.

Some of our laboratory assay business is subject to the Medicare Physician Fee Schedule and, under the current statutory formula, the rates for these services are updated annually. For the past several years, the application of the statutory formula would have resulted in substantial payment reductions if Congress failed to intervene. In the past, Congress passed interim legislation to prevent the decreases. If Congress fails to intervene to prevent the negative update factor in future years, the resulting decrease in payment may adversely affect our revenue and results of operations. If in future years Congress does not adopt interim legislation to block or offset, and/or CMS does not moderate, any substantial CMS-proposed reimbursement reductions, the resulting decrease in payments from Medicare could adversely impact our revenues and results of operations.

We cannot predict whether future health care initiatives will be implemented at the federal or state level. For example, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. The expansion of government’s role in the U.S. health care industry, and changes to the reimbursement amounts paid by Medicare and other payors for our current assays and our planned future assays, may reduce our profits, if any, and have a materially adverse effect on our business, financial condition, results of operations and cash flows. Moreover, Congress has proposed on several occasions to impose a 20% coinsurance payment requirement on patients for clinical laboratory tests reimbursed under the CLFS, which would require us to bill patients for these amounts. In the event that Congress were to ever enact such legislation, the cost of billing and collecting for our assays could often exceed the amount actually received from the patient.

Our commercial success could be compromised if hospitals or other clients do not pay our invoices or if third-party payors, including managed care organizations and Medicare, do not provide coverage and reimbursement, breach, rescind or modify their contracts or reimbursement policies or delay payments for our current assays and our planned future assays.

Medical oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists and other physicians may not order our current assays and our planned future assays unless third-party payors, such as managed care organizations and government payors (e.g., Medicare and Medicaid), pay a substantial portion of the assay price. Coverage and reimbursement by a third-party payor may depend on a number of factors, including a payor's determination that assays using our technologies are:

- not experimental or investigational;
- medically necessary;
- appropriate for the specific patient;
- cost-effective;
- supported by peer-reviewed publications; and
- included in clinical practice guidelines.

Uncertainty surrounds third-party payor coverage and adequate reimbursement of any test incorporating new technology, including tests developed using our technologies. Technology assessments of new medical tests conducted by research centers and other entities may be disseminated to interested parties for informational purposes. Third-party payors and health care providers may use such technology assessments as grounds to deny coverage for a test or procedure. Technology assessments can include evaluation of clinical utility studies, which define how a test is used in a particular clinical setting or situation.

Because each payor generally determines for its own enrollees or insured patients whether to cover or otherwise establish a policy to reimburse our diagnostic assays, seeking payor approvals is a time-consuming and costly process. We cannot be certain that coverage for our current assays and our planned future assays will be provided in the future by additional third-party payors or that existing agreements, policy decisions or reimbursement levels will remain in place or be fulfilled under existing terms and provisions. If we cannot obtain coverage and adequate reimbursement from private and governmental payors such as Medicare and Medicaid for our current assays, or new assays or assay enhancements that we may develop in the future, our ability to generate revenues could be limited, which may have a material adverse effect on our financial condition, results of operations and cash flow. Further, we may experience delays and interruptions in the receipt of payments from third-party payors due to missing documentation and/or other issues, which could cause delay in collecting our revenue.

In addition, to the extent that our assays are ordered for Medicare inpatients and outpatients, only the hospital may receive payment from the Medicare program for the technical component of pathology services and any clinical laboratory services that we perform, unless the testing is ordered at least 14 days after discharge and certain other requirements are met. We therefore must look to the hospital for payment for these services under these circumstances. If hospitals refuse to pay for the services or fail to pay in a timely manner, our ability to generate revenues could be limited, which may have a material adverse effect on our financial condition, results of operations and cash flow.

We expect to depend on Medicare and a limited number of private payors for a significant portion of our revenues and if these or other payors stop providing reimbursement or decrease the amount of reimbursement for our current assays and our planned future assays, our revenues could decline.

Approximately 36% and 56% of total net revenues during the years ended December 31, 2022 and 2021, respectively, were associated with Medicare and CARES Act reimbursement. Approximately 16% and 17% of total net revenues during the years ended December 31, 2022 and 2021, respectively, were associated with Blue Cross Blue Shield reimbursement. Approximately 16% and 6% of total net revenues during the years ended December 31, 2022 and 2021, respectively, were associated with Kaiser Permanente reimbursement. We cannot assure you that, even if our current assays and our planned future assays are otherwise successful, reimbursement for the currently Medicare and Blue Cross Blue Shield covered portions of our current assays and our planned future assays would, without such contracted payor reimbursement for the capture/enumeration portion, produce sufficient revenues to enable us to reach profitability and achieve our other commercial objectives.

Medicare and other third-party payors may change their coverage policies or cancel future contracts with us at any time, review and adjust the rate of reimbursement or stop paying for our assays altogether, which would reduce our total revenues. Payors have increased their efforts to control the cost, utilization and delivery of health care services. In the past, measures have been undertaken to reduce payment rates for and decrease utilization of clinical laboratory testing generally. Because of the cost-trimming trends, third-party payors that currently cover and provide reimbursement for our current assays and our planned future assays may suspend, revoke or discontinue coverage at any time, or may reduce the reimbursement rates payable to us. Any such action could have a negative impact on our revenues, which may have a material adverse effect on our financial condition, results of operations and cash flows.

In addition, we are currently considered a "non-contracted provider" by many private payors because we have not entered into a specific contract to provide diagnostic assays to their insured patients at specified rates of reimbursement. Additionally, a significant amount of our non-Medicare business (private payors) has historically not been contracted, and reimbursement for this business has historically not been at "in network" rates and has therefore been inconsistent. We first began to contract private payor networks in 2015, and since then our number of accessions treated as "in network" has increased as we continue to execute additional contracts, and reimbursement is improving. We are currently contracted with nine preferred provider organization networks, three large health plans, and five regional independent physician associations, and expect to continue to gain contracts in order to be considered as an "in-network" provider with additional plans. If we were to become a contracted provider with additional payors in the future, the amount of overall reimbursement we receive would likely decrease because we could be reimbursed less money per assay performed at a contracted rate than at a non-contracted rate, which could have a negative impact on our revenues. Further, we typically are unable to collect payments from patients beyond that which is paid by their insurance and will continue to experience lost revenue as a result.

Because of certain Medicare billing policies, we may not receive complete reimbursement for assays provided to Medicare patients. Medicare reimbursement revenues are an important component of our business model, and private payors sometimes look to Medicare determinations when making their own payment determinations; therefore, incomplete or inadequate reimbursement from Medicare would negatively affect our business.

Medicare has coverage policies that can be national or regional in scope. Coverage means that the assay is approved as a benefit for Medicare beneficiaries. If there is no coverage, neither the supplier nor any other party, such as a reference laboratory, may receive reimbursement from Medicare for the service. There is currently no national coverage policy regarding the CTC enumeration portion of our assays. Because our laboratory is in California, the regional Medicare Administrative Contractor, or MAC, for California is the relevant MAC for all our assays. The previous MAC for California, Palmetto, which is contracted with CMS to administer the Molecular Diagnostic Services, or MolDX, program that sets guidelines for coding, coverage and reimbursement of molecular diagnostic assays, adopted a negative coverage policy for CTC enumeration. The current MAC for California, Noridian Healthcare Solutions, LLC, is adopting the coverage policies from Palmetto. Therefore, the enumeration portion of our assays is not currently covered, and we will receive no payment from Medicare for this portion of the service unless and until the coverage policy is changed. Tumor cell enumeration counts disease burden and is a prognostic assay, and although valuable, it does not yet meet many of the medical necessity requirements of Medicare and the payors. We intend to pursue payment for the capture portion of our CNSide technology that allows us to run our diagnostic testing for some of our assays.

We cannot assure you that, even if our current assays and our planned future assays are otherwise successful, reimbursement for the currently Medicare, Blue Cross Blue Shield, and United Healthcare-covered portions of our current assays and our planned future assays would, without such contracted payor reimbursement for the capture/enumeration portion, produce sufficient revenues to enable us to reach profitability and achieve our other commercial objectives.

The processing of Medicare claims is subject to change at CMS' discretion at any time. Cost containment initiatives may be a threat to Medicare reimbursement levels (including for the covered components of our current assays and our planned future assays, including FISH analysis and molecular assays) for the foreseeable future.

Long payment cycles of Medicare, Medicaid and/or other third-party payors, or other payment delays, could hurt our cash flows and increase our need for working capital.

Medicare and Medicaid have complex billing and documentation requirements that we must satisfy in order to receive payment, and the programs can be expected to carefully audit and monitor our compliance with these requirements. We must also comply

with numerous other laws applicable to billing and payment for healthcare services, including, for example, privacy laws. Failure to comply with these requirements may result in, among other things, non-payment, refunds, exclusion from government healthcare programs, and civil or criminal liabilities, any of which may have a material adverse effect on our revenues and earnings. In addition, failure by third-party payors to properly process our payment claims in a timely manner could delay our receipt of payment for our products and services, which may have a material adverse effect on our cash flows.

Complying with numerous regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

We are subject to CLIA, a federal law regulating clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. Our clinical laboratory must be certified under CLIA in order for us to perform testing on human specimens. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. We have a current certificate of accreditation under CLIA to perform high complexity testing, and our laboratory is accredited by one of the CLIA-approved accreditation organizations. To renew this certificate, we are subject to survey and inspection every two years. Moreover, CLIA and CAP inspectors may make periodic inspections of our clinical laboratory outside of the renewal process. The failure to comply with CLIA or CAP requirements can result in enforcement actions, including the revocation, suspension, or limitation of our CLIA and/or CAP certificate of accreditation, as well as a directed plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit and/or criminal penalties. We must maintain CLIA compliance and certification to be eligible to bill for assays provided to Medicare beneficiaries. If we were to be found out of compliance with CLIA program requirements and subjected to sanctions, our business and reputation could be harmed. Even if it were possible for us to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

In addition, our laboratory is located in California and is required by state law to have a California state license; as we expand our geographic focus, we may need to obtain laboratory licenses from additional states. California laws establish standards for operation of our clinical laboratory, including the training and skills required of personnel and quality control. In addition, we hold licenses from the states of Pennsylvania, Maryland and Rhode Island to test specimens from patients in those states or received from ordering physicians in those states. In addition, our clinical reference laboratory is required to be licensed on a product-specific basis by New York as an out of state laboratory and our products, as LDTs, must be approved by the New York State Department of Health before they are offered in New York. As part of this process, the State of New York requires validation of our assays. We currently do not have the necessary New York license, but we are in the process of addressing the requirements for licensure in New York. Other states may have similar requirements or may adopt similar requirements in the future. Finally, we may be subject to regulation in foreign jurisdictions if we seek to expand international distribution of our assays outside the United States.

If we were to lose our CLIA certification or California or other state laboratory license, whether as a result of a revocation, suspension or limitation, we would no longer be able to offer our assays, which would limit our revenues and harm our business. If we were to lose, or fail to obtain, a license in any other state where we are required to hold a license, we would not be able to test specimens from those states. If we were to lose our CAP accreditation, our reputation for quality, as well as our business, financial condition and results of operations, could be significantly and adversely affected.

If the FDA were to begin requiring approval or clearance of our current products or assays and our planned future products or assays, we could incur substantial costs and time delays associated with meeting requirements for pre-market clearance or approval or we could experience decreased demand for, or reimbursement of, our assays.

We provide our assays as LDTs. Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required laboratories that offer LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). In recent years, however, the FDA has stated it intends to end its policy of enforcement discretion and regulate certain LDTs as medical devices. To this end, on October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)", respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The FDA has indicated that it does not intend to modify its policy of enforcement discretion until the draft guidance documents are finalized. In January 2017, the FDA announced that final guidance on the

oversight of LDTs would allow for further public discussion. On January 13, 2017 the FDA issued a "Discussion Paper on Laboratory Developed Tests (LDTs)," which states that the material in the document does not represent a final version of the LDT draft guidance documents that were published in 2014 or position of the FDA; rather, the document is a method to encourage additional dialogue. The timing of when, if at all, the draft guidance documents will be finalized is unclear, and even then, the new regulatory requirements are proposed to be phased-in consistent with the schedule set forth in the guidance. Nevertheless, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time. LDTs with the same intended use as a cleared or approved companion diagnostic are defined in FDA's draft guidance as "high-risk LDTs (Class III medical devices)" for which premarket review would be first to occur.

FDA review, if required and successfully accomplished, would be expected to have some advantages. Certain health insurance payors have paid higher amounts over LDT prices for FDA approved or cleared tests, recognizing the additional costs of bringing a test through regulatory review. Some payors also accept FDA approval or clearance as a presumptive evidence of an assay's analytic validity and clinical validity, which can reduce the barriers to coverage since the payor can focus its review on clinical utility.

The container we provide for collection and transport of blood samples from a health care provider to our clinical laboratory, as well as our SCTs, may be medical devices subject to the FDA regulation but are currently exempt from pre-market review by the FDA. While we believe that we are currently in material compliance with applicable laws and regulations, we cannot assure you that the FDA or other regulatory agencies would agree with our determination, and a determination that we have violated these laws, or a public announcement that we are being investigated for possible violations of these laws, could adversely affect our business, prospects, results of operations or financial condition.

Some of the materials we use for our current products, assays and services and may use in our planned future products, assays and services are labeled for RUO. In November 2013, the FDA finalized guidance regarding the sale and use of products labeled for research or investigational use only. Among other things, the guidance advises that the FDA continues to be concerned about distribution of research or investigational use only products intended for clinical diagnostic use and that the manufacturer's objective intent for the product's intended use will be determined by examining the totality of circumstances, including advertising, instructions for clinical interpretation, presentations that describe clinical use, and specialized technical support, surrounding the distribution of the product in question. The FDA has advised that if evidence demonstrates that a product is inappropriately labeled for research or investigational use only, the device would be misbranded and adulterated within the meaning of the Federal Food, Drug and Cosmetic Act. Some of the materials and reagents obtained by us from suppliers for use in our current products, assays and services and our planned future products, assays and services are currently labeled as research or investigational use only products. If the FDA were to undertake enforcement actions, some of our suppliers might cease selling research or investigational use products to us, and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations, including increasing the cost of materials or reagents used in our current products, assays and services or planned future products, assays and services or delaying, limiting or prohibiting the purchase of materials or reagents necessary to sell our current products or planned future products or to perform our current assays or our planned future assays.

Our SCTs are marketed for RUO and distributed and sold to end users, some of which will be researchers and institutions while other end users could be labs performing clinical testing that will create their own LDTs. Some end users may assert that our ROU products caused their assays to perform inadequately or give erroneous results. If that was the case, we could potentially incur additional liabilities.

Further, the Department of Health and Human Services, or HHS, requested that its Advisory Committee on Genetics, Health and Society make recommendations about the oversight of genetic testing. A final report was published in April 2008. If the report's recommendations for increased oversight of genetic testing were to result in further regulatory burdens, they could negatively affect our business and delay the commercialization of assays in development.

Additionally, on March 16, 2018, CMS issued a final determination decision memo for Next-Generation Sequencing, or NGS, tests for Medicare Beneficiaries with Advanced Cancer (CAG-00450N). Under this final determination, NGS tests that gain FDA approval or clearance as a companion diagnostic will receive coverage, and the final determination of coverage for NGS tests that are LDTs will be left up to the local MAC. Currently, only 2 of our 17 CLIA validated assays utilized in CNSide is NGS-based; however, we plan to offer additional NGS assays in the future. To gain coverage for those assays, we will need to apply to Palmetto, which is the MAC that evaluates and recommends payment coverage or denial for molecular testing in our jurisdiction. Historically, Palmetto has offered a path to reimbursement by providing coverage while data is being gathered

known as Coverage with Data Development, or CDD. Going forward, the extent to which CDD will be continued, if at all, or to the extent that a process will be available in its place, if any, are unclear.

The requirement of pre-market review could negatively affect our business until such review is completed and clearance to market or approval is obtained. The FDA could require that we stop selling our products or diagnostic assays pending pre-market clearance or approval. If the FDA allows our products or assays to remain on the market but there is uncertainty about our products or assays, if they are labeled investigational by the FDA or if labeling claims the FDA allows us to make are very limited, orders from laboratory supply distributors and physicians, or reimbursement from third-party payors, may decline. The regulatory approval process may involve, among other things, successfully completing additional clinical trials and making a 510(k) submission or filing a pre-market approval application with the FDA. If the FDA requires pre-market review, our products or assays may not be cleared or approved on a timely basis, if at all. We may also decide voluntarily to pursue FDA pre-market review of our products or assays if we determine that doing so would be appropriate.

If we were required to conduct additional clinical studies or trials before continuing to offer assays that we have developed or may develop as LDTs, those studies or trials could lead to delays or failure to obtain necessary regulatory approval, which could cause significant delays in commercializing any future products and harm our ability to achieve sustained profitability.

If the FDA decides to require that we obtain clearance or approvals to commercialize our current assays or our planned future assays, we may be required to conduct additional pre-market clinical testing before submitting a regulatory notification or application for commercial sales. In addition, as part of our long-term strategy we may plan to seek FDA clearance or approval, so we can sell our assays outside our CLIA laboratory; however, we would need to conduct additional clinical validation activities on our assays before we can submit an application for FDA approval or clearance. Clinical trials must be conducted in compliance with FDA regulations or the FDA may take enforcement action or reject the data. The data collected from these clinical trials may ultimately be used to support market clearance or approval for our assays. It may take two years or more to conduct the clinical studies and trials necessary to obtain approval from the FDA to commercially launch our current assays and our planned future assays outside of our clinical laboratory. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our assay claims or that the FDA or foreign authorities will agree with our conclusions regarding our assay results. Success in early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior clinical trials and studies. If we are required to conduct pre-market clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase our assay development costs and delay commercialization. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial. Moreover, the clinical trial process may fail to demonstrate that our current assays and our planned future assays are effective for the proposed indicated uses, which could cause us to abandon an assay candidate and may delay development of other assays.

We have engaged a contract research organization to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials. We may also depend on clinical investigators, medical institutions and contract research organizations to perform the trials properly. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our current assays and our planned future assays. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our assays or to achieve sustained profitability.

We are subject to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.

We are subject to health care fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. These health care laws and regulations include, for example:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or services for which payment may be made under a federal health care program such as the Medicare and Medicaid programs;
- the federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of "designated health services" with whom the physician or a member of the physician's immediate family has an ownership interest or compensation arrangement, unless a statutory or regulatory exception applies;
- the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, which prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA's reach extends beyond federal health care programs to include private insurance (i.e., it is an "all payor" statute);
- HIPAA, which established additional federal civil and criminal liability for, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services;
- HIPAA, as amended by HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, and their subcontractors that use, disclose or otherwise process individually identifiable health information;
- federal false claims and civil monetary penalties laws, which, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to the federal government;
- the federal Physician Payments Sunshine Act requirements under the ACA, which require certain manufacturers of drugs, devices, biologics and medical supplies to report to CMS information related to payments and other transfers of value made to or at the request of covered recipients, such as physicians, (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, and certain physician ownership and investment interests held by physicians and their immediate family members; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Further, the ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal health care fraud statutes. Where the intent requirement has been lowered, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may now assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Any action brought against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including, among others, significant administrative, civil and criminal penalties, damages and fines, imprisonment, integrity oversight and reporting obligations, and exclusion from participation in government funded healthcare programs such as Medicare, Medicaid programs, including the California Medical Assistance Program (Medi-Cal-the California Medicaid program) or other state or federal health care programs. Additionally, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

We are or may become subject to stringent and changing U.S. and foreign laws, regulations, rules, standards, policies, contractual obligations and other obligations related to data privacy and security, including laws and regulations related to health information. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions, enforcement or litigation, fines and penalties), a disruption of the development or delivery of our products and services, reputational harm, loss of revenue or profits, or other adverse business consequences.

We collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect, secure, dispose of, transmit and share (collectively, process) personal data and other sensitive information, including but not limited to proprietary and confidential business information, trade secrets, intellectual property, health information and sensitive third-party information. Accordingly, we are, or may become, subject to numerous federal, state, local and foreign data privacy and security laws, regulations, guidance and industry standards, including laws that specifically regulate health information, as well as external and internal privacy and security policies, contracts and other obligations that apply to the processing of personal data by us and on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. For example, HIPAA, as amended by HITECH, and the respective implementing regulations, imposes limitations on certain entities' processing of individual health information, and also grants individuals rights with respect to their health information. HITECH also made significant increases in the penalties for improper processing of an individual's health information under HIPAA and extended enforcement authority to state attorneys general. For more information regarding risks associated with HIPAA, please refer to the section above titled *Confidentiality and Security of Personal Health Information*.

As another example, the California Consumer Privacy Act of 2018, or CCPA, applies to personal information of consumers, business representatives, and employees, and requires covered businesses to provide specific disclosures related to a business's processing of personal data, new operational practices, and requirements to respond to certain requests from California residents related to their personal data. The CCPA provides for significant civil penalties of up to $7,500 per violation as well as a private right of action for data breaches and statutory damages. Although there are limited exemptions for clinical trial data and some other health data under the CCPA, the CCPA and other similar laws may impact our business activities and increase our compliance costs. In addition the California Privacy Rights Act of 2020, or CPRA, effective January 1, 2023, expanded the CCPA's rights, including by, among other things, giving California residents the ability to correct their personal data and limit use of certain sensitive personal data, establishing restrictions on the retention of personal data, expanding the types of data breaches subject to the CCPA's private right of action, and establishing a new California Privacy Protection Agency to implement and enforce the new law. In addition, other states have enacted or proposed data privacy laws, which could further complicate the legal landscape. For example, Virginia recently passed the Consumer Data Protection Act which became effective on January 1, 2023, and Colorado recently passed the Colorado Privacy Act, both of which differ from the CPRA and become effective in July 2023. Other data privacy and security laws have also been proposed at the federal, state, and local levels, and may be enacted.

Additionally, outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR, governs the processing of personal data of European persons, and sets out extensive compliance requirements. The EU GDPR provides for fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. Additionally, we may be subject to the United Kingdom's GDPR or UK GDPR, which largely mirrors the EU GDPR in UK national law. In addition, privacy advocates and industry groups have proposed, and may propose, standards with which we may be legally or contractually bound to comply.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU or in other foreign jurisdictions). Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

The number and scope of obligations related to data privacy and security, including but not limited to the complex requirements of HIPAA, GDPR and US state data privacy law requirements, are rapidly evolving, subject to change and potentially in conflict with each other. As a result, preparing for and complying with these obligations requires significant resources and may necessitate changes to our services, information technologies, systems and practices, as well as those of any third-party

collaborators, service providers, contractors, consultants or other third parties that process personal data on our behalf, any of which could have a negative impact on our operations. Our business model materially depends on our ability to process personal data, so we are particularly exposed to the risks associated with the rapidly changing legal landscape. Adding to the complexity is that our operations are evolving, and these laws will apply differently depending on our operations, for example whether we electronically bill for our services.

Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees, partners, third-party collaborators, service providers, contractors or consultants fail to comply with such obligations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to foreign, federal, state, or local government enforcement actions that could include investigations, fines, penalties, audits and inspections; litigation (including class-action claims); additional reporting requirements and/or oversight; temporary or permanent bans on all or some processing of personal data (including in relation to clinical trials); and orders to destroy or not use personal data. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to loss of actual or prospective customers, collaborators or partners; interruption or stoppage in clinical trials; inability to process personal data or to operate in certain jurisdictions; limit our ability to develop or commercialize our products; or require us to revise or restructure our operations. Moreover, such claims, even if we are not found liable, could be expensive and time-consuming to defend and could divert management's attention and cause adverse publicity that could harm our business or have other material adverse effects.

Clinical research is heavily regulated and failure to comply with human subject protection regulations may disrupt our research program leading to significant expense, regulatory enforcement, private lawsuits and reputational damage.

Clinical research is subject to federal, state and, for studies conducted outside of the United States, foreign regulation. At the federal level, the FDA imposes regulations for the protection of human subjects and requirements such as initial and ongoing institutional review board review; informed consent requirements, adverse event reporting and other protections to minimize the risk and maximize the benefit to research participants. Many states impose human subject protection laws that mirror or in some cases exceed federal requirements. HIPAA also regulates the use and disclosure of protected health information in connection with research activities. Research conducted overseas is subject to a variety of national protections such as mandatory ethics committee review, as well as laws regulating the use, disclosure and cross-border transfer of personal data. For example, if we obtain certain personal information regarding residents in the European Union, we may be subject to the GDPR. The costs of compliance with these laws may be significant and compliance with regulatory requirements may result in delay of our clinical research and other business operations. Noncompliance may disrupt our research and result in data that is unacceptable to regulatory authorities, data lock or other sanctions that may significantly disrupt our operations.

Violation of a state's prohibition on the corporate practice of medicine could result in a material adverse effect on our business.

A number of states, including California, do not allow business corporations to employ physicians to provide professional services. This prohibition against the "corporate practice of medicine" is aimed at preventing corporations such as us from exercising control over the medical judgments or decisions of physicians. The state licensure statutes and regulations and agency and court decisions that enumerate the specific corporate practice rules vary considerably from state to state and are enforced by both the courts and regulatory authorities, each with broad discretion. If regulatory authorities or other parties in any jurisdiction successfully assert that we are engaged in the unauthorized corporate practice of medicine, we could be required to restructure our contractual and other arrangements. In addition, violation of these laws may result in significant civil, criminal and administrative penalties imposed against us and/or the professional through licensure proceedings, and exclusion from state and federal health care programs.

Intellectual Property Risks Related to Our Business

If we are unable to obtain and maintain effective patent rights for our products or services, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to our technologies, products and services. Our success depends in large part on our ability to obtain and

maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and products.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The possibility exists that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of diagnostic companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we own, or in-license, may fail to result in issued patents with claims that cover our products or services in the United States or in other foreign countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our products and services, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our products and services, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We, independently or together with our licensors, have filed several patent applications covering various aspects of our products and services. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. For example, our U.S. patent related to our SCTs is currently under a reexamination procedure in the U.S. Patent Office and was issued a Reexamination Certificate. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any products and services that we may offer. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product or service under patent protection could be reduced.

Patent policy and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. We therefore cannot be certain that we or our licensors were the first to make the invention claimed in our owned and licensed patents or pending applications, or that we or our licensor were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, in the United States prior to March 15, 2013, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act, or the Leahy-Smith Act, enacted on September 16, 2011, the United States has moved to a first to file system. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. The effects of these changes are currently unclear as the United States Patent and Trademark Office, or USPTO, must still implement various regulations, the courts have yet to address any of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. In general, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

If we are unable to maintain effective proprietary rights for our products or services, we may not be able to compete effectively in our markets.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our products and services that involve proprietary know-how, information or technology that is not

covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have conducted commercially reasonable due diligence on these individuals, organizations and systems, our agreements with such partners or our or their security measures may nevertheless be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and reexamination proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products and services. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products and services may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our products and services. We have conducted freedom to operate analyses with respect to only certain of our products and services, and therefore we do not know whether there are any third-party patents that would impair our ability to commercialize these products and services. We also cannot guarantee that any of our analyses are complete and thorough, nor can we be sure that we have identified each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our products and services. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our products or services may infringe.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our products or services. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may not be successful in obtaining or maintaining necessary rights to our products or services through acquisitions and in-licenses.

We currently have rights to the intellectual property, through licenses from third parties and under patents that we own, to develop our products and services. Because our programs may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license, or use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our products or services. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization

capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

We sometimes collaborate with U.S. and foreign institutions to accelerate our research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer.

Although we are not currently involved in any litigation, we may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. Although we are not currently involved in any litigation, if we or one of our licensing partners were to initiate legal proceedings against a third-party to enforce a patent covering one of our products or services, the defendant could counterclaim that the patent covering our product or service is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise sufficient capital to continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help commercialize our products or services.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ certain individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and independent contractors do not use the proprietary information or know-how of others in their work for us, and we are not currently subject to any claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties, we may in the future be subject to such claims. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

Although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our products or services. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involves both technological and legal complexity. Therefore, obtaining and enforcing biotechnology patents is costly, time consuming, and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on products and services in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Our collaborators may assert ownership or commercial rights to inventions we develop from our use of the biological materials which they provide to us, or otherwise arising from the collaboration.

We collaborate with several institutions, physicians and researchers in scientific matters. We do not have written agreements with certain of such collaborators, or the written agreements we have do not cover intellectual property rights. Also, we rely on numerous third parties to provide us with blood samples and biological materials that we use to develop assays. If we cannot

successfully negotiate sufficient ownership and commercial rights to any inventions that result from our use of a third-party collaborator's materials, or if disputes arise with respect to the intellectual property developed with the use of a collaborator's samples, or data developed in a collaborator's study, we may be limited in our ability to capitalize on the market potential of these inventions or developments.

Risks Relating to Our Common Stock

The price of our common stock may be volatile.

Market prices for our common stock have historically been volatile. The factors that may cause the market price of our common stock to fluctuate include, but are not limited to:

- progress, or lack of progress, in performing, developing and commercializing our current assays and our planned future assays;
- favorable or unfavorable decisions about our assays from government regulators, insurance companies or other third-party payors;
- our ability to recruit and retain qualified research and development personnel;
- changes in investors' and securities analysts' perception of the business risks and conditions of our business;
- changes in our relationship with key collaborators;
- changes in the market valuation or earnings of our competitors or companies viewed as similar to us;
- changes in key personnel;
- depth of the trading market in our common stock;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- disruptions caused by geopolitical conflicts (such as the current Russia-Ukraine conflict) man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic;
- changes in the structure of healthcare payment systems;
- the granting or exercise of employee stock options or other equity awards;
- realization of any of the risks described herein; and
- general market and economic conditions.

In addition, the equity markets have experienced significant price and volume fluctuations that have affected the market prices for the securities of public companies for a number of reasons, including reasons that may be unrelated to our business or operating performance. These broad market fluctuations may result in a material decline in the market price of our common stock and you may not be able to sell your shares at prices you deem acceptable. In the past, following periods of volatility in the equity markets, securities class action lawsuits have been instituted against public companies. Such litigation, if instituted against us, could result in substantial cost and the diversion of management attention.

Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our common stock.

If we fail to satisfy the continued listing requirements of The Nasdaq Capital Market, such as the corporate governance requirements, the minimum closing bid price requirement, or the minimum stockholders' equity requirement, Nasdaq may take steps to de-list our common stock. For example, in May 2016, we received a letter from Nasdaq indicating that we are not in compliance with the minimum stockholders' equity requirement of Nasdaq Listing Rule 5550(b)(1), and in each of June 2016, November 2016, January 2018, September 2019 and October 2022, we received letters from Nasdaq indicating that we were not in compliance with the minimum bid price requirement of Nasdaq Listing Rule 5550(a)(2), which requires that companies listed on The Nasdaq Capital Market maintain a minimum closing bid price of at least $1.00 per share. We were able to regain

compliance with the Nasdaq continued listing requirements discussed in the May 2016, June 2016, November 2016, January 2018 and September 2019 letters. With respect to the October 2022 letter, we initially had 180 calendar days (or until April 17, 2023) to regain compliance with the minimum bid price requirement, and we expect to be afforded an additional 180 days as a result of our meeting the requirements for the 180-day extension, including the notice we provided to Nasdaq of our intention to cure the bid price deficiency through a reverse stock split, if necessary. On April 10, 2023, we filed a preliminary proxy statement for a special meeting of stockholders to be held on May 21, 2023 for the purpose of approving a reverse split of our outstanding common stock. There can be no assurance that we will be able to regain and maintain compliance with the minimum bid price requirement. In addition, we were unable to timely file our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, which resulted in us not being in compliance with Nasdaq Listing Rule 5250(c)(1). We subsequently filed such Quarterly Report on Form 10-Q within the additional period granted by Nasdaq. However, it is possible that we will be unable to timely file future periodic reports in a timely manner. If we fail to regain and maintain compliance with Nasdaq's continued listing requirements, Nasdaq may take steps to de-list our common stock. Such a de-listing would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a de-listing, we would take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, or prevent future non-compliance with Nasdaq's listing requirements.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- the rate of adoption and/or continued use of our current assays and our planned future assays by healthcare practitioners;
- variations in the level of expenses related to our development programs;
- addition or reduction of resources for sales and marketing;
- addition or termination of clinical utility studies;
- any intellectual property infringement lawsuit in which we may become involved;
- the impact that a resurgence in COVID-19 or another health epidemic or pandemic may have on our core oncology business;
- third-party payor coverage and reimbursement determinations affecting our assays; and
- regulatory developments affecting our assays.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

Future sales of our common stock or other securities, or the perception that future sales may occur, may cause the market price of our common stock to decline, even if our business is doing well.

Sales of substantial amounts of our common stock or other securities, or the perception that these sales may occur, could materially and adversely affect the price of our common stock and could impair our ability to raise capital through the sale of additional equity securities.

We had outstanding 17,070,071 shares of common stock as of December 31, 2022 most of which are not subject to resale restrictions under Rule 144 of the Securities Act. In addition, as of December 31, 2022, we had outstanding preferred stock convertible into 46,541 shares of our common stock, 2,263,401 options to purchase shares of our common stock and 844,460 shares of our common stock were issuable upon the exercise of outstanding warrants. Shares issued upon the exercise of stock options generally will be eligible for sale in the public market, except that affiliates will continue to be subject to volume limitations and other requirements of Rule 144 under the Securities Act. The issuance or sale of such shares could depress the market price of our common stock.

In the future, we also may issue our securities if we need to raise additional capital. The number of new shares of our common stock issued in connection with raising additional capital could constitute a material portion of the then-outstanding shares of our common stock.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired and our public reporting may be unreliable.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. In connection with the restatement of our condensed financial statements as of, and for the three and nine months ended, September 30, 2021, we determined that we had a material weakness as of September 30, 2021, namely that our review control over the completeness and accuracy of our accounts payable did not operate effectively, resulting in a material error in the financial statements. Subsequently, in connection with the preparation and review of our Annual Report on Form 10-K for the year ended December 31, 2021, management determined that a deficiency existed related to the methods used to develop certain estimates and the timely review of such estimates. Additionally, in connection with the preparation and review of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, as well as in connection with the preparation and review of our Annual Report on Form 10-K for the year ended December 31, 2022, management determined that a material weakness existed related to our controls to review and approve certain revenue-related manual journal entries, including the review of the completeness and the accuracy of the information used. In addition, in connection with the preparation and review of our Annual Report on Form 10-K for the year ended December 31, 2022, management determined that a material weakness existed related to our review control over the completeness and accuracy of information used when calculating stock-based compensation expense, which resulted in a material error in the financial statements included in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022. A material weakness means a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis.

Except for the material weakness discovered in connection with the preparation and review of our Annual Report on Form 10-K for the year ended December 31, 2022, we have implemented certain aspects of a plan to remediate the material weaknesses in our internal control over financial reporting, including steps to design and implement new controls and expand the review of any potential unrecorded liabilities. We will also need to design and implement additional controls related to the material weaknesses identified above. However, we cannot assure you that these efforts will remediate our material weaknesses in a timely manner, or at all, or that we will be able to maintain effective controls and procedures even if we remediate our material weaknesses. If we are unable to successfully remediate our material weaknesses, implement and maintain effective controls and procedures, or identify any future material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports and we may experience a loss of public confidence, which could have an adverse effect on our business, financial condition and the market price of our common stock.

We are required to disclose changes made in our internal control procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are a "non-accelerated filer", our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to future financial statement restatements and require us to incur additional expenses of remediation.

Warrants to purchase common stock issued in our December 2019 public offering include a right to receive the Black-Scholes value of the unexercised portion of the warrants in the event of a fundamental transaction, which payment could be significant.

The warrants to purchase shares of common stock issued by us in connection with our December 2019 public offering provide that, in the event of a "fundamental transaction" that is approved by our board of directors, including, among other things, a merger or consolidation of our company or sale of all or substantially all of our assets, the holders of such warrants have the option to require us to pay to such holders an amount of cash equal to the Black-Scholes value of the warrants. Such amount could be significantly more than the warrant holders would otherwise receive if they were to exercise their warrants and receive the same consideration as the other holders of common stock, which in turn could reduce the consideration that holders of common stock would be concurrently entitled to receive in such fundamental transaction. Any future equity financing we conduct may require us to issue warrants that have a similar feature.

Anti-takeover provisions of our certificate of incorporation, our bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove the current members of our board and management.

Certain provisions of our amended certificate of incorporation and amended and restated bylaws could discourage, delay or prevent a merger, acquisition or other change of control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove members of our Board of Directors. For example, Delaware law provides that if a corporation has a classified board of directors, stockholders cannot remove any director during his or her term without cause. These provisions also could limit the price that investors might be willing to pay in the future for our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions, among other things:

- classify our Board of Directors into three classes of equal (or roughly equal) size, with all directors serving for a three-year term and the directors of only one class being elected at each annual meeting of stockholders, so that the terms of the classes of directors are "staggered";
- allow the authorized number of directors to be changed only by resolution of our Board of Directors;
- authorize our Board of Directors to issue, without stockholder approval, preferred stock, the rights of which will be determined at the discretion of the Board of Directors and that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that our Board of Directors does not approve;
- establish advance notice requirements for stockholder nominations to our Board of Directors or for stockholder proposals that can be acted on at stockholder meetings; and
- limit who may call a stockholders meeting.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of the voting rights on our common stock, from merging or combining with us for a prescribed period of time.

Because we do not expect to pay cash dividends for the foreseeable future, you must rely on appreciation of our common stock price for any return on your investment. Even if we change that policy, we may be restricted from paying dividends on our common stock.

We do not intend to pay cash dividends on shares of our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our Board of Directors and will depend upon results of operations, financial performance, contractual restrictions, restrictions imposed by applicable law and other factors our Board of Directors deems relevant. Accordingly, you will have to rely on capital appreciation, if any, to earn a return on your investment in our common stock. Investors seeking cash dividends in the foreseeable future should not purchase our common stock.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation known as the Tax Cuts and Jobs Act of 2017, the Coronavirus Aid, Relief, and Economic Security Act and the Inflation Reduction Act of 2022 enacted many significant changes to the U.S. tax laws. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are subject to taxation in numerous U.S. states and territories. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than

experienced in the past due to numerous factors, including the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

Our ability to use our estimated net operating loss carryforwards and certain other tax attributes may be limited.

Under current law, federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited to 80% of current year taxable income. It is uncertain if and to what extent various states will conform to federal tax laws. In addition, under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change," generally defined as a cumulative change in its equity ownership by "5-percent shareholders" of greater than 50 percentage points (by value) over a three-year period, the corporation's ability to use its estimated pre-change net operating loss carryforwards and certain other tax attributes (such as research tax credits) to offset its post-change taxable income and taxes, as applicable, may be limited. As of December 31, 2022, we had estimated federal and state net operating loss carryforwards of approximately $91.3 million and $66.8 million, respectively, and estimated federal and California research and development tax credits of approximately $1.0 million and $4.0 million, respectively, which could be limited if we have experienced or do experience any "ownership changes." We have not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation, due to the complexity and cost associated with such a study, and the fact that there may be additional ownership changes in the future. We believe, however, that multiple ownership changes have likely occurred. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. We have estimated that the use of our net operating loss is limited and the amounts above remain fully offset by a valuation allowance.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because early-stage life sciences companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

General Risk Factors

General economic or business conditions may have a negative impact on our business.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates and uncertainty about economic stability. For example, the COVID-19 pandemic resulted in increased unemployment, economic slowdown and extreme volatility in the capital markets. Similarly, the ongoing Russia-Ukraine conflict, high interest rights, inflation and recent bank failures have created extreme volatility in the global capital markets and may have further global economic consequences. Continuing concerns over United States health care reform legislation have also contributed to increased volatility. Any such volatility and disruptions may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive.

We have incurred and will continue to incur significant costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, the listing requirements of The Nasdaq Stock Market and other applicable securities rules and regulations. Compliance with these rules and regulations includes significant legal and financial compliance costs, makes some activities more difficult, time-consuming or costly, and increases demand on our systems and resources. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve

our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could harm our business and operating results. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

If securities or industry analysts issue an adverse opinion regarding our stock or do not publish research or reports about our company, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that equity research analysts publish about us, our business and our competitors. We do not control these analysts or the content and opinions or financial models included in their reports. Securities analysts may elect not to provide research coverage of our company, and such lack of research coverage may adversely affect the market price of our common stock. The price of our common stock could also decline if one or more equity research analysts downgrade our common stock or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

We have a lease for approximately 39,600 square feet of space in San Diego, California for use as a clinical reference laboratory and corporate headquarters, including manufacturing and research laboratories. As of December 31, 2022, the average rent for the remaining lease period is approximately $150,000 per month. This lease expires in June 2031. We believe that our existing facilities are adequate for our current and reasonably foreseeable future needs.

Item 3. Legal Proceedings.

In the normal course of business, we may be involved in legal proceedings or threatened legal proceedings. We are not party to any legal proceedings or aware of any threatened legal proceedings which are expected to have a material adverse effect on our financial condition, results of operations or liquidity.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is traded on The Nasdaq Capital Market under the symbol "BIOC."

Holders of Record

As of March 31, 2023, there were 11 holders of record of our common stock. The actual number of common stockholders is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared dividends on our equity securities, and currently do not plan to declare dividends on shares of our common stock in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. Subject to the foregoing, the payment of cash dividends in the future, if any, will be at the discretion of our Board of Directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors deemed relevant by our Board of Directors.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion of our financial condition and results of operations should be read together with our financial statements and related notes included elsewhere in the Annual Report. This discussion contains forward-looking statements based upon our current plans, estimates, beliefs and expectations that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under the sections entitled "Risk Factors," "Special Note Regarding Forward-Looking Statements" and elsewhere in this Annual Report.

We are a molecular oncology diagnostics company that develops and commercializes proprietary clinical diagnostic laboratory assays designed to identify rare tumor cells and cell-free tumor DNA from blood and cerebrospinal fluid, or CSF. The identification of tumor cells and cell-free tumor DNA in CSF has become our principal development focus following our early commercial expansion into CSF in 2020. This product was branded and trademarked as CNSide™ in April 2021.

The identification of circulating tumor cells, or CTCs, and circulating cell-free tumor DNA and RNA, or ctDNA and ctRNA, deriving from solid tumors such as breast cancer or lung cancer using a standard blood sample has been described as a "liquid biopsy." This term reflects the ease with which peripheral blood can be drawn compared to performing a surgical biopsy, but this technology is not limited to a peripheral blood approach.

In January 2020, we adapted and validated our proprietary blood-based liquid biopsy technology for commercial and clinical research use in CSF to identify tumor cells that have metastasized to the central nervous system, or CNS, in patients with advanced lung cancer or breast cancer. CNSide has been designed to improve the clinical management of patients with suspected metastatic cancer involving the CNS by enabling the quantitative analysis and molecular characterization of tumor cells and ctDNA and ctRNA in the CSF. Since then, we have worked extensively with leading neuro-oncologists and other cancer experts to further define and characterize the use of this unique assay.

Our efforts have culminated in the presentation of our early clinical experience at several leading academic forums, including most recently the Society of Neuro-Oncology, or SNO, Brain Metastases meeting in August 2021, as well as the Annual SNO meeting in November 2021, the San Antonio Breast Cancer Symposium, or SABCS, in December 2021, the American Academy of Neurology in April 2022, and the annual SNO meeting in November 2022. We believe these presentations have illustrated the feasibility of this assay to inform three critical questions important for the care of patients with suspected or confirmed metastatic cancer involving the CNS: Is there tumor (diagnosis)? Is there target (presence of a biomarker to aid treatment selection)? Is there trend (a response to therapy)?

The question "Is there tumor?" is essential for the diagnostic work-up of these patients. Tumor cells in the blood can shed from either primary or metastatic tumors. They can be rapidly removed in the capillary beds of the spleen, liver, kidneys, lungs and other organs, so they are rarely found. They are the defining feature of metastasis to the leptomeningeal space within the CNS and hence define the presence or absence of leptomeningeal metastasis, or LM. To distinguish tumor cells derived from CSF and blood we often refer to tumor cells in CSF as CSF tumor cells, rather than CTCs.

Regarding the second clinical question, "Is there target?" our CNSide assay provides a vehicle for several different diagnostic assay profiles which combined with our molecular test menu and next generation sequencing, or NGS, services can identify tumor cell biomarkers that are intended to help physicians make decisions related to the evolution or course of metastatic tumor that may inform treatment decisions. Cancer cells typically acquire genetic alterations which differ from that of normal cells. Metastatic cancers often acquire additional genetic alterations which distinguish them from the primary tumor site. This marked genetic variation between areas of tumor growth is termed "genetic heterogeneity," and findings related to this were featured in our SABCS presentation in December 2021 illustrating the value of CNSide in identifying "genetic heterogeneity" of a targetable biomarker called HER2.

Finally, regarding the third clinical question, "Is there trend?" over the past year we have gained considerable experience with cases that have been sampled multiple times over the course of a patient's treatment. The association of quantitative CSF tumor cell counts with response to treatment has been noted in both lung and breast cancer, as well as other tumors examined. In August 2021, at the SNO Brain Metastases meeting, we presented data obtained from a single institution experience showing how serial monitoring of CSF tumor cells by CNSide was used to determine the response to treatment in patients with Non-Small Cell Lung Cancer having LM. In addition, in November 2021 at SNO, we presented the early findings of several patients with breast cancer having LM which had been followed with multiple CSF samples drawn at different time points on each

patient. The downward progression of tumor cell counts has been noted by several treating physicians to correlate with response to treatment and resolution of symptoms. Serial monitoring of genetic alterations present in CSF tumor cells may create opportunities to change the therapy of certain patients throughout treatment. These observations presented in abstracts and poster presentations in 2021 have informed our clinical study strategy which is the basis for our 2022 efforts to further explore these observations in a prospective clinical trial.

Our first CNSide multi-center prospective clinical trial, named FORESEE (NCT05414123) is now enrolling patients. at one site in Los Angeles, CA. The trial's primary outcome measure will assess the impact of CNSide on treatment decisions. Assuming the results of the trial are favorable, we intend to pursue the inclusion of CNSide in the standard National Comprehensive Cancer Network, NCCN, guideline for diagnosis and monitoring of LM disease. With the help of a leading Clinical Research Organization, we have established the infrastructure for the trial, have opened two sites (one in Los Angeles and one in Dallas) and are now in the process of opening at least three additional clinical sites where patients with breast or non-small cell lung cancer, NSCLC, who have suspicious or confirmed LM will be enrolled.

COVID-19 Pandemic Response Summary

In June 2020, to respond to a national public health emergency precipitated by the COVID-19 pandemic, we introduced molecular testing for SARS-CoV2, the virus responsible for COVID-19, using a United States Food and Drug Administration, or FDA, Emergency Use Authorization, or EUA, based "RT-PCR" method developed by Thermo-Fisher.

Since launch of our COVID-19 testing program, we performed more than 1,000,000 assays for customers. We primarily marketed our COVID- 19 testing services to skilled nursing facilities in the western United States and to certain community colleges within California.

Our COVID-19 testing services were responsible for most of our revenues during the year ended December 31, 2022 and 2021. However, as a result of increased vaccination and immunization levels, as well as decreased COVID-19 hospitalizations, reported cases and mandatory COVID-19 testing, we experienced reduced demand for our COVID-19 testing services during 2022. We ceased COVID-19 service offerings in February 2023.

Additional Oncology Testing Services

In addition to CNSide, we previously offered blood-based testing through our Target Selector technologies which enable detection of specific gene mutations, such as EGFR, KRAS or BRAF, in ctDNA from blood and CSF samples. In May 2022, after a thorough business review, we decided to discontinue certain unprofitable blood-based molecular testing services including our Target Selector offerings. We also offer, and received MolDX reimbursement approval for, certain specific protein and gene alterations, such as HER2 amplification, in tumor cells isolated from blood or present in CSF. We continue to offer these HER2 based tests as they are an important aspect of our CNSide offering. We will also continue to provide certain other blood-based testing services for biopharma partners and to support investigator-initiated studies involving CNSide. We believe our multi-modality combination of a proprietary cell capture and analysis method in combination with an extensive menu of molecular testing modalities that includes ICC, FISH, PCR testing and NGS testing provides us with the necessary tools to service a broad range of diagnostic applications in patients with neurological metastatic cancers. We continue to seek other diagnostic modalities that may benefit neuro-oncology patients and their caregivers.

At our corporate headquarters facility located in San Diego, California, we operate a clinical laboratory that is CLIA-certified, CAP accredited and licensed by the California Department of Public Health. In this facility we also develop novel assays that are part of our project pipeline for future commercial launch and we manufacture our microfluidic channels and various assay reagents and products used in our testing processes. We also work closely with external manufacturers to outsource certain products such as collection tubes and to manufacture items that we intend to use in the near future to reduce costs and improve efficiency.

The assays we offer and intend to offer are classified as CLIA laboratory developed tests, or LDTs, under CLIA regulations. CLIA certification and state licensure in California and certain other states under the supervision of a qualified laboratory medical director is required before any clinical laboratory, including ours, may perform testing on human specimens for the purpose of obtaining information for the diagnosis, prevention, or treatment of disease or the assessment of health. In addition,

we participate in and have received CAP accreditation, which includes rigorous bi-annual laboratory inspections and requires adherence to specific quality standards.

Commercial Strategy

Our primary sales strategy is to engage neuro-oncologists, oncologists and other physicians in the United States at private and group practices, hospitals, laboratories and cancer centers to educate them about our unique products and services. In addition, we market our clinical trial and research services to pharmaceutical and biopharmaceutical companies and clinical research organizations.

Our revenue generating efforts are focused in the following areas:

- providing laboratory services to neuro-oncologists, oncologists and other physicians or healthcare providers treating patients with cancer who use the biomarker information we provide in order to determine the best treatment plan for their patients;
- providing laboratory services using both our CSF tumor cell and ctDNA and ctRNA assays in order to help pharmaceutical and biopharmaceutical companies run clinical studies establishing the use of novel drug therapies used to treat cancer; and
- licensing our proprietary technology and selling our distributed products, including our SCTs and assay kits, to partners in the United States and abroad.

We plan to grow our business by directly offering our CNSide and molecular assays to neuro-oncologists, oncologists and other physicians or heath care providers who treat patients with cancer. Based on our product development data, as well as discussions with our key collaborators, we believe that our planned future assays, particularly those related to CSF, should provide important information and clinical value to physicians.

We believe our ability to rapidly translate insights about the utility of cytogenetic, immunocytochemical and molecular biomarkers to provide information to neuro-oncologists, oncologists and other physicians for treatment decisions in the clinical setting will improve patient treatment and management, and that these assays will become a key component of the standard of care for personalized cancer treatment.

Key Factors Affecting our Results of Operations and Financial Condition

Our overall long-term growth plan depends on our ability to continue to develop and commercialize products and assays through our CLIA-certified, CAP-accredited, and state-licensed laboratory. We have now commercialized our CNSide assays for breast cancer, non-small cell lung cancer, small cell lung cancer, melanoma, esophageal cancer, gastric cancer, colorectal cancer, head and neck cancers, ovarian cancer, endometrial cancer, renal cancer, bladder cancer, prostate cancer, liver cancer, pancreatic cancer, neuroendocrine cancer, melanoma and plan to continue to launch a series of cancer diagnostic assays for different predictive biomarkers assays in the United States as LDTs performed in our laboratory and enhance revenue for these products through the efforts of our sales and marketing organization. Our sales strategy is to engage medical oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists and other physicians in the United States at private and group practices, hospitals and cancer centers. We also have a research and development program focused on technology enhancements, novel platform development, and evaluating clinical applications for our cancer diagnostic tests in different cancer types and clinical settings.

To facilitate market adoption of our products and assays, we anticipate having to successfully complete additional clinical utility studies with clinical samples to generate clinical utility data and then publish our results in peer-reviewed scientific journals, including the FORESEE study for CNSide. Our ability to complete such clinical studies is dependent upon our ability to leverage our collaborative relationships with leading institutions to facilitate our research, to conduct the appropriate clinical studies and to obtain favorable clinical data. We currently collaborate with key thought leaders, physicians and clinical researchers across the country, including those at Sarah Cannon Research Institute, University of Colorado, Northwestern University Lurie Cancer Center, Stanford University, Penn State University, University of California, San Diego, St John's Cancer Institute at Santa Monica (formerly John Wayne Cancer Institute), Columbia University, Emory University, Johns Hopkins Medical Institute, University of Texas Southwestern Medical Center, Yale University, Ohio State University, Vanderbilt University, Georgetown University and many others and plan to expand our collaborative relationships to include other key thought leaders at other institutions for the cancer types we target with our CNSide commercialized assays and our planned future assays, as well as for our current and planned future products. Such relationships help us develop and validate the effectiveness and utility of our products, commercialized assays and our planned future assays in specific, clinical settings and provide us access to patient samples and data.

We believe that the factors discussed in the following paragraphs have had and are expected to continue to have a material impact on our results of operations and financial condition.

Revenues

Our commercial revenues are generated from diagnostic services provided to patient's physicians and billed to third-party insurance payors such as managed care organizations, Medicare and Medicaid and patients for any deductibles, coinsurance or copayments that may be due. The Company recognizes revenue in accordance with Accounting Standards Codification (Topic 606), Revenue from Contracts with Customers, or ASC 606, which requires that an entity recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services.

We bill third-party payors on a fee-for-service basis at our list price and third-party commercial revenue is recorded net of contractual discounts, payor-specific allowances and other reserves. Our development services revenues are supported by contractual agreements and generated from assay development services provided to entities, as well as certain other diagnostic services provided to physicians. Diagnostic services are completed upon the delivery of assay results to the prescribing physician, at which time we bill for the service.

Our gross commercial revenues billed are subject to estimated deductions for such contractual discounts, payor-specific allowances and other reserves to arrive at reported net revenues, which relate to differences between amounts billed and corresponding amounts estimated to be subsequently collected. These third-party payor discounts and sales allowances are estimated based on a number of assumptions and factors, including historical payment trends, seasonality associated with the annual reset of patient deductible limits on January 1 of each year, and current and estimated future payments. The estimates of amounts that will ultimately be realized from commercial diagnostic services require significant judgment by us. Patients do not enter into direct agreements with us that commit them to pay any portion of the cost of the tests in the event that they have not met their annual deductible limit under their insurance policy, if any, or if their insurance otherwise declines to reimburse us. Adjustments to the estimated payment amounts are recorded at the time of final collection and settlement of each transaction as an adjustment to net revenue.

Costs and Expenses

We classify our costs and expenses into four categories: cost of revenues, research and development, sales and marketing, and general and administrative. Our costs and expenses principally consist of facility costs and overhead, personnel costs, outside services and consulting costs, laboratory consumables, development costs, and legal fees.

Cost of Revenues. Our cost of revenues consists principally of facility costs and overhead, personnel costs, and laboratory and manufacturing supplies and materials. We are pursuing various strategies to reduce and control our cost of revenues, including automating aspects of our processes, developing more efficient technology and methods, and attempting to negotiate improved terms and volume discounts with our suppliers.

Research and Development Expenses. We incur research and development expenses principally in connection with our efforts to develop and improve our tests. Our primary research and development expenses consist of direct personnel costs, laboratory equipment and consumables, and overhead expenses. We anticipate that research and development expenses will increase in the near-term, principally to develop and validate tests in our pipeline and to perform work associated with clinical utility studies, including the FORESEE study for CNSide, and development collaborations. In addition, we expect that our costs related to collaborations with research and academic institutions will increase. All research and development expenses are charged to operations in the periods in which they are incurred.

Sales and Marketing Expenses. During the periods presented, our sales and marketing expenses consisted principally of personnel and related overhead costs for our sales team and their support personnel, travel and entertainment expenses, and other selling costs including sales collaterals and trade shows. In January 2023 as part of a reduction in force that was completed in the first quarter of 2023, we eliminated our field-based sales force in an effort to conserve our cash resources. Once we have adequate resources to do so, as part of our business strategy, we plan to hire and develop a field-based sales force to educate physicians directly on the benefits of our assays and the clinical data supporting them, as well as provide support to and serve as technical specialists for our partners, which will increase our sales and marketing expenses.

General and Administrative Expenses. General and administrative expenses consist principally of personnel-related expenses, professional fees, such as legal, accounting and business consultants, insurance costs, and other general expenses. We expect that our general and administrative expenses will remain relatively flat for the foreseeable future.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reported periods. While we believe these estimates are reasonable and consistent, they are by their very nature estimates of amounts that will depend on future events. Accordingly, actual results could differ from these estimates. Our Audit Committee periodically reviews our significant accounting policies. Our critical accounting policies arise in conjunction with the following:

- revenue recognition;
- stock-based compensation; and
- going concern.

Revenue Recognition

We initiate a revenue transaction when we receive a requisition order to perform a diagnostic test. The information provided on the requisition form is used to determine the party that will be billed for the testing performed and the expected reimbursement. We recognize revenue and satisfy our performance obligation for services rendered when the testing process is complete, and associated results are reported. Revenues flow from clients, patients, Medicare and Medicaid and other third-party payors. We consider negotiated discounts and anticipated adjustments, including historical collection experience for the payor portfolio, when revenues are recorded.

The following are descriptions of our payors:

Clients

Client payors represent the portion of revenue related to physicians, hospitals, health systems, accountable care organizations, employers and other entities where payment is received exclusively from the entity ordering the testing service.

Patients

Patient revenues include revenue from uninsured patients and member cost-share for insured patients (e.g., coinsurance, deductibles and non-covered services). Uninsured patients are billed based upon our fee schedules. We bill insured patients as directed by their health plan and after consideration of the fees and terms associated with an established health plan contract.

Medicare and Medicaid

Medicare and Medicaid revenues are received from traditional Medicare and Medicaid programs. Net revenue from these programs is based on the fee schedule established by the related government authority. In addition, other adjustments including anticipated payor denials are considered when determining net revenue. Any remaining adjustments to revenue are recorded at the time of final collection and settlement. These adjustments are not material to our results of operations in any period presented.

Third Party

Third party includes revenue related to insurance companies. Most of our third-party revenue is reimbursed on a fee-for-service basis. These payors are billed based on our established list price and revenue is recorded net of contractual discounts. Revenues are recorded based upon contractually negotiated fee schedules, with revenues for non-contracted managed care organizations recorded based on historical reimbursement experience.

Revenue Recognition and Related Reserves

Our commercial revenues are generated from diagnostic services provided to patient's physicians and billed to third-party insurance payors such as managed care organizations, Medicare and Medicaid and patients for any deductibles, coinsurance or copayments that may be due. We recognize revenue in accordance with ASC 606, Revenue from Contracts with Customers, or ASC 606, which requires that an entity recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services.

Contracts

For our commercial revenues, while we market directly to physicians, our customer is the patient. Patients do not enter into direct agreements with us, however, a patient's insurance coverage requirements would dictate whether or not any portion of the cost of the tests would be patient responsibility. Accordingly, we establish a contract with a commercial patient in accordance with other customary business practices, as follows:

- Approval of a contract is established via the order and accession, which are submitted by the patient's physician.
- We are obligated to perform our diagnostic services upon receipt of a sample from a physician, and the patient and/or applicable payor are obligated to reimburse us for services rendered based on the patient's insurance benefits.
- Payment terms are a function of a patient's existing insurance benefits, including the impact of coverage decisions with CMS and applicable reimbursement contracts established between us and payors, unless the patient is a self-pay patient, whereby we bill the patient directly after the services are provided.

- Once we deliver a patient's assay result to the ordering physician, the contract with a patient has commercial substance, as we are legally able to collect payment and bill an insurer and/or patient, regardless of payor contract status or patient insurance benefit status.
- Consideration associated with commercial revenues is considered variable and constrained until fully adjudicated, with net revenues recorded to the extent that it is probable that a significant reversal will not occur.

Our development services revenues are supported by contractual agreements and generated from assay development services provided to entities, as well as certain other diagnostic services provided to physicians, and revenues are recognized upon delivery of the performance obligations in the contract.

Performance Obligations

A performance obligation is a promise in a contract to transfer a distinct good or service, or a bundle of goods or services, to the customer. For our commercial and development services revenues, our contracts have a single performance obligation, which is satisfied upon rendering of services, which culminates in the delivery of a patient's assay result(s) to the ordering physician or entity. The duration of time between accession receipt and delivery of a valid assay result to the ordering physician or entity is typically less than two weeks, and for our RT-PCR COVID-19 testing, was typically 48 hours or less. Accordingly, we elected the practical expedient and therefore, we do not disclose the value of unsatisfied performance obligations.

Transaction Price

The transaction price is the amount of consideration that we expect to collect in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties, such as sales taxes. The consideration expected from a contract with a customer may include fixed amounts, variable amounts, or both. Our gross commercial revenues billed, and corresponding gross accounts receivable, are subject to price concessions to arrive at reported net revenues, which relate to differences between amounts billed and corresponding amounts estimated to be subsequently collected and is deemed to be variable although the variability is not explicitly stated in any contract. Rather, the variability is due to several factors, such as the payment history or lack thereof for third-party payors, reimbursement rate changes for contracted and non-contracted payors, any patient co-payments, deductibles or compliance incentives, the existence of secondary payors and claim denials. We estimate the amount of variable consideration using the most likely amount approach to estimating variable consideration for third-party payors, including direct patient bills, whereby the estimated reimbursement for services is established by payment histories on CPT codes for each payor, or similar payor types. When no payment history is available, the value of the account is estimated at Medicare rates, with additional other payor-specific reserves taken as appropriate. Collection periods for billings on commercial revenues range from less than 30 days to several months, depending on the contracted or non- contracted nature of the payor, among other variables. The estimates of amounts that will ultimately be realized from commercial diagnostic services for non-contracted payors require significant judgment by management.

We limit the amount of variable consideration included in the transaction price to the unconstrained portion of such consideration. Revenue is recognized up to the amount of variable consideration that is not subject to a significant reversal until additional information is obtained or the uncertainty associated with the additional payments or refunds is subsequently resolved. Differences between original estimates and subsequent revisions, including final settlements, represent changes in the estimate of implicit price concessions and are included in the period in which such revisions are made. We monitor our estimates of transaction price to depict conditions that exist at each reporting date. If we subsequently determine that we will collect more consideration than we originally estimated for a contract with a customer, we will account for the change as an increase in the estimate of the transaction price in the period identified as an increase to revenue. Similarly, if we subsequently determine that the amount we expect to collect from a customer is less than we originally estimated, we will generally account for the change as a decrease in the estimate of the transaction price in the period identified as a decrease to revenue.

Allocate Transaction Price

For our commercial revenues, the entire transaction price is allocated to the single performance obligation contained in a contract with a customer. For our development services revenues, the contracted transaction price is allocated to each single performance obligation contained in a contract with a customer as performed.

Point-in-time Recognition

Our single performance obligation is satisfied at a point in time, and that point in time is defined as the date a patient's successful assay result is delivered to the patient's ordering physician or entity. We consider this date to be the time at which the patient obtains control of the promised diagnostic assay service.

Contract Balances

The timing of revenue recognition, billings and cash collections results in accounts receivable recorded in our balance sheets. Generally, billing occurs subsequent to delivery of a patient's test result to the ordering physician or entity, resulting in an account receivable.

Practical Expedients

We do not adjust the transaction price for the effects of a significant financing component, as at contract inception, we expect the collection cycle to be one year or less.

We expense sales commissions when incurred because the amortization period is one year or less, which are recorded within sales and marketing expenses.

We incur certain other costs that are incurred regardless of whether a contract is obtained. Such costs are primarily related to legal services and patient communications. These costs are expensed as incurred and recorded within general and administrative expenses.

Stock-Based Compensation

We account for stock-based compensation under the provisions of ASC 718, Compensation—Stock Compensation, which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors based on estimated fair values on the grant date. We estimate the fair value of stock option awards on the date of grant using the Black-Scholes option pricing model, or Black-Scholes valuation model. The fair value of RSUs is determined by the price of our common stock on the date of grant. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods using the straight-line method. In addition, forfeitures are recorded when incurred.

Going Concern

We assess and determine our ability to continue as a going concern under the provisions of ASC Topic 205-40, Presentation of Financial Statements—Going Concern, which requires us to evaluate whether there are conditions or events that raise substantial doubt about our ability to continue as a going concern within one year after the date that our annual and interim financial statements are issued. Certain additional financial statement disclosures are required if such conditions or events are identified. If and when an entity's liquidation becomes imminent, financial statements should be prepared under the liquidation basis of accounting.

Determining the extent, if any, to which conditions or events raise substantial doubt about our ability to continue as a going concern, or the extent to which mitigating plans sufficiently alleviate any such substantial doubt, as well as whether or not liquidation is imminent, requires significant judgment by us. We have determined that it is probable based on projected cash flows that substantial doubt about our ability to continue as a going concern exists for the one-year period following the date that the financial statements for the year ended December 31, 2022 were issued. We currently expect that our existing resources will only be sufficient to fund our planned operations and expenditures into the third quarter of 2023. Management intends to continue its efforts to contain costs and to raise additional capital until we can generate sufficient cash from commercial sales to support operations, if ever.

Results of Operations

Years Ended December 31, 2022 and 2021

The following table sets forth certain information concerning our results of operations for the periods shown (in thousands):

	For the years ended December 31,		Change	
	2022	2021	$	%
Net revenues	$ 25,858	$ 61,249	$ (35,391)	(58%)
Costs and expenses:				
Cost of revenues	28,440	37,764	(9,324)	(25%)
Research and development expenses	6,161	4,960	1,201	24%
General and administrative expenses	16,113	12,614	3,499	28%
Sales and marketing expenses	7,127	8,320	(1,193)	(14%)
Total costs and expenses	57,841	63,658	(5,817)	(9%)
Loss from operations	(31,983)	(2,409)	(29,574)	1,228%
Other (expense):				
Interest expense, net	(316)	(290)	(26)	9%
Other income, net	87	-	87	100%
Total other (expense):	(229)	(290)	61	(21%)
Loss before income taxes	(32,212)	(2,699)	(29,513)	1,093%
Income tax benefit (expense)	125	(125)	250	(200%)
Net loss	(32,087)	(2,824)	(29,263)	1,036%
Net loss attributable to common shareholders	$ (32,087)	$ (2,824)	$ (29,263)	1,036%

Net Revenues

Net revenues were approximately $25.9 million for the year ended December 31, 2022, compared with approximately $61.2 million for the year ended December 31, 2021. The composition of our net revenues recognized during the years ended December 31, 2022 and 2021, disaggregated by source and upon delivery, are as follows (in thousands):

	For the year ended December 31,			
	2022	2021	Change	%
Net revenues from non-contracted payors	$ 17,612	$ 25,671	$ (8,059)	(31%)
Net revenues from contracted payors*	8,004	35,260	$ (27,256)	(77%)
Net commercial revenues	25,616	60,931	(35,315)	(58%)
Development services revenues	240	147	93	63%
Kits and Specimen Collection Tubes (SCTs)	2	171	(169)	(99%)
Total net revenues	$ 25,858	$ 61,249	$ (35,391)	(58%)

*Includes Medicare and Medicare Advantage as reimbursements are fixed.

The 58% decrease in net commercial revenues was attributable to decreased accession volumes related to RT-PCR COVID-19 testing and changes in implicit price concessions due to payor class changes. Total commercial accessions delivered for the years ended December 31, 2022 and 2021 were 294,182 and 532,520, respectively.

The net estimated revenue per commercial accession delivered during the year ended December 31, 2022 was $87 per commercial accession delivered while during the year ended December 31, 2021 it was approximately $115 per commercial accession delivered. The decrease in revenue per commercial accession delivered, as compared to the prior year, is primarily the result of lower reimbursement rates related to our RT-PCR COVID-19 testing, results of payor-mix and change in implicit price concessions.

The following table sets forth certain information regarding commercial accessions and development services cases delivered during the years ended December 31, 2022 and 2021, as follows:

	Year ended December 31,		Change	
	2022	2021	#/ $	%
# Commercial accessions delivered	294,182	532,520	(238,338)	(45%)
$ Value estimated per commercial accession delivered	$ 87	$ 115	$ (28)	(24%)

Overall development revenue increased slightly compared with the same period in the prior year due to higher average value per development accession delivered. The following table sets forth certain information regarding development cases delivered during the years ended December 31, 2022 and 2021:

	Year ended December 31,		Change	
	2022	2021	#/ $	%
# Development services cases delivered	420	468	(48)	(10%)
$ Value estimated per development accession delivered	$ 318	$ 314	$ 4	1%

Costs and Expenses

Cost of Revenues. Cost of revenues was approximately $28.4 million for the year ended December 31, 2022, compared with approximately $37.8 million for the year ended December 31, 2021. The decrease is primarily due to a decrease in our RT-PCR COVID-19 testing volume, including a $6.8 million decrease in direct materials and supplies, and a $2.8 million decrease in PCR COVID-19 related labor and kit costs. Cost of revenues are comprised of, but not limited to, expenses related to personnel costs, materials, supplies, and other direct cost, as well as equipment depreciation and software amortization expense. Our cost of revenues as a percentage of net revenues was 110% and 62% for the years ended December 31, 2022 and 2021, respectively.

Research and Development Expenses. Research and development expenses were approximately $6.2 million for year ended December 31, 2022, compared with approximately $5.0 million for the year ended December 31, 2021. Research and development expenses in 2022 related to costs associated with our FORESEE clinical trial, including $0.7 million of costs incurred related to work performed by our Contract Research Organization or "CRO", and an increase in materials and supplies of $0.4 million. Research and development expenses in 2021 primarily related to materials used in our laboratory to advance our research programs. Research and development expenses are comprised of, but not limited to, personnel costs, material, shipping and other direct costs, computer and laboratory equipment maintenance and facility related costs.

General and Administrative Expenses. General and administrative expenses were approximately $16.1 million for the year ended December 31, 2022, compared with approximately $12.6 million for the year ended December 31, 2021. General and administrative expenses were comprised of, but not limited to, personnel costs, facilities, depreciation, repairs and maintenance costs, stock-based compensation expenses, patent and legal costs, accounting and audit fees, as well as insurance, office and other expenses. The increase is predominately due to an increase in severance and stock-based compensation expenses of approximately $0.9 million and $1.1 million, respectively, due to the resignation of our former Chief Executive Officer and Chief Financial Officer and complying with the terms of their separation agreements, which required, among other terms, payment of salary, annual bonus, COBRA premiums and an acceleration of stock options previously granted. Furthermore, audit and accounting fees increased by approximately $0.9 million due to additional internal control review services performed and an increase in fees for the year end audit and interim reviews. Legal expenses increased by approximately $0.4 million due to increased services for SEC filings as well as legal costs associated with the sales commission settlement. Consulting service expenses increased by $0.4 million due to accounting consulting services utilized.

Sales and Marketing Expenses. Sales and marketing expenses were approximately $7.1 million for the year ended December 31, 2022, compared with approximately $8.3 million for the year ended December 31, 2021. Sales and marketing expenses were comprised of, but not limited to, personnel costs, which included commissions, trade show and other marketing related expenses, as well as office and other costs. The decrease is primarily due to a decrease of $1.1 million of commission related expenses due to less sales representatives and overall lower revenue volume to earn commissions against.

Interest Expenses, net. Interest expenses, net were approximately $0.3 million for each of the years ended December 31, 2022 and 2021.

Income Tax Expense

Except as disclosed below, over the past several years we have generated operating losses in all jurisdictions in which we may be subject to income taxes. As a result, we have accumulated significant net operating losses and other deferred tax assets. Because of our history of losses and the uncertainty as to the realization of those deferred tax assets, a full valuation allowance has been recognized.

We have not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation, due to the complexity and cost associated with such a study, and the fact that there may be additional ownership changes in the future, however, we believe multiple ownership changes likely occurred. As a result, we have estimated that the use of our net operating loss is limited and the remaining net operating loss carryforwards and research and development credits we estimate can be used in the future remain fully offset by a valuation allowance to reduce the net asset to zero.

Inflation

We do not believe that inflation has had a material adverse impact on our business or operating results during the periods presented.

Liquidity and Capital Resources

As of December 31, 2022, our cash totaled $12.9 million.

Cash Flows

Our net cash flow from operating, investing and financing activities for the periods below were as follows (in thousands):

	For the year ended December 31,	
	2022	2021
Cash provided by (used in):		
Operating activities	$ (13,289)	$ 3,690
Investing activities	(807)	(1,572)
Financing activities	(1,871)	12,378
Net increase (decrease) in cash	$ (15,967)	$ 14,496

Operating Activities. Net cash used in operating activities was approximately $13.3 million for the year ended December 31, 2022, compared with net cash provided by operating activities of approximately $3.7 million for the year ended December 31, 2021. The cash used in operations for the year ended December 31, 2022 was primarily related to our net loss in operations of $32.1 million. Exclusive of our non-cash transactions such as depreciation, amortization and stock-based compensation, cash used in operations was primarily due to a reduction of our accounts payable of $5.8 million based on timing of payments attributable to legal, accounting, and audit fees, rent, as well as payments related to the sales commissions settlement of $1.7 million, a reduction of our accrued liabilities of $0.8 million and a reduction in accounts receivables of $11.6 million primarily due to overall reduction in revenue.

Investing Activities. Net cash used in investing activities was approximately $0.8 million for the year ended December 31, 2022, compared to net cash used in investing activities of approximately $1.6 million for the year ended December 31, 2021. Our cash used in investing activities relates to lab equipment purchases.

Financing Activities. Net cash used in financing activities was approximately $1.9 million for the year ended December 31, 2022, compared with net cash provided by financing activities of approximately $12.4 million for the year ended December 31, 2021. Our primary outflows of cash from financing activities during year ended December 31, 2022 consisted of $0.8 million of supplier financing payments and $1.3 million of finance lease payments for equipment used in our laboratory operations. This is offset by net cash proceeds of $0.2 million from issuance of common stock from our at-the-market equity facility.

Liquidity, Capital Resources and Material Cash Requirements

We expect to continue to incur substantial operating losses in the future. We expect that we will use the net proceeds from our sale of equity securities, if any, cash received from the licensing of our technology, if any, and our revenues from operations to hire sales and marketing personnel, support increased sales and marketing activities, fund further research and development, clinical utility studies and future enhancements of our assays, acquire equipment, implement automation and scale our capabilities to prepare for significant assay volume, for general corporate purposes and to fund ongoing operations and the expansion of our business, including the increased costs associated with expanded commercial activities. We may also use the net proceeds from our sale of equity securities, if any, cash received from the licensing of our technology, if any, and our revenues from operations to acquire or invest in businesses, technologies, services or products, although we do not have any current plans to do so.

In May 2021, we entered into the Sales Agreement with the Sales Agent, under which we may issue and sell from time to time up to $25.0 million of our common stock through or to the Sales Agent, as sales agent or principal. Sales of our common stock under the Sales Agreement are made at market prices by any method that is deemed to be an “at the market offering” as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended. During the year ended December 31, 2022, we received net proceeds of approximately $0.2 million from the sale of our common stock and issued 219,910 shares of our common stock at a weighted average price of $1.29 pursuant to the Sales Agreement. We are not eligible to use Form S-3 as of the filing of this Annual Report on Form 10-K and consequently may not make any further sales under the Sales Agreement unless and until we file, and the SEC has declared effective, a new shelf registration statement on Form S-3.

As of December 31, 2022, our cash totaled $12.9 million.

We can provide no assurances that any sources of a sufficient amount of financing will be available to us on favorable terms, if at all. If we are unable to raise a sufficient amount of financing in a timely manner, we would likely need to further scale back our general and administrative activities and certain of our research and development activities. Our forecast pertaining to our current financial resources and the costs to support our general and administrative and research and development activities are forward-looking statements and involve risks and uncertainties. Actual results could vary materially and negatively as a result of a number of factors, including:

- our ability to secure financing and the amount thereof;
- the costs of operating and enhancing our laboratory facilities;
- the costs of developing our anticipated internal sales and marketing capabilities;
- the scope, progress and results of our research and development programs, including clinical utility studies;
- the scope, progress, results, costs, timing and outcomes of the clinical utility studies for our diagnostic assays;
- our ability to manage the costs for manufacturing our microfluidic channels;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- our ability to obtain adequate reimbursement from governmental and other third-party payors for our assays and services;
- the costs of additional general and administrative personnel, including accounting and finance, legal and human resources, as a result of becoming a public company;
- our ability to collect revenues; and
- other risks discussed in our other filings with the SEC.

To fund our current and planned operations in the short-term (within the next 12 months) and long-term (beyond 12 months), we may seek to raise additional capital through public or private equity offerings, debt financings, borrowings or strategic partnerships coupled with an investment in our company or a combination thereof. If we raise additional funds through the issuance of convertible debt securities, or other debt securities, these securities could be secured and could have rights senior to those of our common stock. In addition, any new debt incurred by us could impose covenants that restrict our operations. The issuance of any new equity securities will also dilute the interest of our current stockholders. Given the risks associated with our business, including our unprofitable operating history and our ability or inability to develop additional assays, additional capital may not be available when needed on acceptable terms, or at all. There is no assurance that we will be able to raise adequate funds when needed or on favorable terms. If adequate funds are not available when needed, we will need to delay, scale back or discontinue one or more product development programs, curtail our commercialization activities, significantly reduce expenses, sell assets (potentially at a discount to their fair value or carrying value), enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop or commercialize independently, pursue an acquisition of our company at a price that may result in a significant loss on investment to our stockholders, file for bankruptcy, seek other protection from creditors, or liquidate all of our assets.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

As a “smaller reporting company,” we are not required to provide the information under this item.

Item 8. Financial Statements and Supplementary Data

Biocept, Inc.
Index to Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Biocept, Inc.

Opinion on the Financial Statements
We have audited the accompanying balance sheet of Biocept, Inc. (the Company) as of December 31, 2022, the related statements of operations, stockholders' equity and cash flows, for the year then ended, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

Going Concern
The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations, declining revenues and negative cash flows from operations. The Company is working towards commercial expansion of its proprietary clinical diagnostics laboratory assays and will require additional capital to continue its expansions and to fund its operations. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion
These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matters
The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Revenue and Accounts Receivable
As discussed in Note 3 to the financial statements, the Company generates revenues from diagnostic services provided to patient's physicians and billed to third-party insurance payers such as managed care organizations, Medicare and Medicaid and patients for any deductibles, coinsurance or copayments that may be due. The Company's net revenue was $25.9 million and accounts receivable was $2.2 million for the year ended December 31, 2022. Revenues are recorded using payor-specific transaction prices based on amounts in effect or contractually agreed by Medicare, Medicaid, third-party and patient payors, and are adjusted for estimated implicit price concessions, to reflect the net revenues which the Company expects to receive. The Company utilizes historical reimbursement experience to determine the estimated implicit price concessions.

We identified the evaluation of the implicit price concession estimate as a critical audit matter. Complex and subjective auditor judgment was required to evaluate the historical collection experience.

Our audit procedures related to management's estimate of the implicit price concessions used to determine the value of net revenue and accounts receivable included the following, among others:

- We evaluated the methods and assumptions used by management to estimate the implicit price concessions by:
  - Testing the historical cash collections data by payor to evaluate whether the inputs to management's estimate were reasonable.
  - Comparing management's prior-year estimate to current year actual collection results.
  - Obtaining subsequent cash collections and evaluating the reasonableness of accounts receivable recorded as of December 31, 2022 by comparing to expected cash collections through the subsequent collection period.
  - Evaluating the reasonableness of accounts receivable remaining after a period of subsequent collections based on historical cash collection trends and reimbursement rates.

/s/ RSM US LLP

We have served as the Company's auditor since 2022.

Dallas, Texas
April 17, 2023

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of **Biocept, Inc.**

Opinion on the Financial Statements

We have audited the accompanying balance sheet of Biocept, Inc. (“Company”) as of December 31, 2021, and the related statements of operations and comprehensive loss, shareholders’ equity and cash flows for the year ended December 31, 2021, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021, and the results of its operations and its cash flows for the year ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Revenue Recognition and Accounts Receivable

As described in Note 3 to the financial statements, the Company's revenues are generated from diagnostic services provided to patient’s physicians and billed to third-party insurance payers such as managed care organizations, Medicare and Medicaid and patients for any deductibles, coinsurance or copayments that may be due. The Company’s gross revenues billed, and corresponding gross accounts receivable, represent variable consideration subject to estimated deductions for allowances and reserves to derive reported net revenues and receivables, which relate to differences between amounts billed and corresponding amounts estimated to be subsequently collected. The Company estimates the amount of variable consideration using the most likely amount approach to estimating variable consideration for third-party payers, including direct patient bills, whereby the estimated reimbursement for services are established based on published reimbursement rates from Medicare and Medicaid by

payment histories on Current Procedural Terminology, or CPT, codes for each payer, or similar payer types. The estimates of amounts that will ultimately be realized from commercial diagnostic services require significant judgment.

We identified auditing the measurement of the Company's transaction price for revenue recognition and the corresponding valuation of accounts receivable as a critical audit matter. The principal consideration for our determination that performing procedures relating to the transaction price for revenue, and corresponding net accounts receivable, is a critical audit matter is the significant judgment by management in estimating the amount to be collected, which in turn led to significant auditor judgment, subjectivity and effort in performing procedures and evaluating audit evidence for revenue recognition and net accounts receivable.

The primary procedures we performed to address this critical audit matter included:

- Evaluating the appropriateness of the methods used, by evaluating management's process for developing the estimated transaction price which includes related reserves, as well as the accuracy and relevance of the historical billing and collection data used as an input to derive the estimated transaction price.
- Testing the accuracy of the estimated transaction price for a sample of revenue transactions from the historical billing data and historical collection data used in management's estimation of the transaction price, including agreeing the revenue transactions selected to supporting documentation such as physician requisition, cash collected, and delivery of final reports, as applicable.
- Identifying and evaluating the significant assumptions used in developing the reserves estimate, including:
    - Evaluating the historical accuracy of management's process for developing the estimate of the amount which will ultimately be collected by comparing actual cash collections to the previously recorded transaction price and the net accounts receivable balance.
    - Analyzing the subsequent cash collections of the accounts receivable recorded at December 31, 2021.
    - Evaluated the remaining accounts receivable balances as of December 31, 2021 which have not been collected by developing an independent expectation of the net accounts receivable balance, by payer, based on historical collection trends.

Management's Assessment over Going Concern

The Company's financial statements have been prepared on the going concern basis, which contemplates the continuity of normal business activities and the realization of assets and settlement of liabilities in the normal course of business. As discussed in Note 2 to the financial statements, the Company's COVID-19 testing revenue has provided the Company with increased levels of cash inflows from operations, and therefore increased liquidity. As a result, the Company believes that based on its current and planned cash flow and liquidity needs, its cash balances along with projected COVID-19 testing revenue will be sufficient to support operations for at least one-year from the issuance date of these financial statements. As such, the Company determined that the current facts and circumstances do not indicate it is probable that substantial doubt about the Company's ability to continue as a going concern exists for the one year period following the date that the financial statements for the year ended December 31, 2021 are issued.

We identified the Company's assessment of the current indicators and their impact on the Company's ability to continue as a going concern and the related disclosures as a critical audit matter. The principal considerations for our determination include the high degree of management subjectivity in determining significant assumptions included in the Company's estimation of future cash flows, specifically management's estimates related to COVID-19 diagnostic testing revenues and related costs. Performing audit procedures and evaluating audit evidence obtained related to these considerations required a high degree of auditor judgment and effort.

The primary procedures we performed to address this critical audit matter included:

- Obtaining an understanding of management's process to develop their estimates included in the cash flow projections used to perform the going concern assessment. We also evaluated the design of certain controls used by management to develop their estimates.

- Assessing the reasonableness of the forecasted revenue and operating expenses in management's going concern assessment of whether the Company projects to have sufficient liquidity to fund operations for at least one year from the financial statement issuance date. This assessment included:
    - Evaluating management's estimates with respect to projected COVID-19 diagnostic testing demand during the going concern assessment period in relation to historical demand and the changing demand for COVID-19 testing.
    - Performing sensitivity analyses to evaluate the impact of lower than projected demand for COVID-19 testing revenues on management's projections.
    - Evaluating management's intent and ability to manage costs and liquidity if the actual demand for COVID-19 testing revenues are less than the demand projected by management.
    - Evaluating management's cash flow projections with recent experience, taking into account changes in conditions and events affecting the Company, and whether other evidence obtained in other areas of the audit supported or contradicted the conclusions reached by management.
- Evaluating the adequacy of the Company's disclosures in Note 2 in relation to the going concern assessment.

We served as the Company's auditor from 2005 to 2022.

/s/ Mayer Hoffman McCann P.C.

San Diego, California
April 5, 2022

Biocept, Inc.
Balance Sheets
(in thousands, except share and per share data)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash	$ 12,897	$ 28,864
Accounts receivable	2,151	13,786
Inventories, net	757	2,651
Prepaid expenses and other current assets	538	391
Total current assets	16,343	45,692
Fixed assets, net	2,572	2,401
Lease right-of-use asset - operating	8,486	9,026
Lease right-of-use assets - finance	3,086	2,842
Other non-current assets	386	456
Total assets	$ 30,873	$ 60,417
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,523	$ 7,246
Accrued liabilities	2,249	3,018
Current portion of lease liability - operating	518	426
Current portion of lease liabilities - finance	1,099	1,083
Supplier financing	117	-
Total current liabilities	5,506	11,773
Non-current portion of lease liability - operating	9,175	9,736
Non-current portion of lease liabilities - finance	1,200	1,428
Payor liability	6,132	-
Total liabilities	22,013	22,937
Commitments and contingencies (see Note 13)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 5,000,000 shares authorized; 2,090 shares and 2,106 shares issued and outstanding at December 31, 2022 and 2021, respectively.	—	—
Common stock, $0.0001 par value, 150,000,000 shares authorized; 17,070,071 shares and 16,849,805 shares issued and outstanding at December 31, 2022 and 2021, respectively.	2	2
Additional paid-in capital	307,296	303,829
Accumulated deficit	(298,438)	(266,351)
Total stockholders' equity	8,860	37,480
Total liabilities and stockholders' equity	$ 30,873	$ 60,417

The accompanying notes are an integral part of these financial statements.

Biocept, Inc.
Statements of Operations
(in thousands, except shares and per share data)

	For the years ended December 31,	
	2022	2021
Net revenues	$ 25,858	$ 61,249
Costs and expenses:		
Cost of revenues	28,440	37,764
Research and development expenses	6,161	4,960
General and administrative expenses	16,113	12,614
Sales and marketing expenses	7,127	8,320
Total costs and expenses	57,841	63,658
Loss from operations	(31,983)	(2,409)
Other (expense):		
Interest expense, net	(316)	(290)
Other income, net	87	-
Total other (expense):	(229)	(290)
Loss before income taxes	(32,212)	(2,699)
Income tax benefit (expense)	125	(125)
Net loss	(32,087)	(2,824)
Net loss attributable to common shareholders	$ (32,087)	$ (2,824)
Weighted-average shares outstanding used in computing net loss per share attributable to common shareholders:		
Basic	16,953,812	14,775,805
Diluted	16,953,812	14,775,805
Net loss per common share:		
Basic	$ (1.89)	$ (0.19)
Diluted	$ (1.89)	$ (0.19)

The accompanying notes are an integral part of these financial statements.

Biocept, Inc.
Statements of Stockholders' Equity
(in thousands, except for shares)

	Common Stock		Series A Convertible Preferred Stock		Additional	Accumulated	
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Total
Balance at December 31, 2020	13,397,041	$1	2,111	$—	$287,218	$(263,527)	$23,692
Stock-based compensation expense	—	—	—	—	2,462	—	2,462
Shares issued upon exercise of common stock warrants	7,212	—	—	—	28	—	28
Shares issued upon cashless exercise of common stock warrants	16,200	—	—	—	—	—	—
Shares issued for ATM transaction, net of issuance costs	3,428,680	1	—	—	14,119	—	14,120
Shares issued upon exercise of stock options	537	—	—	—	2	—	2
Shares issued upon conversion of preferred stock	135	—	(5)	—	—	—	—
Net loss	—	—	—	—	—	(2,824)	(2,824)
Balance at December 31, 2021	16,849,805	$2	2,106	$—	$303,829	$(266,351)	$37,480
Stock-based compensation expense	—	—	—	—	3,227	—	3,227
Shares issued for ATM transaction, net of issuance costs	219,910	—	—	—	240	—	240
Shares issued upon conversion of preferred stock	356	—	(16)	—	—	—	—
Net loss	—	—	—	—	—	(32,087)	(32,087)
Balance at December 31, 2022	17,070,071	$2	2,090	$—	$307,296	$(298,438)	$8,860

The accompanying notes are an integral part of these financial statements.

Biocept, Inc.
Statements of Cash Flows
(in thousands)

	For the years ended December 31, 2022	2021
Cash Flows from Operating Activities		
Net loss	$ (32,087)	$ (2,824)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	1,655	1,530
Noncash operating lease expense	540	1,107
Stock-based compensation	3,227	2,462
Loss on disposal of fixed assets	9	4
Non-cash credit card rewards	82	-
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	11,636	358
Inventory	1,894	(721)
Landlord reimbursement	-	1,856
Prepaid expenses and other current assets	693	505
Other non-current assets	28	(29)
Accounts payable	(5,860)	(411)
Accrued liabilities	(770)	(147)
Operating lease liability	(468)	-
Payor liability	6,132	-
Net cash (used in) provided by operating activities	(13,289)	3,690
Cash Flows from Investing Activities:		
Purchases of fixed assets	(807)	(1,572)
Net cash used in investing activities	(807)	(1,572)
Cash Flows from Financing Activities:		
Net proceeds from issuance of common stock	240	14,120
Proceeds from exercise of common stock warrants	-	28
Proceeds from exercise of stock options	-	2
Payments on finance leases	(1,305)	(1,150)
Payments on supplier financing	(806)	(622)
Net cash (used in) provided by financing activities	(1,871)	12,378
Net (decrease) increase in cash	(15,967)	14,496
Cash at Beginning of Period	28,864	14,368
Cash at End of Period	12,897	28,864
Supplemental Disclosures of Cash Flow Information:		
Cash paid for interest	$ 316	$ 290

	2022	2021
Non-cash Investing and Financing Activities		
Financed insurance premiums	$ 893	$ 622
Fixed assets purchased through financed lease obligations	$ 1,049	$ 1,237
Unpaid fixed asset purchases	$ 137	$ 240

The accompanying notes are an integral part of these financial statements.

1. The Company and Business Activities

Biocept, Inc., the Company, was founded in California in May 1997 and is a molecular oncology diagnostics company that develops and commercializes proprietary circulating tumor cell and circulating cell-free tumor DNA and RNA assays utilizing a standard blood sample, or liquid biopsy. The Company's current and planned assays are intended to provide information to aid healthcare providers to identify specific oncogenic alterations that may qualify a subset of cancer patients for targeted therapy at diagnosis, progression or for monitoring to identify specific resistance mechanisms. Sometimes traditional procedures, such as surgical tissue biopsies, result in tumor tissue that is insufficient and/or unable to provide the molecular subtype information necessary for clinical decisions. The Company's assays, performed on blood and cerebral spinal fluid, have the potential to provide more contemporaneous information on the characteristics of a patient's disease when compared with tissue biopsy and radiographic imaging. Further, sales to laboratory supply distributors of the Company's proprietary SCTs commenced in June 2018, which allow for the intact transport of liquid biopsy samples for research use only, or RUO, from regions around the world.

The Company operates a clinical laboratory that is CLIA-certified (under the Clinical Laboratory Improvement Amendment of 1988) and CAP-accredited (by the College of American Pathologists), and manufactures cell enrichment and extraction microfluidic channels, related equipment and certain reagents to perform the Company's diagnostic assays in a facility located in San Diego, California. CLIA certification and accreditation are required before any clinical laboratory may perform testing on human specimens for the purpose of obtaining information for the diagnosis, prevention, treatment of disease, or assessment of health. The assays the Company offers are classified as laboratory developed tests under the CLIA regulations.

In July 2013, the Company effected a reincorporation to Delaware by merging itself with and into Biocept, Inc., a Delaware corporation, which had been formed to be and was a wholly-owned subsidiary of the Company since July 23, 2013.

The Company experienced increased revenue levels in 2022 and 2021 related to its COVID-19 testing business. In February, 2023, due to reduced demand, the Company ceased COVID-19 testing services.

2. Liquidity

As of December 31, 2022, cash totaled $12.9 million, and the Company had an accumulated deficit of $298.4 million. For the years ended December 31, 2022 and 2021, the Company incurred net losses of $32.1 million and $2.8 million, respectively.

The Company has historically funded its operations primarily through sales of its equity securities. During the year ended December 31, 2022, net revenues were approximately $25.9 million compared with approximately $61.2 million for the same period in the prior year. For the year ended December 31, 2021, revenue from the Company's COVID-19 testing business provided an increased level of cash flow. In February 2023, the Company ceased COVID-19 testing services.

The Company incurred operating losses for the year ended December 31, 2022 and 2021. The Company had net cash used to fund operations for the year ended December 31, 2022, and net cash provided by operations for the year ended December 31, 2021. The Company does not anticipate it will be profitable until, if ever, it has commercial expansion of its proprietary clinical diagnostic laboratory assays designed to identify rare tumor cells from cerebrospinal fluid, trademarked as CNSide. Accordingly, management performed the required going concern assessment and determined substantial doubt exists about the Company's ability to continue as a going concern within one year after the issuance date of this Annual Report on Form 10-K. We currently expect that our existing resources will only be sufficient to fund our planned operations and expenditures into the third quarter of 2023. Management intends to continue its efforts to contain costs, reducing staff, and to raise additional capital until it ultimately generates sufficient cash to support operations from commercial sales. Management's plans are based on events that are not within its control and therefore substantial doubt about the Company's ability to continue as a going concern has not been alleviated.

3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements and notes are prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP, and are prepared on the basis that the Company will continue as a going concern (see Note 2). The accompanying financial statements and notes do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of the Company to continue as a going concern.

Reclassification

The Company reclassified the change in inventory reserve for the year ended December 31, 2021 of approximately $0.1 million within the statement of cash flows to conform to the current year presentation. The change in inventory reserve is now included in the increase (decrease) in cash resulting from changes in inventory within the cash flows from operating activities. This reclassification had no effect on previously reported cash flows from operating activities in the statement of cash flows.

Going Concern

The Company assesses and determines its ability to continue as a going concern in accordance with the provisions of ASC Topic 205-40, Presentation of Financial Statements—Going Concern, which requires the Company to evaluate whether there are conditions or events that raise substantial doubt about its ability to continue as a going concern within one year after the date that its annual and interim financial statements are issued (see Note 2). Certain additional financial statement disclosures are required if such conditions or events are identified. If and when an entity's liquidation becomes imminent, financial statements should be prepared under the liquidation basis of accounting. Determining the extent, if any, to which conditions or events raise substantial doubt about the Company's ability to continue as a going concern, or the extent to which mitigating plans sufficiently alleviate any such substantial doubt, as well as whether or not liquidation is imminent, requires significant judgment by management.

Use of Estimates

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates these estimates and judgments, including those related to accounts receivable reserves, inventory reserves, long-lived asset impairment and useful lives, income taxes, including uncertain tax benefits, estimated transaction price for revenues, stock-based compensation, incremental borrowing rate estimates, and the determination of the Company's ability to continue as a going concern. The Company bases its estimates on various assumptions that it believes are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

Revenue Recognition and Accounts Receivable

The Company's commercial revenues are generated from diagnostic services provided to patient's physicians and billed to third-party insurance payors such as managed care organizations, Medicare and Medicaid and patients for any deductibles, coinsurance or copayments that may be due. The Company recognizes revenue in accordance with ASC 606, Revenue from Contracts with Customers, which requires that an entity recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services.

Contracts

For its commercial revenues, while the Company markets directly to physicians and other healthcare providers, the Company provides services that benefit the patient. Patients do not typically enter into direct agreements with the Company; however, a patient's insurance coverage requirements would dictate whether or not any portion of the cost of the tests would be patient responsibility. Accordingly, the Company establishes contracts with commercial insurers in accordance with customary business practices, as follows:

- Approval of a contract is established via the order and accession, which are submitted by the patient's physician.
- The Company is obligated to perform its diagnostic services upon receipt of a sample from a physician, and the patient and/or applicable payor are obligated to reimburse the Company for services rendered based on the patient's insurance benefits.

- Payment terms are a function of a patient's existing insurance benefits, including the impact of coverage decisions with the Centers for Medicare & Medicaid Services, or CMS, and applicable reimbursement contracts established between the Company and payors, unless the patient is a self-pay patient, whereby the Company bills the patient directly after the services are provided.
- Once the Company delivers a patient's assay result to the ordering physician, the contract with a patient has commercial substance, as the Company is legally able to collect payment and bill an insurer and/or patient, regardless of payor contract status or patient insurance benefit status.
- Consideration associated with commercial revenues is considered variable and constrained until fully adjudicated, with net revenues recorded to the extent that it is probable that a significant reversal will not occur.

The Company's development services revenues are supported by contractual agreements and generated from assay development services provided to entities, such as pharma or biotech organizations, as well as certain other diagnostic services provided to physicians, and revenues are recognized upon satisfaction of the performance obligations in the contract.

Performance Obligations

A performance obligation is a promise in a contract to transfer a distinct good or service, or a bundle of goods or services, to the customer. For its commercial and development services revenues, the Company's contracts have a single performance obligation, which is satisfied upon rendering of services, which culminates in the delivery of a patient's assay result(s) to the ordering physician or entity. The duration of time between accession receipt and delivery of a valid assay result to the ordering physician or entity is typically less than two weeks, and for our RT-PCR COVID-19 testing, was typically 48 hours or less. Accordingly, the Company elected the practical expedient and therefore, does not disclose the value of unsatisfied performance obligations.

Transaction Price

The transaction price is the amount of consideration that the Company expects to collect in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties, such as sales taxes. The consideration expected from a contract with a customer may include fixed amounts, variable amounts, or both. The Company's gross commercial revenues billed, and corresponding gross accounts receivable, subject to price concessions to arrive at reported net revenues, which relate to differences between amounts billed and corresponding amounts estimated to be subsequently collected and is deemed to be variable although the variability is not explicitly stated in any contract. Rather, the variability is due to several factors, such as the payment history or lack thereof for third-party payors, reimbursement rate changes for contracted and non-contracted payors, any patient co-payments, deductibles or compliance incentives, the existence of secondary payors and claim denials. The Company estimates the amount of variable consideration using the most likely amount approach to estimating variable consideration for third-party payors, including direct patient bills, whereby the estimated reimbursement for services is established by payment histories on CPT codes for each payor, or similar payor types. When no payment history is available, the value of the account is estimated at Medicare rates, with additional other payor-specific reserves taken as appropriate. Collection periods for billings on commercial revenues range from less than 30 days to several months, depending on the contracted or non- contracted nature of the payor, among other variables. The estimates of amounts that will ultimately be realized from commercial diagnostic services for non-contracted payors require significant judgment by management.

The Company limits the amount of variable consideration included in the transaction price to the unconstrained portion of such consideration. Revenue is recognized up to the amount of variable consideration that is not subject to a significant reversal until additional information is obtained or the uncertainty associated with the additional payments or refunds is subsequently resolved. Differences between original estimates and subsequent revisions, including final settlements, represent changes in the estimate of implicit price concessions and are included in the period in which such revisions are made. The Company monitors its estimates of transaction price to depict conditions that exist at each reporting date. If the Company subsequently determines that it will collect more consideration than it originally estimated for a contract with a customer, it will account for the change as an increase in the estimate of the transaction price in the period identified as an increase to revenue. Similarly, if the Company subsequently determines that the amount it expects to collect from a customer is less than it originally estimated, it will generally account for the change as a decrease in the estimate of the transaction price as a decrease to revenue.

Allocate Transaction Price

For the Company's commercial revenues, the entire transaction price is allocated to the single performance obligation contained in a contract with a customer. For the Company's development services revenues, the contracted transaction price is allocated to each single performance obligation contained in a contract with a customer as performed.

Point-in-time Recognition

The Company's single performance obligation is satisfied at a point in time, and that point in time is defined as the date a patient's successful assay result is delivered to the patient's ordering physician or entity. The Company considers this date to be the time at which the patient obtains control of the promised diagnostic assay service.

Contract Balances

The timing of revenue recognition, billings and cash collections results in accounts receivable recorded in the Company's balance sheets. Generally, billing occurs subsequent to delivery of a patient's test result to the ordering physician or entity.

Practical Expedients

The Company does not adjust the transaction price for the effects of a significant financing component, as at contract inception, the Company expects the collection cycle to be one year or less.

The Company expenses sales commissions when incurred because the amortization period is one year or less; such amounts are recorded within sales and marketing expenses.

The Company incurs certain other costs that are incurred regardless of whether a contract is obtained. Such costs are primarily related to legal services and patient communications. These costs are expensed as incurred and recorded within general and administrative expenses.

Disaggregation of Revenue and Concentration of Risk

The composition of the Company's net revenues recognized during the years ended December 31, 2022 and 2021, disaggregated by source and nature, are as follows (in thousands):

	For the year ended December 31,	
	2022	2021
Net revenues from non-contracted payors	$ 17,612	$ 25,671
Net revenues from contracted payors*	8,004	35,260
Net commercial revenues	25,616	60,931
Development services revenues	240	147
Kits and Specimen Collection Tubes (SCTs)	2	171
Total net revenues	$ 25,858	$ 61,249

*Includes Medicare and Medicare Advantage, as reimbursement amounts are fixed.

At December 31, 2022 and 2021, unbilled accounts receivable totaled approximately $0.8 million and $3.5 million, respectively.

Concentration of Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of temporary cash investments.

Concentrations of credit risk with respect to revenues are primarily limited to geographies to which the Company provides a significant volume of its services, and to specific third-party payors of the Company's services such as Medicare, insurance companies, and other third-party payors. The Company's client base consists of a large number of geographically dispersed clients diversified across various customer types.

The Company's third-party payors that represent more than 10% of total net revenues in any period presented during the years ended December 31, 2022 and 2021 were as follows:

	For the year ended December 31,	
	2022	2021
Medicare and Medicare Advantage/CARES Act	36%	56%
Blue Cross Blue Shield	16%	17%
Kaiser Permanente	16%	6%

The Company's third-party payors that represent more than 10% of total net accounts receivable as of December 31, 2022 and 2021 were as follows:

	For the year ended December 31,	
	2022	2021
Medicare and Medicare Advantage/CARES Act	5%	31%
Blue Cross Blue Shield	23%	19%

The Company operates in one reportable business segment and historically has derived most revenues only from within the United States.

Certain components used in the Company’s current or planned products are currently sourced from one supplier, for which alternative suppliers exist but the Company has not validated the product(s) of such alternative supplier(s), and substitutes for these components may not be obtained easily or may require substantial design or manufacturing modifications.

Cash

The Company places its cash with reputable financial institutions that are insured by the Federal Deposit Insurance Corporation, or FDIC. At times, deposits held may exceed the amount of insurance provided by the FDIC. The Company has not experienced any losses in its cash and believes they are not exposed to any significant credit risk.

Inventories

Inventories are valued at the lower of cost (first-in, first-out) or net realizable value. The two primary components of inventory balances are raw materials and subassemblies. Subassemblies are in process raw materials used in our laboratory operations. The Company records adjustments to its inventory for estimated obsolescence or diminution in net realizable value equal to the difference between the cost of the inventory and the estimated net realizable value. At the point of loss recognition, a new cost basis for that inventory is established, and subsequent changes in facts and circumstances do not result in the restoration or increase in that newly established cost basis. In addition, the Company records a liability for firm, non-cancelable, and unconditional purchase commitments with contract manufacturers and suppliers for quantities in excess of the Company’s future demand forecasts consistent with its valuation of excess and obsolete inventory.

Fixed Assets

Fixed assets consist of machinery and equipment, furniture and fixtures, computer equipment and software, leasehold improvements, financed equipment and construction in-process. Fixed assets are stated at cost less accumulated depreciation and amortization. Additions, improvements, and major renewals are capitalized. Maintenance, repairs, and minor renewals are expensed as incurred. Depreciation and amortization are recorded using the straight-line method over the estimated useful lives of the assets, which range from three to seven years. Leasehold improvements are amortized over the life of the lease or the asset, whichever is shorter. Depreciation and amortization expense for the years ended December 31, 2022 and 2021 was approximately $1.7 million and $1.5 million, respectively.

Upon sale or disposal of fixed assets, the accounts are relieved of the cost and the related accumulated depreciation or amortization with any gain or loss recorded to the statement of operations and comprehensive loss.

Fixed assets are reviewed for impairment whenever changes in circumstances indicate that the carrying amount of an asset may not be recoverable. These computations utilize judgments and assumptions inherent in the estimates of future cash flows to determine recoverability of these assets. If the assumptions about these assets were to change as a result of events or circumstances, the Company may be required to record an impairment loss. No material impairment losses were recorded in 2022 and 2021.

Stock-based Compensation

The Company measures and recognizes compensation expense for all stock-based awards made to employees and directors based on their grant date fair values. The Company estimates the fair value of stock option awards on the date of grant using the Black-Scholes option pricing model, while the fair value of restricted stock unit awards, or RSUs, is determined by the Company's stock price on the date of grant. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods using the straight-line method. In addition, forfeitures are recorded when incurred. The Company determines the fair value of the stock-based compensation awards granted as either the fair value of the consideration received, or the fair value of the equity instruments issued, whichever is more reliably measurable.

Calculating the fair value of stock-based awards requires the input of highly subjective assumptions into the Black-Scholes valuation model. Stock-based compensation expense is calculated using the Company's best estimates, which involves inherent uncertainties, and the application of management's judgment. Significant estimates include the expected life of the stock option, stock price volatility and risk-free interest rate.

Research and Development

Research and development costs are expensed as incurred. The amounts expensed in the years ended December 31, 2022 and 2021 were approximately $6.2 million and $5.0 million, respectively, which includes salaries of research and development personnel.

Income Taxes

The Company provides for income taxes utilizing the liability method. Under the liability method, current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is computed for the expected future impact of differences between the financial reporting and tax bases of assets and liabilities and for the expected future tax benefit to be derived from tax credits. Tax rate changes are reflected in the computation of the income tax provision during the period such changes are enacted.

Deferred tax assets are reduced by a valuation allowance when, in management's opinion, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. The Company's valuation allowance is based on available evidence, including its current year operating loss, evaluation of positive and negative evidence with respect to certain specific deferred tax assets including evaluation sources of future taxable income to support the realization of the deferred tax assets. The Company has established a full valuation allowance on the deferred tax assets as of December 31, 2022 and 2021, and therefore has not recognized any income tax benefit or expense in the periods presented for federal tax purposes. The Company did recognize income tax expense of $125,000 for the year ended December 31, 2021 for state tax purposes. That has been reversed as an income tax benefit for the year ended December 31, 2022.

A tax benefit from uncertain tax positions may be recognized by the Company when it is more-likely-than-not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits of the position. Income tax positions must meet a more-likely-than-not recognition threshold to be recognized.

The Company recognizes interest and/or penalties related to income tax matters in income tax expense. There is no accrual for interest or penalties for income taxes on the balance sheets at December 31, 2022 and 2021, and the Company has not recognized interest and/or penalties in the statements of operations and comprehensive loss for the years ended December 31, 2022 and 2021.

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments- Credit Losses*, which requires the measurement of expected credit losses for financial instruments carried at amortized cost, such as accounts receivable, held at the reporting date based on historical experience, current conditions and reasonable forecasts. The main objective of this standard is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting period. In November 2018, the FASB issued ASU 2018-19, *Codification Improvements to Topic 326, Financial Instruments- Credit Losses*, which included an amendment of the effective date. The standard is effective for the Company for annual reporting periods beginning after December 15, 2022. The Company does not expect the adoption of this standard to have a significant impact on its financial statements.

In September 2022, the FASB issued ASU 2022-04, *Liabilities-Supplier Finance Programs*, to enhance the transparency of supplier finance programs. The main objective of this standard requires a buyer in a supplier finance program to disclose sufficient information about the program to allow a user of financial statements to understand the program's nature, activity during the period, changes from period to period, and potential magnitude. The standard is effective for the Company for annual reporting periods beginning after December 15, 2022, including interim periods within those fiscal years. The Company is currently evaluating the expected impact the adoption of this standard will have on its financial statements.

4. Sales of Equity Securities

As part of a warrant repricing and exchange transaction, in January 2020, the Company issued an aggregate of 692,725 new warrants in exchange for the exercise of certain warrants issued by the Company in February 2019 and March 2019 for an aggregate of 692,725 shares of common stock and received net proceeds of approximately $2.3 million. As a result of the warrant repricing, the exercise price of warrants to purchase an aggregate of 89,657 shares of common stock issued by the Company in January 2018 was adjusted from $4.05 to $3.495 per share. In January 2020, the Company issued 192,750 shares of common stock pursuant to the partial exercise of the underwriters' overallotment option from the Company's December 2019 public offering. The net proceeds to the Company from the overallotment closing was approximately $700,000. The warrants issued in connection with the warrant repricing and exchange transaction were considered inducement warrants and are classified in equity. In addition, the modification expense associated with the change in fair value due to the repricing of February and March 2019 warrants is recorded as inducement expense, which was approximately $191,000. The fair value of the warrants issued was approximately $1.9 million. The fair value of the inducement warrants and warrant modification of $2.1 million was expensed as warrant inducement expense in the accompanying statement of operations for the year ended December 31, 2021.

On May 12, 2021, the Company entered into a Controlled Equity Offering^{SM} Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. (the "Sales Agent"), under which the Company could issue and sell from time to time up to $25,000,000 of its common stock through or to the Sales Agent, as sales agent or principal. The issuance and sale of these shares under the Sales Agreement, if any, is subject to the continued effectiveness of a shelf registration statement on Form S-3 cover the sale of such shares. Our shelf registration statement on Form S-3, filed with the SEC on April 24, 2020, is no longer available and we will not be able to file a new Form S-3 until, at the earliest, September 1, 2023. Sales of the Company's common stock, under the Sales Agreement are made at market prices by any method that is deemed to be an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended. Each time the Company wishes to issue and sell common stock under the Sales Agreement, it notifies the Sales Agent of the number of shares to be issued, the dates on which such sales are anticipated to be made and any minimum price below which sales may not be made. Once the Company has so instructed the Sales Agent, unless the Sales Agent declines to accept the terms of the notice, the Sales Agent has agreed to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell such shares up to the amount specified on such terms.

The obligations of the Sales Agent under the Sales Agreement to sell the Company's common stock are subject to a number of conditions that the Company must meet. The offering of common stock pursuant to the Sales Agreement will terminate

upon the earlier of (1) the sale of all common stock subject to the Sales Agreement and (2) termination of the Sales Agreement as permitted therein. The Sales Agreement may be terminated by either party at any time upon ten days' prior notice. The Sales Agent is entitled to compensation from the Company at a fixed commission rate equal to 3.0% of the gross sales price per share of any common stock sold under the Sales Agreement.

During 2022, the Company received net proceeds of $0.2 million from the sale of our common stock and issued 219,910 shares of our common stock at a weighted average purchase price of $1.29. During 2021, the Company received net proceeds of $14.1 million from the sale of our common stock and issued 3,428,680 shares of our common stock at a weighted average purchase price of $4.31 pursuant to the Sales Agreement.

5. Payor Liability

In March 2022, the U.S. Health Resources and Services Administration, or HRSA, informed providers that, after March 22, 2022, it would stop accepting claims for testing and treatment for uninsured individuals under the HRSA COVID-19 Uninsured Program and that claims submitted prior to that date would be subject to eligibility and availability of funds. HRSA's procedure for recouping credits due from service providers had been to net these amounts against reimbursements for services provided. Given that no further payments are expected from HRSA, there is no longer a mechanism for recoupments. The Company has therefore recorded a liability for outstanding HRSA credits which were previously netted against accounts receivable.

6. Balance Sheet Details

The following provides certain balance sheet details (in thousands):

	December 31, 2022	December 31, 2021
Inventories		
Raw materials	$ 1,564	$ 2,486
Subassemblies	401	324
Finished goods	36	42
	2,001	$ 2,852
Less: inventory reserve	(1,244)	$ (201)
Total inventories, net	$ 757	$ 2,651
Fixed Assets		
Machinery and equipment	$ 3,183	$ 3,063
Furniture and office equipment	160	161
Computer equipment and software	3,824	2,931
Leasehold improvements	689	634
Construction in process	39	245
	$ 7,895	$ 7,034
Less accumulated depreciation and amortization	(5,323)	(4,633)
Total fixed assets, net	$ 2,572	$ 2,401
Accrued Liabilities		
Accrued payroll	605	725
Accrued vacation	799	961
Accrued bonuses	90	178
Accrued sales commissions	52	600
Accrued 401(k) match	220	283
Accrued other	483	271
Total accrued liabilities	$ 2,249	$ 3,018

7. Leases

Financed Leases

The Company leases certain laboratory equipment under arrangements previously accounted for as capital leases, classified on the Company's balance sheet as fixed assets and related lease liabilities, and depreciated on a straight-line basis over the lease term. The equipment under finance leases is depreciated on a straight-line basis over periods ranging from approximately 5 to 7 years. The total gross value of equipment capitalized under such lease arrangements was approximately $7.2 million and $6.0 million at December 31, 2022 and 2021, respectively. Total accumulated depreciation related to equipment under finance leases was approximately $4.1 million and $3.2 million at December 31, 2022 and 2021, respectively. Total depreciation expense related to equipment under finance leases was approximately $0.9 million during the years ended December 31, 2022 and 2021.

During the year ended December 31, 2022, the Company entered into finance leases for a total capitalized amount of $1.1 million for three pieces of equipment. Under the terms of the financing agreements, the principal balance plus interest for the equipment are to be paid in installments of 36 to 60 monthly installments of approximately $20,000 totaling approximately $0.9 million through August 2027.

During the year ended December 31, 2021, the Company entered into finance leases for a total capitalized amount of $1.2 million for seven pieces of equipment. Under the terms of the financing agreements, the principal balance plus interest for the equipment are to be paid in installments ranging from 36 to 60 months totaling approximately $1.6 million through March 2026.

Operating Lease

On June 1, 2020, the Company entered into a lease for a 39,000 square foot headquarters, manufacturing and laboratory facility at 9955 Mesa Rim Road in San Diego, California. The lease commenced on December 1, 2020 and is for a term of 127 months from the commencement date. The lease included a rent abatement period of seven months, from January 2021 through July of 2021, during which period the Company was exempt from paying the amount of base rent of $111,000. In addition, the lease stipulated an additional two months of lease abatement period in the event that the property is sold within the first six months of the initial lease period. In March 2021, the Company was notified that the original landlord had sold the building, hence the Company was eligible for an additional two months of rent abatement period. In addition, the landlord agreed to pay for certain preapproved leasehold improvement costs through a one-time leasehold improvement allowance of approximately $1.6 million. The amount of additional leasehold improvement allowance of approximately $1.6 million is to be paid back to the landlord during the term of the lease by the Company, amortized at an agreed upon annual rate of 7% as an additional rent payment of approximately $18,000 per month. The average monthly cash payment including payment for the additional leasehold improvement allowance for the lease is approximately $140,000 per month with initial monthly lease payments of $128,000 per month. The Company recorded a lease right-of-use asset and lease liability of $9.8 million as of December 31, 2020, based on the present value of payments and an incremental borrowing rate of 12%. As the Company's lease did not provide an implicit rate, the Company estimated the incremental borrowing rate based on the credit quality of the Company and by comparing interest rates available in the market for similar borrowings. The Company recorded $1.6 million in other current assets related to reimbursable leasehold improvement costs incurred as of December 31, 2020. The landlord reimbursed the Company $1.8 million during the year ended December 31, 2021.

The following schedule represents the components of lease expense for the years ended December 31, 2022 and 2021 (in thousands):

	December 31, 2022	December 31, 2021
Lease cost		
Finance lease cost		
Amortization of right-of-use assets	$ 920	$ 863
Interest on lease liabilities	196	277
Operating lease cost	1,658	1,656
Total	$ 2,774	$ 2,796

The following schedule represents maturities of operating and finance lease liabilities as of December 31, 2022 (in thousands):

	Finance Minimum Lease Payments	Operating Minimum Lease Payments
2023	$ 1,200	$ 1,629
2024	770	1,672
2025	396	1,715
2026	192	1,762
2027	15	1,805
Thereafter	-	6,713
Total payments	2,573	15,296
Less amount representing interest	(274)	(5,603)
Present value of payments	$ 2,299	$ 9,693

The following schedule sets forth supplemental cash flow information related to operating and finance leases as of December 31, 2022 and 2021 (in thousands):

	December 31, 2022	December 31, 2021
Other information		
Operating cash flows from finance leases	$ 196	$ 277
Operating cash flows from operating lease	$ 1,586	$ 549
Financing cash flows from finance leases	$ 1,305	$ 1,150

The aggregate weighted average remaining lease term was 2.55 years on finance leases and 8.50 years on operating leases as of December 31, 2022. The aggregate weighted average discount rate was 9.07% on finance leases and 12% on the operating lease as of December 31, 2022.

8. Stock-Based Compensation

Equity Incentive Plans

The Company has two equity incentive plans: The Amended and Restated 2013 Equity Incentive Plan, or the 2013 Plan, and the 2007 Equity Incentive Plan, or the 2007 Plan. The 2013 Plan includes a provision that shares available for grant under the Company's 2007 plan become available for issuance under the 2013 Plan and are no longer available for issuance under the 2007 Plan.

At the Company's annual meeting of stockholders held on July 16, 2021, the Company's stockholders approved amendments to the 2013 Plan, which included an increase in the number of non-inducement shares of common stock authorized for issuance under the 2013 Plan by 1,300,000 shares. On February 14, 2022 and March 22, 2022, the board of directors approved an increase of 1,000,000 and 500,000 shares, respectively, in the inducement shares of common stock authorized for issuance under the 2013 Plan.

Stock Options

Non-performance options granted under either plan vest over a maximum period of four years and expire ten years from the date of grant. Non-performance options generally vest either (i) over four years, 25% on the one-year anniversary of the date of grant and monthly thereafter for the remaining three years; or (ii) over four years, monthly vesting beginning month-one after the grant and monthly thereafter.

The fair value of stock options is determined on the date of grant using the Black-Scholes valuation model. For non-performance awards, such value is recognized as expense over the requisite service period using the straight-line method. The amount and timing of compensation expense recognized for performance awards is based on management's estimate of the most likely outcome and when the achievement of the performance objectives is probable. The determination of the fair value

of stock options is affected by the Company's stock price, as well as assumptions regarding a number of complex and subjective variables. The volatility assumption is based on the historical volatility of the Company's common stock over a period of time equal to the expected term of the stock options. The expected term of employee stock options represents the weighted-average period the stock options are expected to remain outstanding. The expected term assumption is estimated based primarily on the options' vesting terms and remaining contractual life and employees' expected exercise and post-vesting employment termination behavior. The risk-free interest rate assumption is based upon observed interest rates on the grant date appropriate for the term of the employee stock options. The dividend yield assumption is based on the expectation of no future dividend payouts by the Company.

The assumptions used in the Black-Scholes pricing model for options granted during the years ended December 31, 2022 and 2021 are as follows:

	2022	2021
Stock and exercise prices	$0.74 - $2.39	$3.62 - $6.03
Expected dividend yield	0.00%	0.00%
Discount rate-bond equivalent yield	0.51% - 4.36%	0.52 % - 1.15 %
Expected life (in years)	5.50 - 6.03	5.0 - 5.98
Expected volatility	160% - 180%	163.1% - 173.9%

A summary of stock option activity for the years ended December 31, 2022 and 2021 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term in Years
Outstanding at December 31, 2020	1,078,704	$ 11.64	9.36
Granted	1,558,510	$ 3.96	
Exercised	(537)	3.14	
Cancelled/forfeited/expired	(256,681)	$ 7.83	
Outstanding at December 31, 2021	2,379,996	$ 7.07	9.06
Granted	1,412,900	$ 2.10	
Cancelled/forfeited/expired	(1,529,495)	$ 7.28	
Outstanding at December 31, 2022	2,263,401	$ 3.85	8.86
Vested and unvested expected to vest, December 31, 2022	2,236,680	$ 3.89	8.81

The intrinsic values of options outstanding, options exercisable, and options vested and unvested expected to vest at December 31, 2022 and 2021 were $0 and $610, respectively.

Stock-based Compensation Expense

The following table presents the effects of stock-based compensation related to equity awards to employees and nonemployees on the statement of operations during the periods presented (in thousands):

	Years Ended December 31,	
	2022	2021
Stock Options		
Cost of revenues	$ 628	$ 598
Research and development expenses	300	231
General and administrative expenses	1,860	1,266
Sales and marketing expenses	439	367
Total stock-based compensation	$ 3,227	$ 2,462

As of December 31, 2022, total unrecognized share-based compensation expense related to unvested stock options was approximately $3.7 million and such amount is expected to be recognized over a weighted-average period of approximately 2.46 years.

9. Common Stock Warrants Outstanding

A summary of equity-classified common stock warrant activity, for warrants other than those underlying unexercised overallotment option warrants, during 2022 and 2021 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Average Remaining Contractual Term in Years
Outstanding at December 31, 2020	997,167	$ 35.48	3.3
Issued	—	$ —	
Exercised	(126,330)	$ 3.52	
Expired	(13,576)	$ 569.89	
Outstanding at December 31, 2021	857,261	$ 31.73	2.2
Issued	—	$ —	
Exercised	—	$ —	
Expired	(12,801)	$ 606.22	
Outstanding at December 31, 2022	844,460	$ 23.02	1.3

All warrants outstanding at December 31, 2022 and 2021 are exercisable.

Warrants issued in the February 2019 financing transaction have an expiration date of February 12, 2024, warrants issued in the March 2019 transaction have an expiration date of September 19, 2024, warrants issued in the May 2019 inducement offering have an expiration date of December 2, 2024, warrants issued in the December 2019 have an expiration date of December 11, 2024, and warrants issued in the January 2020 inducement offering have an expiration date of July 10, 2025.

The intrinsic value of equity-classified common stock warrants outstanding at December 31, 2022 and 2021 was $0 and $16,000, respectively.

10. Net Loss per Common Share

Basic and diluted net loss per common share is determined by dividing net loss applicable to common shareholders by the weighted-average common shares outstanding during the period. Because there is a net loss attributable to common shareholders for the years ended December 31, 2022 and 2021, the outstanding RSUs, warrants, and common stock options have been excluded from the calculation of diluted loss per common share because their effect would be anti-dilutive. Therefore, the weighted-average shares used to calculate both basic and diluted loss per share are the same.

The following potentially dilutive securities have been excluded from the computations of diluted weighted-average shares outstanding for the periods presented, as they would be anti-dilutive:

	December 31, 2022	December 31, 2021
Common warrants outstanding	844,460	857,261
RSUs outstanding	-	36
Convertible preferred stock outstanding (number of common stock equivalents)	46,541	46,541
Common options outstanding	2,263,401	2,379,996
Total anti-dilutive common share equivalents	3,154,402	3,283,834

11. Income Taxes

For the years ended December 31, 2022 and 2021, the provision for income taxes was calculated as follows (in thousands):

	December 31, 2022	December 31, 2021
Current:		
Federal	$ —	$ —
State	(125)	125
Total	(125)	125
Deferred		
Federal	—	—
State	—	—
Total	—	—
Provision for income tax	$ (125)	$ 125

The following table reconciles income taxes computed at the federal statutory rate and the Company's provision for income taxes (in thousands):

	December 31, 2022	December 31, 2021
Income tax at statutory rate	$ (6,766)	$ (567)
Change in federal tax rate		—
State liability	(1,694)	66
Permanent items	210	278
Stock compensation	960	178
Warrant inducement	—	—
Expiration of net operating losses	710	594
Research and development credit	(178)	(377)
Unrecognized tax benefits	125	2,956
State rate change	76	(480)
Estimated section 382 limitation	(358)	(485)
Return to provision	(132)	(8)
Other	131	28
Valuation allowance	6,791	(2,058)
Provision for income tax	$ (125)	$ 125

Deferred income taxes are provided for temporary differences in recognizing certain income and expense items for financial and tax reporting purposes. The deferred tax assets consisted primarily of the income tax benefits from accruals, estimated net operating loss carryforwards, and estimated research and development credits. Valuation allowances have been recorded to fully offset deferred tax assets at December 31, 2022 and 2021, as it is more likely than not that the assets will not be utilized.

At December 31, 2022, the Company had estimated federal net operating loss carryforwards of approximately $91.3 million with $80.7 million net operating losses generated in tax years beginning after December 31, 2017 carrying forward indefinitely and may generally be used to offset up to 80% of future taxable income. Additionally, the remaining estimated net operating loss carryforwards of approximately $10.6 million will begin to expire in 2023. The Company has additional state net operating losses of $66.8 million with $3.6 million net operating losses generated after December 31, 2017, carrying forward indefinitely and may generally be used to offset up to 80% of future taxable income. Additionally, the remaining estimated net operating loss carryforwards of approximately $63.2 million will begin to expire in 2027. Additionally, at December 31, 2022, the Company had estimated research and development tax credits of approximately $1.0 million and $4.0 million for federal and California purposes, respectively. The federal research and development tax credits will begin to expire in 2023. The California research and development tax credits do not expire.

For the years ended December 31, 2022 and 2021, the Company has evaluated the various tax positions reflected in its income tax returns for both federal and state jurisdictions, to determine if the Company has any uncertain tax positions on the historical tax returns. The Company recognizes the impact of an uncertain tax position on an income tax return at the largest amount that the relevant taxing authority is more-likely-than not to sustain upon audit. The Company does not recognize uncertain income tax positions if they have less than 50% likelihood of being sustained. Based on this assessment, the Company believes there are tax positions for which a liability for unrecognized tax benefits should be recorded as of December 31, 2022 and 2021. The following table summarizes the activity related to our gross unrecognized tax benefits (in thousands):

	December 31, 2022	December 31, 2021
Current:		
Balance at the beginning of the year	$ 3,679	$ —
Adjustments related to prior year tax positions	25	3,640
Increases related to current year tax positions	118	39
Decreases for tax positions from prior years	—	—
Provision for income tax	$ 3,822	$ 3,679

The Company is subject to U.S. federal income tax as well as income tax in multiple state jurisdictions. With few exceptions, the Company is no longer subject to U.S. federal income tax examinations for tax years ending on or before December 31, 2018, and state and local income tax examinations for tax periods ending on or before December 31, 2001. However, to the extent allowed by law, the tax authorities may have the right to examine prior periods where net operating losses were generated and carried forward and make adjustments up to the amount of the net operating loss carryforward amount. The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. Due to the existence of the valuation allowance, future changes in unrecognized tax benefits will not impact the Company's effective tax rate. The Company is currently not under examination by any taxing authorities and does not believe its unrecognized tax benefits will significantly change in the next twelve months.

The tax effects of carryforwards and other temporary differences that give rise to deferred tax assets consist of the following (in thousands):

	For the year ended December 31,	
	2022	2021
Estimated net operating loss carryforward	$ 23,598	$ 18,482
Estimated research and development credits	1,032	1,026
Capitalized research and development	1,490	470
Accruals and other	3,234	2,046
Operating lease liability	2,648	2,821
Fixed assets	417	368
Stock based compensation	617	1,164
	33,036	26,377
Right-of-use asset	(3,161)	(3,295)
Gross deferred tax liabilities	(3,161)	(3,295)
Less valuation allowance	(29,875)	(23,082)
Net deferred tax assets	$ —	$ —

Utilization of the estimated domestic net operating loss and research and development tax credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by Sections 382 and 383 of the Code, as well as similar state provisions. These ownership changes may limit the amount of estimated net operating loss and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points by value of the outstanding stock of a company by certain stockholders. Since the Company's formation, the

Company has raised capital through the issuance of capital stock on several occasions which on its own or combined with the purchasing stockholders' subsequent disposition of those shares, likely resulted in such an ownership change, or could result in an ownership change in the future.

Upon the occurrence of an ownership change under Sections 382 and 383 of the Code as outlined above, utilization of the estimated net operating loss and research and development credit carryforwards are subject to an annual limitation, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term, tax-exempt rate, which could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the estimated net operating loss or research and development tax credit carryforwards before utilization. The Company has not yet completed an analysis to determine whether an ownership change has occurred, however, the Company believes multiple ownership changes have likely occurred. As a result, the Company has estimated that the use of its net operating loss carryforwards is limited and has disclosed in the table above only the amounts it estimates could be used in the future, which remain fully offset by a valuation allowance to reduce the net asset to zero.

The Tax Cuts and Jobs Act (TCJA) requires tax payors to capitalize and amortize research and development (R&D) expenditures under section 174 for tax years beginning after December 31, 2021. This rule became effective for the Company during the year and resulted in the capitalization of R&D costs of approximately $5.2 million. The Company will amortize these costs for tax purposes over 5 years if the R&D was performed in the U.S. and over 15 years if the R&D was performed outside the U.S.

12. Related Party Transactions

A former member of the Company's management is the controlling person of Aegea Biotechnologies, Inc., or Aegea. On September 2, 2012, the Company entered into an Assignment and Exclusive Cross-License Agreement, or the Cross-License Agreement, with Aegea. The Company received payments totaling approximately $0 and $49,000 during the years ended December 31, 2022 and 2021, respectively, from Aegea as reimbursements for shared patent costs under the Cross-License Agreement. On December 11, 2019, the Company entered into a First Amendment to Assignment and Exclusive Cross-License Agreement with Aegea pursuant to which the Company obtained a royalty bearing license for a certain patent. On May 22, 2022, the Company entered into a Second Amendment to Assignment and Exclusive Cross-License Agreement with Aegea pursuant to which the Company obtained a royalty-free license for a certain patent and Aegea obtained certain patents.

13. Commitments and Contingencies

In the normal course of business, the Company may be involved in legal proceedings or threatened legal proceedings. The Company is not party to any legal proceedings or aware of any threatened legal proceedings except as provided in the paragraph below, and except for those proceedings that are not expected to have a material adverse effect on the Company's financial condition, results of operations or liquidity.

The Company was in mediation with former employees regarding disputed claims for certain sales commissions. Although the Company was not in agreement with their interpretations or claims, the Company entered into settlement negotiations related to the disputed commissions. The matter was resolved in June 2022 for approximately $1.7 million and was recorded within sales and marketing expense.

14. Subsequent Events

From January 1, 2023 through the issuance of the financial statements, the Company sold and issued 707,114 shares of our common stock at a weighted average purchase price of $0.57 under the Company's at-the-market equity facility, for net proceeds of $0.4 million.

On January 6, 2023, the Company announced that it had commenced a process to explore and evaluate strategic alternatives to enhance shareholder value, and that in connection with such process and in order to extend the Company's resources, the Company has implemented a restructuring plan that resulted in a reduction of the Company's workforce by approximately 36%. The Company has incurred charges of approximately $0.8 million for severance and other employee termination-related costs in the first quarter of 2023. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with its workforce reduction.

On March 16, 2023, the Company terminated the employment of Michael C. Dugan, M.D., the Company's Senior Vice President, Chief Medical Officer and Medical Director, effective March 17, 2023. In connection with his termination, the Company entered into a separation agreement, in exchange for a release of claims, and agreed to provide severance benefits of approximately $0.1 million, to be made during the year ending December 31, 2023.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

We carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of December 31, 2022, the end of the period covered by this report. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were not effective at the reasonable assurance level as of December 31, 2022 due to the material weaknesses in internal control over financial reporting described below.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Because of its inherent limitations, internal control over financial reporting may not prevent or detect all misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Following the original issuance of our financial statements for the three and nine months ended September 30, 2021 included in our quarterly report on Form 10-Q, filed with the SEC on November 15, 2021 (the "Original September 30, 2021 Financial Statements"), we discovered that we had failed to accrue for, and reflect in the Original September 30, 2021 Financial Statements, certain expenses incurred during the third quarter of 2021 in the amount of approximately $1.1 million. This resulted in the restating of our financial statements as of and for the nine months ended September 30, 2021. We determined that our review control over the completeness and accuracy of our accounts payable did not operate effectively, resulting in a material error in the Original September 30, 2021 Financial Statements.

In connection with the preparation of our Annual Report on Form 10-K for the year ended December 31, 2021 and the preparation of our Quarterly Report on Form 10-Q as of and for the three month period ended March 31, 2022, we discovered additional material weaknesses related to the (i) operating effectiveness of our internal controls to determine certain estimates and the timely review of such estimates and (ii) operating effectiveness of our internal controls to review and approve certain revenue related manual journal entries, including the review of the completeness and accuracy of information used.

While preparing the financial statements included in this Annual Report on Form 10-K, we discovered that there was an error in the inputs used within the black-scholes calculation for options granted in April 2019. Further, we discovered there was an error associated with the acceleration of stock-based compensation recorded in the financial statements included in our quarterly report on Form 10-Q for the quarter ended March 31, 2022 (the "Original March 31, 2022 Financial Statements"). We determined that our review control over the completeness and accuracy of information used when calculating stock-based

compensation expense did not operate effectively, resulting in a material error in the Original March 31, 2022 Financial Statements.

In addition, we discovered an error in our revenue and accounts receivable reconciliation process, such that the correct accounts receivable and corresponding revenue activity was not properly reflected in the Original June 30, 2022 Financial Statements. We also discovered through our revenue recognition and accounts reconciliation process that changes in payor class and implicit price concessions were not appropriately reflected in the Original September 30, 2022 Financial Statements, which is the period in which they were known. We determined that our review control over the completeness and accuracy of data used in estimating net revenues and accounts receivable, as well as our control over the reconciliation process did not operate effectively, resulting in a material error in the Original June 30, 2022 Financial Statements and the Original September 30, 2022 Financial Statements.

We conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework (2013 Framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control—Integrated Framework, our management concluded that our internal control over financial reporting was not effective as of December 31, 2022 based on the material weaknesses described above, none of which have been remediated yet.

A material weakness, as defined in Rule 12b-2 under the Exchange Act, is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Our report was not subject to attestation by our independent registered public accounting firm pursuant to the rules of the SEC that permit us to provide only management's report in this report.

Changes in Internal Control Over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any changes in our internal control over financial reporting that occurred during the three months ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Remediation Actions to Date

We implemented certain improvements to our internal control and financial reporting processes to address the material weaknesses identified above. These improvements include the following:

- During the first quarter of 2022, we engaged a "Big Four" accounting firm under an advisory engagement to be conducted under the AICPA Standards for Consulting Services to assist management with their internal controls review.
- During the second quarter of 2022, we began the process for designing and implementing the recommendations from the internal control review done during the first quarter of 2022.
- During the second and third quarters of 2022, our accounting department was substantially overhauled.
- During the third and fourth quarters of 2022, we continued the process of designing and implementing controls based off the recommendation from the "Big Four" internal controls review.

We are committed to maintaining a strong internal control environment and implementing measures to ensure that the control deficiencies identified above are remediated as soon as possible. Management is in the process of implementing a remediation plan, which includes steps to design and implement new controls and expand the review of any potential unrecorded liabilities.

We have implemented certain aspects of our remediation plan but will need to design and implement additional controls related to the material weaknesses identified above. Moreover, we do not believe that any of our remedial controls have been fully

implemented or operated for a sufficient period of time or number of occurrences to allow for sufficient testing to determine the controls' operating effectiveness.

The remediation actions are being monitored by the Audit Committee of our Board of Directors.

Item 9B. Other Information.

Not applicable.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Code of Conduct and Ethics

We have adopted a code of ethics that applies to our Chief Executive Officer and other senior financial officers (our Chief Financial Officer, Controller and other senior financial officers performing similar functions), which we refer to as the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at www.biocept.com under the Corporate Governance section of the Investor Relations portion of the website. Our Code of Business Conduct and Ethics is designed to meet the requirements of Section 406 of Regulation S-K and the rules promulgated thereunder. We will promptly disclose on our website (i) the nature of any amendment to the Code of Business Conduct and Ethics that applies to any covered person, and (ii) the nature of any waiver, including an implicit waiver, from a provision of the Code of Business Conduct and Ethics that is granted to one of the covered persons.

EXECUTIVE OFFICERS AND DIRECTORS

Our executive officers and non-employee directors, and their respective ages and positions with us as of the date of this Annual Report, are as follows:

Name	Age	Position
Executive Officers		
Samuel D. Riccitelli	64	Interim President and Chief Executive Officer and Chair of the Board of Directors
Antonino Morales, CPA	67	Interim Chief Financial Officer and Director
Philippe Marchand, Ph.D.	59	Chief Operations Officer
Darrell Taylor	58	Chief Legal Officer and Chief Compliance Officer, Corporate Secretary
Non-Employee Directors		
M. Faye Wilson, MBA	85	Lead Independent Director
Marsha A. Chandler, Ph.D.	78	Director
Bruce E. Gerhardt, CPA	72	Director
Quyen Dao-Haddock, CPA	47	Director
Linda Rubinstein	56	Director
Ivor Royston, M.D.	78	Director

Samuel D. Riccitelli has served as our Interim President and Chief Executive Officer since February 2022, as our Chair of the Board since June 2021, and as a member of board of directors since October 2020. Mr. Riccitelli has been in the healthcare industry for more than 35 years. He has served as a member of the Board of Directors of Orthopediatrics, Corp since 2017, a company focused exclusively on the orthopedic implant needs of children. He recently served as Chief Executive Officer of Pathnostics, LLC, a molecular diagnostics company focused on improving antibiotic stewardship, from 2019 to 2020. From 2017 to 2019, Mr. Riccitelli served as Chairman of the Board of Directors of Precipio, Inc., a diagnostic services company. From 2012 to 2017, Mr. Riccitelli served as President and Chief Executive Officer and a Director of Signal Genetics, Inc., a publicly traded molecular diagnostic company that was ultimately sold to Miragen Therapeutics, Inc. Mr. Riccitelli was also previously the Executive Vice President and Chief Operating Officer of Genoptix, Inc., a publicly traded diagnostic company that was sold to Novartis in 2011. Mr. Riccitelli served in a number of research and development and general management leadership positions for Becton, Dickinson and Company and as a board member for BD Ventures, LLC., a venture capital fund. Mr. Riccitelli received a B.A. from Washington and Jefferson College and a M.S. Engineering degree from The University of Texas. We selected Mr. Riccitelli to serve on our board of directors due to his experience and expertise in the healthcare industry.

Antonino Morales, CPA has served as our Interim Chief Financial Officer since February 2022 and as a member of our board of directors since July 2021. Mr. Morales has more than 30 years of broad leadership experience in the United States and Latin America. Mr. Morales served as President and Chief Executive Officer of Apoyo Financiero, Inc. from June 2017 to March 2020. Mr. Morales has held senior executive roles with multiple Fortune 100 companies including Citigroup, Bank of America

and Arthur Andersen. Mr. Morales provides operational, market development and financial consulting services as an independent consultant for early-stage companies and Fortune 500 companies. His clients have included Mazda North America, Mazda de Mexico, PriceSmart, Inc. and Reliance Steel & Aluminum Co. Mr. Morales received a B.S. in Finance from the University of Southern California and is a licensed CPA. We selected Mr. Morales to serve on our board of directors due to his experience in executive leadership and his substantial knowledge and expertise in operational, market development, financial and accounting matters.

Philippe Marchand, Ph.D. joined us as Chief Operations Officer in March 2022. Prior to his appointment as Chief Operations Officer, Dr. Marchand, served as a consultant to our Company since February 2022, providing operational services. Dr. Marchand served as Chief Operating Officer of Biosplice Therapeutics, Inc., or Biosplice, a privately held biopharmaceutical company, from January 2017 until March 2022, and as Senior Vice President, Operations of Biosplice from March 2015 to January 2017. Dr. Marchand received an M.S. and a Ph.D. from the Université de Haute Alsace, France.

Darrell Taylor joined us as Senior Vice President, General Counsel, and Chief Compliance Officer in December 2021. In February 2022, Mr. Taylor was promoted to Chief Legal Officer and Chief Compliance Officer. Before joining our company, Mr. Taylor served as Chief Compliance Officer for Precision Diagnostics from July 2020 to December 2021, and as Associate General Counsel for Sorrento Therapeutics from January 2018 to June 2020. Mr. Taylor was an attorney with DLA Piper from 2005 to 2013. Mr. Taylor earned his J.D. from the University of Notre Dame Law School and his B.S.M.T. from The University of Texas Medical Branch.

Non-Employee Directors

M. Faye Wilson, MBA has served on our board of directors since 2009 and as our lead independent director since February 2022. Ms. Wilson currently serves as chair of our audit committee, as a member of our compensation committee and as a member of our nominating and corporate governance committee. Ms. Wilson is retired CEO of Wilson Boyles and Company, a business consulting firm specializing in the development and implementation of successful business strategies. Prior to co-founding Wilson Boyles in 2003, she served as Senior Vice-President, Value Initiatives and Risk Management for The Home Depot, having joined the company in 1998 following a 21-year career at Bank of America. Ms. Wilson was Executive-Vice President of Bank of America and Chairman and President of Security Pacific Financial Services, a wholly owned subsidiary of Bank of America Corporation. Ms. Wilson began her banking career as a management trainee in the Corporate Banking Group of Security Pacific National Bank, which merged with and became Bank of America in 1992. Prior to assuming the chairmanship of Security Pacific Financial Services, she was the Executive Vice-President responsible for overseeing credit quality and policy for over 80% of Bank of America's loan portfolio. During her Security Pacific career, Ms. Wilson spent time in London as the Managing Director of Corporate Finance for Security Pacific Hoare Govett, where she created new corporate advisory services, debt structuring products and formed a cross-border mergers and acquisitions division for European and U.S. companies. Prior to the London assignment, she was Managing Director of the Leveraged Buyout Group for the Security Pacific Merchant Bank. Earlier, Ms. Wilson served as Senior Vice-President and Regional Manager in the Corporate Banking Division with responsibility for multinational corporations, retail industry companies and California based corporations. Ms. Wilson has served as a director on the boards of BioMed Realty Trust, Inc., a real estate investment trust, until its acquisition by Blackstone Real Estate Partners VIII in 2016, Farmers Insurance Group, The Home Depot, SKM, a Russian public company, Community National Bank and trustee of The Salk Institute. Currently she serves as a member of the Audit Committee of Sharp Health Group and IQHQ REIT. Ms. Wilson received master's degrees in international relations and in business administration from the University of Southern California. We selected Ms. Wilson to serve as Lead Independent Director of our board of directors due to her extensive experience as a director of public companies, her financial acumen and experience, and her expertise in business strategy.

Marsha A. Chandler, Ph.D. has served on our board of directors since 2013. She currently serves as chair of our nominating and corporate governance committee, as a member of our compensation committee, and as a member of our science and technology committee. Dr. Chandler is Senior Vice Chancellor and Professor Emerita at the School of Global Policy and Strategy at the University of California, San Diego (UCSD). She is also currently an Advisor to the College of Health, Lehigh University and Advisor to the Jackson School of Geosciences, and Texas Global at the University of Texas at Austin. Dr. Chandler is also a member of the Board of Directors of the Corporate Directors Forum. She served as the Executive Vice-President and Chief Operating Officer of the Salk Institute for Biological Studies from 2007 to 2015, where she managed approximately 1,000 scientific and administrative personnel and oversaw all institutional fiscal, administrative and fund-raising activities. From 1997 to 2007 she was the Senior Vice Chancellor for Academic Affairs at UCSD, where she was the chief academic officer responsible for the policies and decisions relating to research and teaching programs, faculty appointments and performance, and the fiscal, human resources and facilities functions on the general campus. Dr. Chandler is a Fellow of the Royal Society of Canada. She received her Ph.D. from The University of North Carolina at Chapel Hill. In 2004, she completed the Advanced Management Program at Harvard Business School. We selected Dr. Chandler to serve on our board of directors due to her experience in organizational management, strategy, and her stature in the life sciences community.

Bruce E. Gerhardt, CPA has served on our board of directors since 2010. He currently serves as chair of our compensation committee and as a member of our audit committee. Mr. Gerhardt has been self-employed, practicing as a Certified Public Accountant, since 1986. He is also a tax and business advisor providing tax compliance for small businesses and upper income individuals. Prior to 1986, he was a financial vice-president with several companies and a senior accountant with Peat Marwick Mitchell, now KPMG. He earned his B.A. from the University of Southern California in 1973 and is a member of the American Institute of Certified Public Accountants. We selected Mr. Gerhardt to serve on our board of directors due to his experience and expertise in financial accounting and auditing.

Quyen Dao-Haddock, CPA has served on our board of directors since November 2022. She currently serves as a member of our audit committee. Ms. Dao-Haddock has served as the Controller of IQHQ, Inc. since April 2020. Since September 2021, she has served as a member of the Audit Committee and Compliance Committee of Sharp Healthcare. From January 2019 through March 2020, Ms. Dao-Haddock was the Chief Accounting Officer of Presidio Property Trust, Inc., a publicly traded real-estate investment trust (REIT), where she was responsible for all financial and accounting operations. From November 2011 through January 2019, she was Corporate Controller of American Assets Trust, Inc., an NYSE-listed REIT. From December 2010 through November 2011, Ms. Dao-Haddock was Controller at Pacific Corporate Group, LLC, a private equity firm. She began her career as an Audit Manager at KPMG LLP from 1999 through 2006, and received a BS in Business Administration, Accounting from San Diego State University in 1998. She is a certified public accountant (CPA) with more than 20 years of financial and accounting experience including overseeing technical accounting, budgeting, forecasting, financial modeling, cash management, and SEC reporting. We selected Ms. Dao-Haddock to serve on our board of directors due to her extensive experience and expertise in financial accounting.

Ivor Royston, M.D. has served on our board of directors since 2010. He currently serves as chair of our science and technology committee and as a member of our nominating and corporate governance committee. Dr. Royston has served as President, Chief Executive Officer from 2015 to 2022 and continues to serve on the board of directors of Viracta Therapeutics, Inc., since 2015. From 1990 to 2000, he served as founding President and CEO of The Sidney Kimmel Cancer Center and from 1978 to 1990, he was a member of the oncology faculty of the University of California, San Diego. In addition to being a co-founder of Hybritech, Inc., in 1986 he co-founded IDEC Corporation, which later merged with Biogen to form Biogen Idec. From 1990 to 2017, Dr. Royston was the Founding Managing Partner of Forward Ventures and has been instrumental in the formation, financing and development of numerous biotechnology companies. Dr. Royston received his B.A. and M.D. degrees from Johns Hopkins University and completed post-doctoral training in internal medicine and medical oncology at Stanford University. In 1997, President Clinton appointed Dr. Royston to a six-year term on the National Cancer Advisory Board. In 2022, Dr. Royston was the recipient of the Biotechnology Heritage Award given out each year by BIO and the Science History Institute. We selected Dr. Royston to serve on our board of directors due to his extensive experience with emerging life sciences companies.

Linda Rubinstein has served on our board of directors since July 2021. She currently serves as a member of our compensation committee and as a member of our science and technology committee. Ms. Rubinstein has over 35 years of experience across the finance, capital markets, operations and the life sciences sectors. Since September 2010 she has been a partner at FLG Partners, LLC, a chief financial officer services and board advisory consulting firm. During that time she has served as chief financial officer, interim chief financial officer or financial advisor for multiple clients, including Adverum Biotechnologies, Alector, Apexigen, RenovoRx, Five Prime Therapeutics, Ingenuity Systems (now part of QIAGEN), iPierian (acquired by Bristol-Myers Squibb), Kezar Life Sciences, Medikine, PaxVax, True North Therapeutics and others. From January 2020 to April 2021 Ms. Rubinstein was chief financial officer consultant to Sublimity Therapeutics Holdco Limited (“Sublimity”) and also served as Treasurer of Sublimity Therapeutics, Inc., Sublimity’s indirect subsidiary. Earlier, Ms. Rubinstein was vice president and CFO of Solexa (now part of Illumina), vice president of finance at ChemoCentryx and a senior vice president in Lehman Brothers’ global healthcare investment banking group. She holds a B.A. and an M.A. in Economics from the University of California, Los Angeles. We selected Ms. Rubinstein to serve on our board of directors due to her experience in executive leadership roles at various life sciences companies and her substantial knowledge of strategic finance and business operational issues.

CORPORATE GOVERNANCE

Director Independence

Our board of directors has affirmatively determined that all of our directors, except Mr. Riccitelli and Mr. Morales, meet the definition of “independent director” under the applicable Nasdaq Listing Rules.

Agreements with Directors

None of the directors or nominees for director was selected pursuant to any arrangement or understanding, other than with our directors acting within their capacity as such.

Legal Proceedings with Directors

There are no legal proceedings related to any of the directors or director nominees, officers, or holders of 5% or more of our common stock which require disclosure pursuant to Items 103 or 401(f) of Regulation S-K.

Board Leadership Structure

Historically, the positions of chair of the board and Chief Executive Officer have been separated. The separation of the positions of board chair and Chief Executive Officer was meant to reinforce the independence of the board in its oversight of the business and affairs of the Company. In addition, the Company believed that having an independent board chair created an environment that was conducive to objective evaluation and oversight of management's performance, increasing management accountability and improving the ability of the board to monitor whether management's actions are in the best interests of the Company and its stockholders. In connection with the resignation of our former Chief Executive Officer in February 2022, our board of directors appointed the chair of our board of directors, Samuel D. Riccitelli, as Interim President and Chief Executive Officer. Our board of directors believe this appointment was in the best interests of our stockholders and was necessary to ensure continued leadership of our company by someone with both knowledge of our company and significant and extensive executive and leadership experience, including as the chief executive officer of other molecular diagnostics companies.

Our board of directors continues to believe that independent board leadership helps to reinforce the independence of the board as a whole and is important for effective corporate governance. Accordingly, concurrently with the appointment of Mr. Riccitelli as Interim President and Chief Executive Officer, our board of directors established the position of lead independent director and appointed Faye Wilson to serve in such capacity. The lead independent director is empowered to, among other duties and responsibilities, approve agendas and meeting schedules for regular board meetings, preside over board meetings in the absence of the board chair, preside over and establish the agendas for meetings of the independent directors, act as liaison between the chair and the independent directors, approve information sent to the board, preside over any portions of board meetings at which the evaluation or compensation of the Interim Chief Executive Officer is presented or discussed and, as appropriate upon request, act as a liaison to stockholders. In addition, it is the responsibility of the lead independent director to coordinate between the board and management with regard to the determination and implementation of responses to any problematic risk management issues. As a result, the Company believes that the lead independent director can help ensure the effective independent functioning of the Board in its oversight responsibilities. In addition, the Company believes that the lead independent director is better positioned to build a consensus among directors and to serve as a conduit between the other independent directors and the board chair, for example, by facilitating the inclusion on meeting agendas of matters of concern to the independent directors.

The independent directors regularly meet in executive sessions in connection with regular meetings of the board of directors.

Board Role in Risk Oversight

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including risks relating to our operations, strategic direction, cybersecurity, and intellectual property. Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The role of our board of directors in overseeing the management of our risks is conducted primarily through committees of our board of directors, as disclosed in the descriptions of each of the committees below and in the charters of each of the committees. The full board of directors (or the appropriate board committee in the case of risks that are under the purview of a particular committee) discusses with management our major risk exposures, their potential impact on us, and the steps we take to manage them. When a board committee is responsible for evaluating and overseeing the management of a particular risk or risks, the chairperson of the relevant committee reports on the discussion to the full board of directors during the committee reports portion of the next board meeting.

Board and Committee Meetings

During 2022, our board of directors met 13 times. Each director attended at least 75% of the meetings held while he or she was a director, either in person or by teleconference. Additionally, during 2022, each director attended at least 75% of the meetings for each committee on which he or she served.

Director Attendance at Annual Meetings

Although we do not have a formal policy regarding attendance by members of our board of directors at our annual meetings of stockholders, we encourage all of our directors to attend. All of our directors as of our 2022 annual meeting of stockholders, except Mr. Hale, attended our 2022 annual meeting of stockholders.

Executive Sessions

In accordance with the applicable Nasdaq Listing Rules, our independent directors meet in regularly scheduled executive sessions at which only independent directors are present.

Board Committees

Our board of directors has four standing committees: the audit committee, the compensation committee, the nominating and corporate governance committee, and the science, technology, and clinical affairs committee. In addition, from time to time, special committees may be established under the direction of our board of directors when necessary to address specific issues.

Each of the four standing committees has a written charter that has been approved by our board of directors. A copy of each charter is available on our website at www.biocept.com by selecting the "Investors" icon at the top of the page, followed by the "Corporate Governance" hyperlink.

The members of each committee for the year ended December 31, 2022 are identified in the following table:

Name	Audit Committee	Compensation Committee	Nominating and Corporate Governance Committee	Science, Technology, and Clinical Affairs Committee
David F. Hale[1]	Member	—	—	Member
Marsha A. Chandler, Ph.D.	—	Member	Chair	Member
Bruce E. Gerhardt, CPA	Member	Chair	—	—
Samuel D. Riccitelli	—	—	—	—
Linda Rubinstein[4]	—	Member	—	Member
Ivor Royston, M.D.	—	—	Member	Chair
Antonino Morales, CPA [2]	Member	—	—	—
M. Faye Wilson, MBA[I]	Chair	Member	Member	—
Quyen Dao-Haddock, CPA[3]	Member	—	—	—
Total meetings in 2022	10	3	6	1

(I) Ms. Wilson became the Lead Independent Director in February 2022.
(1) Mr. Hale became a member of the audit committee in February 2022. Mr. Hale was a member of the board of directors until his retirement in July 2022.
(2) Mr. Morales was a member of the audit committee until he was appointed as the Company's Interim Chief Financial Officer in February 2022.
(3) Ms. Dao-Haddock became a member of the board of directors and a member of the audit committee in November 2022.
(4) Ms. Rubinstein became a member of the science, technology, and clinical affairs committee in August 2022 following the retirement of Mr. Hale.

Audit Committee

During 2022, our audit committee met ten times. Our audit committee is currently composed of three directors: Ms. Wilson (who chairs the audit committee), Ms. Dao-Haddock and Mr. Gerhardt. Each of the members of the audit committee has been determined to be an independent director under applicable SEC rules and the applicable Nasdaq Listing Rules. Our board of directors has affirmatively determined that Ms. Wilson is designated as an "audit committee financial expert."

Our audit committee's responsibilities include:

- oversee the integrity of our financial statements and other financial information provided by us to our stockholders and others;

- Monitor the periodic reviews that are conducted by our financial and senior management and by our independent auditors of the adequacy of our auditing, accounting and financial reporting processes and systems of internal control;
- oversee the qualifications, independence and performance of our independent auditors;
- oversee compliance with legal, regulatory and public disclosure requirements; and
- facilitate communication among our independent auditors, our financial and senior management, and the board.

Our board of directors has determined that Ms. Wilson qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of Rule 5605(c)(2) of the Nasdaq listing rules. In making this determination, our board of directors has considered prior experience, business acumen and independence. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

Report of the Audit Committee of the Board of Directors*

The audit committee has reviewed and discussed the audited financial statements for the fiscal year ended December 31, 2022 with management of the Company. The audit committee has discussed with the independent registered public accounting firm the matters required to be discussed by the applicable requirements of the Public Company Accounting Oversight board ("PCAOB") and the Securities and Exchange Commission. The audit committee has also received the written disclosures and the letter from the independent registered public accounting firm required by applicable requirements of the PCAOB regarding the independent accountants' communications with the audit committee concerning independence and has discussed with the independent registered public accounting firm the accounting firm's independence. Based on the foregoing, the audit committee has recommended to the board of directors that the audited financial statements be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

M. Faye Wilson (Chair)
Bruce E. Gerhardt
Quyen Dao-Haddock

** The material in this report is not "soliciting material," is not deemed "filed" with the Securities and Exchange Commission and is not to be incorporated by reference in any filing of the Company under the Exchange Act of 1934, as amended, or the Securities Act of 1933, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.*

Compensation Committee

During 2022, our compensation committee met three times. Our compensation committee is currently composed of four directors: Mr. Gerhardt (who chairs the compensation committee), Ms. Wilson, Dr. Chandler, and Ms. Rubinstein. Each of the members of the compensation committee has been determined to be an independent director under the applicable Nasdaq Listing Rules.

Our compensation committee's responsibilities include:

- oversee our overall compensation programs applicable to executive officers and directors;
- oversee our cash and equity-based compensation plans applicable to all of our directors, officers and employees;
- produce an annual report on executive compensation for inclusion in our annual proxy statement; and
- review and discuss with our management the tables and narrative discussion regarding executive officer and director compensation to be included in our annual proxy statement.

Compensation Committee Processes and Procedures

Typically, the compensation committee meets at least twice annually and with greater frequency if necessary. The agenda for each meeting is usually developed by the Chair of the compensation committee, in consultation with the Chief Executive Officer. The compensation committee meets regularly in executive session. However, from time to time, various members of management and other employees as well as outside advisors or consultants may be invited by the compensation committee to

make presentations, to provide financial or other background information or advice or to otherwise participate in compensation committee meetings. The Chief Executive Officer may not participate in, or be present during, any deliberations or determinations of the compensation committee regarding his compensation. The charter of the compensation committee grants the compensation committee full access to all books, records, facilities and personnel of the Company, as well as authority to obtain, at the expense of the Company, advice and assistance from internal and external legal, accounting or other advisors and consultants and other external resources that the compensation committee considers necessary or appropriate in the performance of its duties. In particular, the compensation committee has the sole authority to retain compensation consultants to assist in its evaluation of executive and director compensation, including the authority to approve the consultant's reasonable fees and other retention terms.

During the fiscal year 2022, the compensation committee engaged Aon/Radford as a compensation consultant. After taking into consideration the six factors prescribed by the SEC and Nasdaq, the compensation committee concluded that there were no conflicts of interest between Aon/Radford and the Company. The compensation committee requested that Aon/Radford review industry-wide compensation practices and trends to assess the competitiveness of our executive and non-employee director compensation programs.

The compensation committee asked Aon/Radford to develop a comparative group of companies and to perform analyses of competitive performance and compensation levels for that group. Aon/Radford also met with certain members of management and human resources to learn more about the Company's business operations and strategy, key performance metrics and strategic goals, as well as the labor markets in which the Company competes. Aon/Radford ultimately developed recommendations primarily pertaining to compensation strategy for the Company's executive officers and non-employee directors that were presented to the compensation committee for its consideration and to the board of directors for its information. Following an active dialogue with Aon/Radford, the compensation committee recommended that the board of directors approve certain recommendations of Aon/Radford.

Historically, the compensation committee has made most of the significant adjustments to annual compensation, determined bonus and equity awards and established new performance objectives at one or more meetings held during the last quarter of the year. However, the compensation committee also considers matters related to individual compensation, such as compensation for new executive hires, as well as high-level strategic issues, such as the efficacy of the Company's compensation strategy, potential modifications to that strategy and new trends, plans or approaches to compensation, at various meetings throughout the year. Generally, the compensation committee's process comprises two related elements: the determination of compensation levels and the establishment of performance objectives for the current year.

For executives other than the Chief Executive Officer, the compensation committee solicits and considers evaluations and recommendations submitted to the committee by the Chief Executive Officer. In the case of the Chief Executive Officer, the evaluation of his performance is conducted by the compensation committee, which makes recommendations to the full board of directors regarding any adjustments to his compensation as well as awards to be granted. In making such recommendations for determining the long-term incentive component of the Chief Executive Officer's compensation, the compensation committee shall take into consideration the Company's performance and relative stockholder return, the value of similar incentive awards given to chief executive officers of comparable companies, the awards given to the Company's Chief Executive Officer in past years, other elements of the Chief Executive Officer's compensation including total compensation and such other criteria as the committee deems advisable.

For all executives and directors as part of its deliberations, the compensation committee may review and consider, as appropriate, materials such as financial reports and projections, operational data, tax and accounting information, tally sheets that set forth the total compensation that may become payable to executives in various hypothetical scenarios, executive and director stock ownership information, company stock performance data, analyses of historical executive compensation levels and current Company-wide compensation levels.

Nominating and Corporate Governance Committee

During 2022, our nominating and corporate governance committee met six times. Our nominating and corporate governance committee is currently composed of three directors: Dr. Chandler (who chairs the nominating and corporate governance committee), Ms. Wilson, and Dr. Royston. Each of the members of the nominating and corporate governance committee has been determined to be an independent director under the applicable Nasdaq Listing Rules.

Our nominating and corporate governance committee's responsibilities include:

- identify individuals qualified to become board members, consistent with criteria approved by the board, and recommend that the board select the director nominees for election at each annual meeting of stockholders or to fill vacancies on board in accordance with our bylaws;
- recommend to the board director nominees for each committee of the board; and
- recommend to the board any appropriate changes in our Code of Ethics, applicable to the Chief Executive Officer and other senior financial officers, and in the Code of Business Conduct, applicable to all of our directors, officers, and employees, and in such other corporate governance policies and documents as the committee determines from time to time, including such policies and documents as the committee may develop and/or recommend to the board for approval; and
- lead the board in its annual review of the performance of the board and any committee thereof, as applicable.

Director Nomination Process

The goal of our nominating and corporate governance committee, which we refer to as the committee for purposes of this section, is to assemble a well-rounded board of directors that consists of directors with backgrounds that are complementary to one another, reflecting a variety of experiences, skills, and expertise. The committee's current selection criteria for prospective nominees, as set forth in the committee's charter, are as follows:

- each director should be committed to enhancing long-term stockholder value and must possess a high level of personal and professional ethics, sound business judgment and integrity;
- each director should be free of any conflicts of interest which would violate applicable laws, rules, regulations or listing standards, or interfere with the proper performance of his or her responsibilities;
- each director should possess experience, skills and attributes which enhance his or her ability to perform duties on our behalf. In assessing these qualities, the committee will consider such factors as (i) personal skills and attributes, (ii) expertise in the areas of accounting, marketing, strategy, financial reporting, or corporate governance, or (iii) professional experience in the healthcare industry, as well as other factors that would be expected to contribute to an effective board of directors;
- each director should have the willingness and ability to devote the necessary time and effort to perform the duties and responsibilities of board membership; and
- each director should demonstrate his or her understanding that his or her primary responsibility is to our stockholders, and that his or her primary goal is to serve the best interests of those stockholders, and not his or her personal interest or the interest of a particular group.

In considering whether to recommend any candidate for inclusion in the slate of recommended nominees for our board of directors, including candidates recommended by stockholders, the committee applies the criteria set forth above.

In our continuing commitment to the crucial value of diverse experiences and perspectives, we seek a broad inclusive pool of board candidates.

The committee believes it is appropriate for our Interim President and Chief Executive Officer to serve as a member of our board of directors.

The committee currently has a policy of evaluating nominees recommended by stockholders in the same manner as it evaluates other nominees. We do not intend to treat stockholder recommendations in any manner different from other recommendations. Under our amended and restated bylaws, stockholders wishing to propose a director nominee should send the required information to our corporate secretary at Biocept, Inc., 9955 Mesa Rim Road, San Diego, California 92121. We have not received director candidate recommendations from our stockholders.

Science, Technology, and Clinical Affairs Committee

During 2022, our science, technology, and clinical affairs committee met one time. Our science, technology, and clinical affairs committee is currently composed of three directors: Dr. Royston (who chairs the science, technology, and clinical affairs committee), Dr. Chandler, and Linda Rubinstein.

Our science, technology, and clinical affairs committee's responsibilities include:

- review and advise the board on the overall strategy, direction and effectiveness of our research and development and our clinical programs;
- evaluate and advise the board on our progress in achieving our long-term strategic research, development and clinical goals and objectives;
- identify and monitor emerging science, technology and regulatory developments, issues and trends which are relevant to our research and development strategy and clinical activities;
- assess and advise the board, as requested, on the committee's view of the quality and competitiveness, from a scientific perspective of our research and development programs and clinical initiatives;
- review and evaluate the infrastructure and resources made available by us for our research and development projects and clinical programs at the request of the board. Upon review, the committee will make recommendations regarding such infrastructure and resources necessary to achieve our objectives;
- review and advise the board regarding the scientific, research and development, and intellectual property aspects of proposed transactions such as investments, acquisitions and intellectual property at the request of the board;
- meet with and liaise with, as well as review the recommendations from, our Scientific Advisory Board and Clinical Advisory Board; and
- conduct quarterly meetings with our Medical Staff and Chief Executive Officer to assess and advise on clinical and scientific progress and initiatives.

Hedging Policy

The Company's insider trading and window period policy provides that no officer, director, other employee or consultant of the Company may engage in short sales, transactions in put or call options, hedging transactions or other inherently speculative transactions with respect to the Company's stock at any time. In addition, no officer, director, other employee or consultant of the Company may margin, or make any offer to margin, any of the Company's stock, including without limitation, borrowing against such stock, at any time.

Stockholder Communications with our Board of Directors

Stockholders seeking to communicate with our board of directors, as a whole, may send such communication to: Biocept, Inc., 9955 Mesa Rim Road, San Diego, California 92121, Attention: Chief Legal Officer and Chief Compliance Officer. Stockholders seeking to communicate with an individual director, in his or her capacity as a member of our board of directors, may send such communication to the same address to the attention of such individual director. We will promptly forward any such stockholder communication to each director to whom such stockholder communication is addressed to the address specified by each such director.

Item 11. Executive Compensation.

EXECUTIVE COMPENSATION

Summary Compensation Table

The following table shows the compensation awarded to or earned in our last two fiscal years by our principal executive officer and our two most highly compensated executive officers other than our principal executive officer who were serving as executive officers as of December 31, 2022. The persons listed in the following table are referred to herein as the "named executive officers."

Name and Principal Position	Year	Salary($)(1)	Bonus($)		Option Awards($)(2)	All Other Compensation ($)		Total ($)
Sam Riccitelli(3)	2022	507,494	30,000	(4)	570,340	18,463	(5)	1,126,297
Interim President and Chief Executive Officer								
Michael W. Nall(6)	2022	64,875	—		—	535,806	(7)	600,681
Former President and Chief Executive Officer	2021	513,000	15,000		645,517	11,974		1,185,491
Antonino Morales(8)	2022	366,073	—		342,204	21,006	(9)	729,283
Interim Chief Financial Officer								
Darrell Taylor(10)	2022	424,867	—		341,006	7,405		773,278
Chief Legal Officer and Chief Compliance Officer, Corporate Secretary								

(1) The "Salary ($)" column includes salary earned for each named executive officer and the net increase/(decrease) in each named executive officer's accrued vacation balance, or accrued vacation, in each of the years ended December 31, 2022.

(2) The amounts in the "Option Awards ($)" column reflect the grant date fair values of stock options granted during the year. These amounts are determined in accordance with the provisions of FASB ASC Topic 718, rather than an amount paid to or realized by the executive officer. For a description of these stock options see "Narrative Disclosure to Summary Compensation Table" within this "Executive Compensation" section.

(3) Mr. Riccitelli was appointed as our Interim President and Chief Executive Officer, effective February 15, 2022.

(4) Represents a sign-on bonus paid to the named executive officer.

(5) Represents (i) $11,158 in Chair and board of directors fees earned prior to Mr. Riccitelli's appointment as Interim President and Chief Executive Officer, effective February 15, 2022 and (ii) $7,305 in employer paid life insurance premiums.

(6) Mr. Nall resigned from the Company effective February 15, 2022.

(7) Represents severance and PTO pay out as part of Mr. Nall's separation agreement.

(8) Mr. Morales was appointed as our Interim Chief Financial Officer, effective February 15, 2022.

(9) Represents (i) $5,889 in board of directors and audit committee fees earned prior to Mr. Morales's appointment as Interim Financial Officer, effective February 15, 2022 and (ii) $9,672 in employer paid life insurance premiums.

(10) Mr. Taylor joined us in December 2021. He was not a named executive officer in 2021.The amount in "All Other Compensation" represents $3,251 in employer paid life insurance premiums.

Narrative Disclosure to Summary Compensation Table

Employment Agreements

We have entered into employment with each of our named executive officers. The employment agreements set forth the executive officer's initial base salary, annual bonus opportunity and eligibility to participate in our employee benefit plans. Each of our named executive officers is employed "at will." For a discussion of the severance pay and other benefits to be provided in connection with a termination of employment and/or a change in control under the arrangements with our named executive officers, see the subsection titled "—Potential Payments upon Termination or Change in Control" below.

Michael W. Nall

We entered into an employment agreement effective as of August 26, 2013, which was subsequently amended on November 6, 2015 and November 1, 2017, with Michael W. Nall, or collectively, the CEO Employment Agreement, in connection with his appointment as our Chief Executive Officer and President. Pursuant to the CEO Employment Agreement, Mr. Nall was initially entitled to receive an annual base salary of $200,000, which was subsequently increased to $350,000 upon the completion of the IPO, and thereafter periodically increased in the discretion of our board of directors or the compensation committee of our board of directors, and was initially eligible to earn an annual performance bonus of $100,000 in the sole

discretion of our board of directors. In 2021, Mr. Nall's base salary was increased to $519,000 and was eligible to receive his annual performance bonus as a participant in our Annual Incentive Plan, as described further below.

Mr. Nall resigned from his position as the President and Chief Executive Officer of the Company effective on February 15, 2022. Pursuant to the Separation Agreement that we entered into with Mr. Nall, we agreed to provide Mr. Nall with the severance benefits he would have been entitled to receive under the CEO Employment Agreement in the event of a termination without cause, as discussed further below.

Sam Riccitelli

In connection with his appointment as our Interim President and Chief Executive Officer in February 2022, we entered into an employment agreement with Mr. Riccitelli. The employment agreement provides that Mr. Riccitelli will receive an annual base salary of $570,000 and will be eligible to receive an annual performance bonus with a target bonus percentage equal to 50% of his base salary. Pursuant to the employment agreement, we paid Mr. Riccitelli a sign-on bonus of $30,000 and granted him an option to purchase 250,000 shares of our common stock. In addition, Mr. Riccitelli is entitled to severance benefits upon a termination without cause or resignation for good reason ("Involuntary Termination"), including continued payment of base salary for six months and payment of his group health insurance premiums for up to six months. In addition, if Mr. Riccitelli's employment is subject to an Involuntary Termination within one month prior to or 12 months following a change in control, then he will be entitled to receive continued payment of base salary for 12 months, payment of his group health insurance premiums for up to 12 months, a pro-rated annual performance bonus and full accelerated vesting of any unvested equity awards. Mr. Riccitelli may also be entitled to receive tax gross up payments in the event any payments made in connection with a change in control are subject to the excise taxes imposed by Sections 280G and 4999 of the Internal Revenue Code.

Antonino Morales

In connection with his appointment as our Interim Chief Financial Officer, we entered into an employment agreement with Mr. Morales. The employment agreement provides that Mr. Morales will receive an annual base salary of $400,000 and will be eligible to receive an annual performance bonus with a target bonus percentage equal to 40% of his base salary. Pursuant to the employment agreement, we granted Mr. Morales an option to purchase 150,000 shares of our common stock. Mr. Morales is entitled to severance benefits upon an Involuntary Termination, including continued payment of base salary for six months and payment of his group health insurance premiums for up to six months. In addition, if Mr. Morales's employment is subject to an Involuntary Termination within one month prior to or 12 months following a change in control, then he will be entitled to receive continued payment of base salary for 12 months, payment of his group health insurance premiums for up to 12 months, a pro-rated annual performance bonus and full accelerated vesting of any unvested equity awards. Mr. Morales may also be entitled to receive tax gross up payments in the event any payments made in connection with a change in control are subject to the excise taxes imposed by Sections 280G and 4999 of the Internal Revenue Code.

Darrell Taylor

We entered into an employment agreement with Mr. Taylor in December 2021, which was subsequently amended in February 2022. Mr. Taylor was initially entitled to receive an annual base salary of $340,000 and was eligible to receive an annual performance bonus with a target bonus percentage equal to 35% of his base salary. In connection with his promotion to Chief Legal Officer in February 2022, his annual bases salary was increased to $400,000 and his target bonus percentage was increased to 40%. Pursuant to his employment agreement, we granted Mr. Taylor an option to purchase 150,000 shares of our common stock. Mr. Taylor is entitled to severance benefits upon an Involuntary Termination, including continued payment of base salary for six months and payment of his group health insurance premiums for up to six months. In addition, if Mr. Taylor's employment is subject to an Involuntary Termination within one month prior to or 12 months following a change in control, then he will be entitled to receive continued payment of base salary for 12 months, payment of his group health insurance premiums for up to 12 months, a pro-rated annual performance bonus and full accelerated vesting of any unvested equity awards. Mr. Taylor may also be entitled to receive tax gross up payments in the event any payments made in connection with a change in control are subject to the excise taxes imposed by Sections 280G and 4999 of the Internal Revenue Code.

Annual Incentive Plan

On May 19, 2014, the compensation committee of our board of directors approved an annual incentive plan, or the Annual Incentive Plan, to provide our employees, including our executive officers, with an incentive for such employees to perform to the best of their abilities, to further our growth, development and financial success, and to enable us to attract and retain highly qualified employees. Each named executive officer is eligible for an award based upon the achievement of certain pre-established corporate performance goals and objectives approved by the compensation committee and, with respect to our named executive officers other than our chief executive officer, pre-established individual performance goals and objectives approved by the compensation committee.

Pursuant to the terms of our Annual Incentive Plan and their respective employment agreements, for 2022, Mr. Riccitelli was eligible to receive an annual bonus in an amount up to 50% of his annual base salary, based solely on the achievement of pre-determined corporate goals and objectives, and each of Messrs. Morales and Taylor were eligible to receive an annual bonus in an amount up to 40% of their respective annual base salary, based 80% on the achievement of pre-determined corporate goals and objectives, and 20% on the achievement of predetermined individual goals and objectives.

In January 2023, our board of directors determined that the pre-established goals for fiscal year ended December 31, 2022 were not achieved at a level sufficient to warrant payout under the Annual Incentive Plan, and no bonuses were to be paid for 2022.

Equity-Based Incentive Awards

Our equity-based incentive awards are designed to align the interests our stockholders with those of our employees, non-employee directors and consultants, including our named executive officers. Our board of directors or an authorized committee thereof is responsible for approving equity grants.

We have historically used stock options and restricted stock unit awards as an incentive for long-term compensation to our named executive officers because stock options allow our named executive officers to realize value from this form of equity compensation only if our stock price increases to align the interests of our named executive officers with the interests of our stockholders generally.

All stock options are granted with an exercise price per share that is no less than the fair market value of our common stock on the date of grant of such award. Our stock option awards to our named executive officers may be subject to acceleration of vesting and exercisability under certain termination and change in control events.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR END

The following table sets forth certain information, on an award-by-award basis, concerning unexercised options to purchase common stock that have not yet vested for each named executive officer, which were outstanding as of December 31, 2022.

		Option Awards(1)			
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable[2]	Option Exercise Price ($)[3]	Option Expiration Date
Samuel D. Riccitelli	10/20/2020	6,667	3,333	4.63	10/20/2030
	7/16/2021	10,000	—	3.77	7/16/2031
	2/28/2022	52,083	197,917	2.39	2/28/2032
Antonino Morales	7/16/2021	3,333	6,667	3.77	7/16/2031
	2/28/2022	31,250	118,750	2.39	2/28/2032
Darrell Taylor	2/28/2022	37,501	112,499	2.39	2/28/2032

(1) All option awards were granted under our 2013 Plan.

(2) The scheduled vesting dates, after December 31, 2022, of these options were as follows:

Mr. Riccitelli: For the option awards granted on July 16, 2021 in the table above, all options awarded are vested and exercisable. For the first option award granted on October 20, 2020, 1/3 of 10,000 shares vest on each of October 20,

2021, October 20, 2022, and October 20, 2023. For the second option award granted on February 28, 2022, 250,000 option shares vests on a monthly basis over four years from the grant date.

Mr. Morales: For the first option award granted on July 16, 2021, 1/3 of 10,000 shares vest on each of July 16, 2022, July 16, 2023, and July 16, 2024. For the second option award granted on February 28, 2022, 150,000 option shares vests on a monthly basis over four years from the grant date.

Mr. Taylor: For the first option award granted on February 28, 2022, 150,000 option shares vests on a monthly basis over four years from the grant date.

(3) All option awards were granted with a per share exercise price equal to the fair market value of one share of our common stock on the date of grant, as determined in good faith by our board of directors or compensation committee thereof.

Options held by certain of our named executive officers may be eligible for accelerated vesting under specified circumstances. Please see the section below titled "—Potential Payments upon Termination or Change-In-Control" for a description of such potential acceleration.

Potential Payments upon Termination or Change-In-Control

Mr. Riccitelli's employment agreement provided that in the event of termination of his employment by us without cause or his resignation for good reason (each, as defined in the Interim CEO Employment Agreement), the vesting of any of his outstanding unvested stock options which would have vested over the following 12 months will accelerate (unless the applicable stock option or agreement provides for more favorable acceleration terms). The Interim CEO Employment Agreement further provided that if he has a separation from service as a result of his termination without cause or his resignation with good reason then, provided that he gives us an effective waiver and release of claims, he will be entitled to 6 months' salary and up to 6 months of COBRA premiums (or substantially equivalent health insurance coverage). Mr. Riccitelli's Interim CEO Employment Agreement also provided that in the event of a change of control (as defined in the Interim CEO Employment Agreement), if the surviving corporation did not assume, continue, or substitute Mr. Riccitelli's then outstanding stock awards, then all unvested awards would accelerate and vest in full immediately prior to the change of control, subject to Mr. Riccitelli's continuous service immediately prior to such change in control. In addition, if during the 1 month period before a change of control or during the 12-month period following a change of control, Mr. Riccitelli's employment was terminated without cause or Mr. Riccitelli resigned for good reason, then the vesting of each of Mr. Riccitelli's outstanding unvested stock awards will accelerate immediately, and he will be entitled to 12 months' salary and up to 12 months of COBRA premiums (or substantially equivalent health insurance coverage).

Mr. Morales's employment agreement provided that in the event of termination of his employment by us without cause or his resignation for good reason (each, as defined in the Interim CFO Employment Agreement), the vesting of any of his outstanding unvested stock options and which would have vested over the following 12 months will accelerate (unless the applicable stock option agreement provides for more favorable acceleration terms). The Interim CFO Employment Agreement further provided that if he has a separation from service as a result of his termination without cause or his resignation with good reason then, provided that he gives us an effective waiver and release of claims, he will be entitled to 6 months' salary and up to 6 months of COBRA premiums (or substantially equivalent health insurance coverage). Mr. Morales's Interim CFO Employment Agreement also provided that in the event of a change of control (as defined in the Interim CFO Employment Agreement), if the surviving corporation did not assume, continue, or substitute Mr. Morales's then outstanding stock awards, then all unvested awards would accelerate and vest in full immediately prior to the change of control, subject to Mr. Morales's continuous service immediately prior to such change in control. In addition, if during the 1-month period before a change of control or during the 12-month period following a change of control, Mr. Morales's employment was terminated without cause or Mr. Morales resigned for good reason, then the vesting of each of Mr. Morales's outstanding unvested stock awards will accelerate immediately, and he will be entitled to 12 months' salary and up to 12 months of COBRA premiums (or substantially equivalent health insurance coverage).

Mr. Taylor's employment agreement provided that in the event of termination of his employment by us without cause or his resignation for good reason (each, as defined in the CLO Employment Agreement), the vesting of any of his outstanding unvested stock options which would have vested over the following 12 months will accelerate (unless the applicable stock option agreement provides for more favorable acceleration terms). The CLO Employment Agreement further provided that if he has a separation from service as a result of his termination without cause or his resignation with good reason then, provided that he gives us an effective waiver and release of claims, he will be entitled to 6 months' salary and up to 6 months of COBRA

premiums (or substantially equivalent health insurance coverage). Mr. Taylor's CLO Employment Agreement also provided that in the event of a change of control (as defined in the CLO Employment Agreement), if the surviving corporation did not assume, continue, or substitute Mr. Taylor's then outstanding stock awards, then all unvested awards would accelerate and vest in full immediately prior to the change of control, subject to Mr. Taylor's continuous service immediately prior to such change in control. In addition, if during the 1-month period before a change of control or during the 12-month period following a change of control, Mr. Taylor's employment was terminated without cause or Mr. Taylor resigned for good reason, then the vesting of each of Mr. Taylor's outstanding unvested stock awards will accelerate immediately, and he will be entitled to 12 months' salary and up to 12 months of COBRA premiums (or substantially equivalent health insurance coverage).

In addition, we only have the discretion to accelerate the vesting of awards under the 2013 Plan in connection with a change of control if an outstanding award is not assumed, continued or substituted for by the surviving or acquiring corporation (or its parent company).

Separation Agreement with Mr. Nall

In connection with his resignation in February 2022, we entered into a separation agreement with Mr. Nall, pursuant to which Mr. Nall agreed to provide us with a full release of claims and we agreed to provide Mr. Nall with the severance benefits he would have been entitled to receive under his employment agreement in the event of a termination without cause.

Equity Compensation Plan Information

The following table sets forth certain information as of December 31, 2022 regarding the shares of our common stock available for grant or granted under stock option plans and other compensation arrangements that were (i) adopted by our security holders and (ii) were not approved by our security holders:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights ($)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in 1st column)
Equity compensation plans approved by security holders[(1)]	1,011,037	$ 2.23	1,325,372
Equity compensation plans not approved by security holders[(2)]	1,252,364	$ 1.63	997,636

(1) Represents 1,011,037 shares of common stock that may be issued pursuant to outstanding non-inducement option awards granted and 36 shares of common stock that may be issued pursuant to outstanding non-inducement restricted stock unit awards granted, and 1,325,372 shares of common stock available for future grant as non-inducement awards, under the 2007 Plan and 2013 Plan. See "Executive Compensation—Equity Compensation Plan Information—2007 Equity Incentive Plan" and "Executive Compensation—Equity Compensation Plan Information—Amended and Restated 2013 Plan" below for a description of these plans.

(2) Represents 1,252,364 shares of common stock that may be issued pursuant to such outstanding inducement option awards granted and 997,636 shares of common stock available for future grant as inducement awards under the 2013 Plan.

Equity Compensation Plan Information

We have two equity incentive plans: the 2007 Plan and the 2013 Plan. We no longer grant awards under the 2007 Plan, but awards granted under the 2007 Plan remain subject to its terms. A brief summary of each of the 2007 Plan and 2013 Plan is below.

2007 Equity Incentive Plan

The 2007 Plan authorized the grant of the following types of awards: (i) nonstatutory stock options, or NSOs; (ii) incentive stock options, or ISOs; (iii) restricted stock awards; (iv) RSUs; (v) stock appreciation rights, or SARs; (vi) performance stock awards; and (vii) other stock awards. Awards may be granted to employees, directors, consultants and other service providers of our company and its affiliates. However, ISOs may not be granted to non-employees.

Corporate Transaction. In the event we are acquired in a corporate transaction, as defined in the 2007 Plan, unless otherwise provided in a written agreement between us and the holder of an outstanding 2007 Plan award, awards will be assumed by the successor company or a similar award will be substituted by the successor company. If the successor company does not agree to assume or substitute an award, if the award is held by a current participant (as defined in the 2007 Plan), the vesting of the award will accelerate, and the award will become exercisable in full, if the award is held by someone other than a current participant, the award will terminate if not exercised prior to the effective time of the corporate transaction.

Change in Control. In the event of a change in control, award may be subject to acceleration of vesting and exercisability, as provided for in the award agreement or in any other written agreement between the Company and the participant, but in the absence of such provision, no such acceleration shall occur.

Amended and Restated 2013 Plan

The 2013 Plan authorized the grant of the following types of awards: (i) nonstatutory stock options, or NSOs; (ii) incentive stock options, or ISOs; (iii) restricted stock awards; (iv) RSUs; (v) stock appreciation rights, or SARs; (vi) performance stock awards; and (vii) other stock awards. Awards may be granted to employees, directors, consultants and other service providers of our company and its affiliates. However, ISOs may not be granted to non-employees. In addition, the 2013 Plan has a separate share reserve that may be used exclusively for the grant of inducement awards to employees who have not previously been an employee or a director of us or an affiliate, or following a bona fide period of non-employment, as an inducement material to the individuals' entering into employment with us within the meaning of the Nasdaq Listing Rules. All such inducement awards must be granted by a committee consisting of the majority of our independent directors or our independent compensation committee, in either case in accordance with Nasdaq Listing Rules.

Change in Control.

In the event of a change in control of us, as defined in the Amended 2013 Plan, in which the surviving corporation or acquiring corporation (or its parent company) does not assume or continue outstanding awards under the Amended 2013 Plan or substitute similar stock awards for such outstanding awards, then the plan administrator may, in its discretion and upon at least 10 days' advance notice to the affected persons, accelerate the vesting (and exercisability, as applicable) of outstanding awards under the 2013 Plan in full or in part to a date prior to the effective time of the change in control transaction and, to the extent not exercised (if applicable) at or prior to the effective time of the transaction, cancel all outstanding awards upon or immediately before the change in control and pay to the holders thereof, in cash or stock, or any combination thereof, the value of such awards (including, at the plan administrator's discretion, any unvested portion of the award) based upon the value per share of common stock received or to be received or deemed received by our other stockholders in the transaction. In the case of any stock option or SAR with an exercise price that equals or exceeds the price paid for a share of common stock in connection with the change in control, the plan administrator may cancel the option or SAR without the payment of consideration therefor.

In addition, in the event of a participant's termination of continuous service without cause or resignation for good reason, as each such term is defined in the 2013 Plan, during the 10 day period before a change in control or during the 12 month period following a change in control, all stock options and SARs under the 2013 Plan will become immediately exercisable with respect to 100% of the shares subject to such stock options or SARs, and/or the restricted period will expire immediately with respect to 100% of the shares of restricted stock or RSUs as of the date of the participant's termination or resignation.

With respect to performance compensation awards, in the event of a change in control, all incomplete performance periods in respect of such award in effect on the date the change in control occurs will end on the date of such change in control and the plan administrator will (i) determine the extent to which performance goals with respect to each such performance period have been met based upon such audited or unaudited financial information then available as it deems relevant and (ii) cause to be paid to the applicable participant partial or full awards with respect to performance goals for each such performance period based upon the plan administrator's determination of the degree of attainment of performance goals or, if not determinable, assuming that the applicable "target" levels of performance have been attained, or on such other basis determined by the plan administrator.

DIRECTOR COMPENSATION

In February 2022, upon recommendation from our compensation committee, our board of directors approved amendments to our non-employee director compensation policy. As amended, our non-employee director compensation policy includes the following cash and equity compensation:

- Annual Retainer.

For service as a director: an annual cash retainer of $40,000 (in addition to any annual cash retainers otherwise paid).

- Board Chair.

For service as Board Chair: an annual cash retainer of $50,000 (in addition to any annual cash retainers otherwise paid).

- Lead Independent Director.

For service as Lead Independent Director: an annual cash retainer of $50,000 (in addition to any annual cash retainers otherwise paid).

- Audit Committee.

For service as Chair of the audit committee: an annual cash retainer of $15,000 (in addition to any annual cash retainers otherwise paid).

For service as member of the audit committee other than as its Chair: an annual cash retainer of $7,500 (in addition to any annual cash retainers otherwise paid).

- Compensation Committee.

For service as Chair of the compensation committee: an annual cash retainer of $10,000 (in addition to any annual cash retainers otherwise paid).

For service as member of the compensation committee other than as its Chair: an annual cash retainer of $5,000 (in addition to any annual cash retainers otherwise paid).

- Nominating and Corporate Governance Committee.

For service as Chair of the nominating and corporate governance committee: an annual cash retainer of $10,000 (in addition to any annual cash retainers otherwise paid).

For service as member of the nominating and corporate governance committee other than as its Chair: an annual cash retainer of $5,000 (in addition to any annual cash retainers otherwise paid).

- Science, Technology, and Clinical Affairs Committee.

For service as Chair of the science, technology, and clinical affairs committee: an annual cash retainer of $10,000 (in addition to any annual cash retainers otherwise paid).

For service as member of the science, technology, and clinical affairs committee other than as its Chair: an annual cash retainer of $5,000 (in addition to any annual cash retainers otherwise paid).

- Initial Awards.

For each non-employee director who is initially elected or appointed to the board: an option to purchase 10,000 shares of common stock.

- Annual Awards.

For each non-employee director who (i) has been serving on the board for at least six months as of the date of any annual meeting of our stockholders and (ii) will continue to serve as a non-employee director immediately following such meeting: an option to purchase 10,000 shares of common stock.

The annual cash retainers shall be earned and paid on a calendar quarterly basis, subject to proration in the case of service during only a portion of a calendar quarter.

The per share exercise price of each option granted to our non-employee directors shall equal the fair market value of a share of common stock on the date the option is granted. Each such initial award shall vest and become exercisable in substantially equal installments on each of the first three anniversaries of the vesting commencement date, subject to continuing in service on the board through each such vesting date; provided, that all stock options under the non-employee director compensation policy shall vest in full upon the occurrence of a change in control. Each such annual award shall fully vest and become exercisable on the first anniversary of the vesting commencement date, subject to continuing in service on the board through each such vesting date; provided, that all stock options under the non-employee director compensation policy shall vest in full upon the occurrence of a change in control. The term of each such stock option shall be ten years from the date the option is granted. Upon a non-employee director's cessation of service on the board for any reason, his or her stock options granted under the non-employee director compensation policy would, to the extent vested on the date of cessation of service, remain exercisable for 12 months following the cessation of his or her service on the board (or such longer period as the board may determine in its discretion on or after the date of such stock options).

On July 8, 2022, option awards exercisable for 10,000 shares of common stock each with a vesting commencement date of July 8, 2022 were granted under the 2013 Plan to each of the then five non-employee members of our board of directors related to the grant of annual awards for the 2022 annual meeting of our shareholders, in accordance with our non-employee director compensation policy in effect at the date of grant. These awards have a term of 10 years from the date of grant and an exercise price of $1.03 per share, which is equal to the closing price of our common stock on the date of grant. The grant date fair value of these awards of $1.03 per share was estimated using a Black-Scholes valuation model. The assumptions used in the Black-Scholes valuation model for these awards include a volatility rate of 179.87%, a risk-free interest rate of 0.51%, a dividend yield of 0.00%, and an expected term of 5.5 years.

On November 17, 2022, option awards exercisable for 10,000 shares of common stock with a vesting commencement date of November 17, 2022 was granted under the 2013 Plan to Quyen Dao-Haddock in connection with her appointment to our board of directors, in accordance with the initial awards amounts noted above in this "Director Compensation" section. These awards have a term of 10 years from the date of grant and an exercise price of $0.81 per share, which is equal to the closing price of our common stock on the date of grant. The grant date fair value of these awards of $3.58 per share was estimated using a Black-Scholes valuation model. The assumptions used in the Black-Scholes valuation model include a volatility rate of 165.56%, a risk-free rate of 3.93%, a dividend yield of 0.00%, and an expected term of 5.08 years.

The following table reflects all compensation awarded to, earned by or paid to the non-employee directors during the fiscal year ended December 31, 2022:

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	Total ($)
M. Faye Wilson, MBA	108,801	10,210	119,011
Marsha A. Chandler, Ph.D.	60,000	10,210	70,210
Bruce E. Gerhardt, CPA	57,500	10,210	67,710
Ivor Royston, M.D.	55,000	10,210	65,210
Linda Rubinstein	47,053	10,210	57,263
David F. Hale	26,487	10,210	36,697
Quyen Dao-Haddock, CPA[(2)]	5,674	7,646	13,320
Samuel D. Riccitelli	11,158	—	11,158
Antonino Morales, CPA	5,889	—	5,889

(1) The amounts in the "Option Awards ($)" column reflect the grant date fair values of stock options granted during the year. These amounts are determined in accordance with the provisions of FASB ASC Topic 718, rather than an amount paid to or realized by the director.

(2) Effective November 17, 2022, Quyen Dao-Haddock was appointed to our board of directors. Upon her appointment to our board of directors, Ms. Dao-Haddock received an option grant to purchase 10,000 shares of our common stock.

The following table sets forth the number of option awards outstanding for each non-employee director as of December 31, 2022:

Name	Option Award (#)
M. Faye Wilson, MBA	23,282
Marsha A. Chandler, Ph.D.	23,270
Ivor Royston, M.D.	23,255
Bruce E. Gerhardt, CPA	23,251
Linda Rubinstein	20,000
Quyen Dao-Haddock, CPA	10,000

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth the beneficial ownership of our common stock as of February 28, 2023 by:

- each person, or group of affiliated persons, whom we know to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our current executive officers and directors as a group.

Applicable percentages are based on 17,728,195 shares outstanding on February 28, 2023, adjusted as required by rules promulgated by the SEC.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or exercisable on or before April 29, 2023, which is 60 days after February 28, 2023. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for persons listed in the table is c/o Biocept, Inc., 9955 Mesa Rim Road, San Diego, California 92121.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Named Executive Officers and Directors:		
Marsha A. Chandler, Ph.D.(1)	13,229	*
Bruce E. Gerhardt, CPA(2)	13,712	*
Quyen Dao-Haddock, CPA(3)	1,389	*
Antonino Morales, CPA (4)	47,083	*
Darrell Taylor (5)	50,000	*
Michael W. Nall (6)	—	*
Samuel D. Riccitelli (7)	89,584	*
Ivor Royston, M.D. (8)	13,249	*
Linda Rubinstein (9)	3,333	*
M. Faye Wilson, MBA(10)	13,292	*
All Current Executive Officers and Directors as a group (11 persons) (11)	285,496	1.61 %

* Less than 1%.

(1) Includes 13,207 shares of common stock underlying stock options. The number of shares beneficially owned also includes 17 shares held by Dr. Chandler and 5 outstanding shares held by a family trust affiliated with Dr. Chandler.

(2) Includes 441 shares of common stock and 13,251 shares of common stock underlying stock options. The calculation of the percentage of shares beneficially owned also includes 83 shares for which common stock warrants held by Mr. Gerhardt are exercisable at per share prices of $150.00 according to prices set in our January 2018 public offering.

(3) Includes 1,389 shares of common stock underlying stock options.

(4) Includes 47,083 shares of common stock underlying stock options.

(5) Includes 50,000 shares of common stock underlying stock options.

(6) Mr. Nall resigned from our company effective February 15, 2022. We are not aware of any shares beneficially owned by him based on our records.

(7) Includes 89,584 shares of common stock underlying stock options.

(8) Includes 13,255 shares of common stock underlying stock options. Includes 32 outstanding shares of common stock owned by Dr. Royston's individual retirement account, 15 shares held in a family trust and 10 shares held in an individual trust account.

(9) Includes 13,312 shares of common stock underlying stock options.

(10) Includes 13,282 shares of common stock underlying stock options. Includes 71 outstanding shares of common stock held by Ms. Wilson and 2 outstanding shares of common stock held by Ms. Wilson's individual retirement account.

(11) Consists of the shares described in notes (1) through (5) and (7) through (10) above, as well 40,625 shares of common stock underlying stock options beneficially owned by executive officers not named in the table above.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Other than compensation arrangements for named executive officers and directors, we describe below each transaction and series of similar transactions, since January 1, 2021, to which we were a party or will be a party, in which the amounts exceeded $120,000 or will exceed $120,000 (or, if less, 1% of the average of our total assets amount at December 31, 2021 and 2022) and in which any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of, or person sharing the household with, the foregoing persons, had or will have a direct or indirect material interest.

Lyle J. Arnold, Ph.D.

Lyle J. Arnold, Ph.D., our former Chief Scientist, Senior Vice-President, is the controlling person of Aegea Biotechnologies, Inc., or Aegea. On September 2, 2012, the Company entered into an Assignment and Exclusive Cross-License Agreement, or

the Cross-License Agreement, with Aegea. The Company received payments totaling approximately $0 and $49,000 during the years ended December 31, 2022 and 2021, respectively, from Aegea as reimbursements for shared patent costs under the Cross-License Agreement. On December 11, 2019, the Company entered into a First Amendment to Assignment and Exclusive Cross-License Agreement with Aegea pursuant to which the Company obtained a royalty bearing license for a certain patent. In February 2022, Dr. Arnold's employment with the Company was terminated. On May 24, 2022, to limit costs and expenses related to the shared intellectual property related to the Switch-Blocker and Primer Switch technology described in the Agreement, Aegea and the Company amended the Cross-License Agreement whereby Aegea became solely responsible for costs associated with such technology.

Indemnification Agreements

We have entered into indemnification agreements with each of our current directors and executive officers. These agreements will require us to indemnify these individuals to the fullest extent permitted under Delaware law against liabilities that may arise by reason of their service to us and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified. We also intend to enter into indemnification agreements with our future directors and executive officers. In addition, our predecessor company Biocept, Inc., a California corporation, entered into indemnification agreements with certain of our current directors and executive officers and certain prior directors and executive officers. These agreements will require us to indemnify these individuals to the fullest extent permitted under California law against liabilities that may arise by reason of their service to us, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified.

Policies and Procedures for Related Party Transactions

We adopted a policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock, any members of the immediate family of any of the foregoing persons and any firms, corporations or other entities in which any of the foregoing persons is employed or is a partner or principal or in a similar position or in which such person has a 5% or greater beneficial ownership interest, collectively, related parties, are not permitted to enter into a transaction with us without the prior consent of our board of directors acting through the audit committee. Any request for us to enter into a transaction with a related party in which the amount involved exceeds $120,000, and in which such related party would have a direct or indirect interest, must first be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our audit committee is to consider the material facts of the transaction, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances, the extent of the benefits to us, the availability of other sources of comparable products or services and the extent of the related person's interest in the transaction.

Item 14. Principal Accounting Fees and Services.

AUDIT AND ALL OTHER FEES

The following table presents the fees billed to us for professional services related to the years ended December 31, 2022 and 2021 by RSM, MHM and its affiliate, CBIZ MHM, LLC:

	RSM		MHM	
	2022	2021	2022	2021
Audit Fees[1]	$ 823,981	$ —	$ 222,226	$ 632,194
Tax Fees[2]	—	—	78,430	20,475
All Other Fees[3]	—	—	—	—
Total	$ 823,981	$ —	$ 300,656	$ 652,669

(1) Audit Fees consist of fees billed for professional services performed by MHM and RSM, including out-of-pocket expenses. The amounts presented relate to the audit of our annual financial statements, the review of financial statements included in our quarterly reports on Form 10-Q, review of our registration statements on Forms S-3 and S-8, and related services that are normally provided in connection with statutory and regulatory filings or engagements.

(2) Tax Fees consist of fees billed for professional services relating to tax compliance, tax advice, and tax planning billed by MHM's affiliate, CBIZ MHM, LLC, including out-of-pocket expenses. MHM leases substantially all of its personnel,

who work under the control of MHM shareholders, from wholly-owned subsidiaries of CBIZ, Inc., including CBIZ MHM, LLC, in an alternative practice structure. Our audit committee approved all of 2022 and 2021 tax fees.

(3) All Other Fees consist of fees for other permissible work that were not "audit-related fees" and not included within the above category descriptions.

AUDIT COMMITTEE PRE-APPROVAL POLICIES AND PROCEDURES

Our audit committee has established a policy that all audit and permissible non-audit services provided by our independent registered public accounting firm will be pre-approved by the audit committee. These services may include audit services, audit- related services, tax services and other services. Our audit committee considers whether the provision of each non-audit service is compatible with maintaining the independence of our auditors. Pre-approval is detailed as to the particular service or category of services and is generally subject to a specific budget. Our independent registered public accounting firm and management are required to periodically report to our audit committee regarding the extent of services provided by our independent registered public accounting firm in accordance with this pre-approval, and the fees for the services performed to date.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Report:

1. *Financial Statements*. The following documents are included in Part II, Item 8 of this Report and are incorporated by reference herein:

2. *Financial Statement Schedules*.

Not required.

3. *Exhibits*.

EXHIBITS

Exhibit No.	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation, as amended by a Certificate of Amendment thereto (incorporated by reference to Exhibit 3.1.4 of the Registrant's Current Report on Form 8-K, filed with the SEC on February 14, 2014).
3.2	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on September 29, 2016).
3.3	Certificate of Amendment to Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on July 6, 2018).
3.4	Certificate of Amendment to Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on September 4, 2020).
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on August 13, 2018).
3.6	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
3.7	Amendment to Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on September 29, 2017).
3.8	Second Amendment to Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on March 24, 2022).
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7. and 3.8
4.2	Specimen Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.2 of the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 16, 2020).
4.3	Description of Common Stock (incorporated by reference to Exhibit 4.3 of the Registrant's Annual Report on Form 10-K filed with the SEC on April 5, 2022).
4.4	Form of Warrant issued to the lenders under the Loan and Security Agreement, dated as of April 30, 2014, by and among Biocept, Inc., Oxford Finance LLC, as collateral agent, and the lenders party thereto from time to time, including Oxford Finance LLC (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on May 6, 2014).
4.5	Form of Series 1 Common Stock Purchase Warrant (incorporated by reference to Exhibit 3.6 of the Registrant's Registration Statement on Form S-1 (File No. 333-225147), as amended, filed with the SEC on July 11, 2018).
4.6	Form of Series A Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K, filed with the SEC on September 24, 2018).
4.7	Form of Series B Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.24 of the Registrant's Registration Statement on Form S-1 (File No. 333-228566), filed with the SEC on November 28, 2018), and issued to investors on February 12, 2019.
4.8	Form of Series B Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on March 18, 2019).
4.9	Form of Series C Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on May 29, 2019).
4.10	Form of Common Stock Warrant (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on December 11, 2019).
4.11	Form of Warrant Amendment (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on January 9, 2020).

Exhibit No.	Description of Exhibit
4.12	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K, filed with the SEC on January 9, 2020).
10.1+	2007 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.2+	Form of Stock Option Grant Notice and Option Agreement under 2007 Equity Incentive Plan (incorporated by reference to Exhibit 10.1.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.3+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under 2007 Equity Incentive Plan (incorporated by reference to Exhibit 10.1.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.4+	Form of Indemnification Agreement between the Registrant and its officers and directors (incorporated by reference to Exhibit 10.3 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.5+	Form of Indemnity Agreement between Biocept, Inc., a California corporation, and its officers and directors (incorporated by reference to Exhibit 10.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.6	Assignment and Exclusive Cross-License Agreement between the Registrant and Aegea Biotechnologies, Inc. dated June 2, 2012 (incorporated by reference to Exhibit 10.22 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), as amended, filed with the SEC on January 30, 2014).
10.7	Second Amendment to Assignment and Cross-License Agreement between the Registrant and Aegea Biotechnologies, Inc., dated May 24, 2022 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed with the SEC on November 10, 2022).
10.8	2014 Management Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 8, 2014).
10.9	Biocept, Inc. Amended and Restated 2013 Equity Incentive Plan, Form of Stock Option Grant Notice, Option Agreement, Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit agreement for use thereunder, as amended (incorporated by reference to Exhibit 10.8 of the Registrant's Annual Report on Form 10-K, filed with the SEC on April 5, 2022).
10.10	Lease Agreement, dated June 1, 2020, by and between Registrant and 9955 Mesa Rim A DE LLC (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 13, 2020).
10.11+	Employment Agreement, dated December 27, 2021, by and between the Registrant and Darrell Taylor, as amended.
10.12	Non-Employee Director Compensation Policy, as amended (incorporated by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K, filed with the SEC on April 5, 2022).
10.13+	Employment Offer Letter, dated February 15, 2022, by and between the Registrant and Samuel D. Riccitelli (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on February 16, 2022).
10.14+	Employment Offer Letter, dated February 15, 2022, by and between the Registrant and Antonino Morales (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on February 16, 2022).
10.15+	Employment Offer Letter, dated March 4, 2022, by and between the Registrant and Philippe Marchand, Ph.D. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on March 8, 2022).
10.16	Non-Employee Director Compensation Policy
23.1	Consent of Mayer Hoffman McCann P.C.
23.2	Consent of RSM US LLP

31.1	Certification of Samuel D. Riccitelli, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Antonino Morales, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Samuel D. Riccitelli, Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Antonino Morales, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Taxonomy Extension Schema Document
101.SCH	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.CAL	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Label Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interact File (formatted as inline XBRL and contained in Exhibit 101)

+ Indicates management contract or compensatory plan.
* This certification is not deemed “filed” for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that the registrant specifically incorporates it by reference.

Item 16. Form 10-K Summary.

None

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BIOCEPT, INC.

Date: April 17, 2023

By: /s/ Samuel D. Riccitelli
Samuel D. Riccitelli
Interim President and Chief Executive Officer

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Samuel D. Riccitelli and Antonino Morales, and each and either of them, his or her true and lawful agent, proxy and attorney-in-fact, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Samuel D. Riccitelli Samuel D. Riccitelli	Interim President and Chief Executive Officer, Chair and Director (Principal Executive Officer)	April 17, 2023
/s/ Antonino Morales Antonino Morales	Interim Chief Financial Officer and Director (Principal Financial Officer and Principal Accounting Officer)	April 17, 2023
/s/ M. Faye Wilson M. Faye Wilson	Director	April 17, 2023
/s/ Marsha A. Chandler Marsha A. Chandler	Director	April 17, 2023
/s/ Bruce E. Gerhardt Bruce E. Gerhardt	Director	April 17, 2023
/s/ Quyen Dao-Haddock Quyen Dao-Haddock	Director	April 17, 2023
/s/ Ivor Royston Ivor Royston	Director	April 17, 2023
/s/ Linda Rubinstein Linda Rubinstein	Director	April 17, 2023

BIOCEPT, INC.

Darrell Taylor, Esq.
1345 Belleview Avenue
Cardiff, CA 92007

Re: Offer of Employment

Dear Darrell:

Biocept, Inc. (the "**Company**") is pleased to offer you at-will employment in the position of Chief Legal and Compliance Officer ("**CLO**") on the terms and conditions set forth in this letter agreement (the "**Agreement**").

1. Employment by the Company. Your employment with the Company shall begin on December 27, 2021 or such date as otherwise agreed to by you and the Company [such actual date your employment begins (the "**Start Date**")]. This is an exempt position, and during your employment with the Company, you will devote your best efforts and substantially all of your business time and attention to the business of the Company, except for approved vacation periods and reasonable periods of illness or other incapacities permitted by the Company's general employment policies. You shall perform such duties as are required by the Company's Chief Executive Officer ("**CEO**"), to whom you will report. You represent to the Company that you are not subject to or a party to any employment agreement, non-competition covenant, or other agreement that would be breached by, or prohibit you from, executing this Agreement and performing fully your duties and responsibilities hereunder. Your primary work location shall be the Company's office located in San Diego, California. The Company reserves the right to reasonably require you to perform your duties at places other than your primary work location from time to time, and to require reasonable business travel. The Company may modify your job title and duties as it deems necessary and appropriate in light of the Company's needs and interests from time to time.

2. Compensation.

2.1 Base Salary. For services to be rendered hereunder, you shall receive a base salary at the rate of Four Hundred Thousand Dollars ($400,000) per year (the "**Base Salary**"), subject to standard payroll deductions and withholdings and payable in accordance with the Company's regular payroll schedule.

2.2 Annual Bonus. During your employment, you will be eligible for an annual discretionary bonus with a target amount of forty percent (40%) of your then current annual Base Salary, prorated for the number of days employed in a calendar year (the **"Annual Bonus"**). Whether you receive an Annual Bonus for any given year, and the amount of any such Annual Bonus, will be determined by the Board of Directors of the Company and/or its Compensation Committee (the "**Board**") in its discretion based upon the achievement of corporate and/or individual objectives and milestones that are determined in the sole discretion of the Board. You must continue to be employed through the date the Annual Bonus is paid in order to earn such bonus. The Annual Bonus, if any, shall be paid to you in a lump sum no later than March 15th of the calendar year that follows the performance year, subject to applicable payroll deductions and withholdings.

2.3 Equity. Subject to approval by the Board, you shall be granted an option to purchase One Hundred Fifty Thousand (150,000) shares of Common Stock in the Company at the fair market value on the date of grant (the "***Option***"). The Option shall vest on a monthly basis over a four (4) year period (1/48th per month) and be governed in all respects by the terms of the governing plan documents and option agreement between you and the Company.

3. Reasonable Business Expenses. You will be eligible for reimbursement of all reasonable, necessary and documented out-of-pocket business, entertainment, and travel expenses incurred by you in connection with the performance of your duties hereunder in accordance with the Company's expense reimbursement policies and procedures.

4. Company Policies; Standard Company Benefits.

4.1 The employment relationship between the parties shall be governed by the general employment policies and practices of the Company, except that when the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

4.2 You shall be entitled to participate in all employee benefit programs for which you are eligible under the terms and conditions of the benefit plans that may be in effect from time to time and provided by the Company to its employees. The Company reserves the right to cancel or change the benefit plans or programs it offers to its employees at any time.

4.3 You will initially be eligible to accrue paid time off, subject to applicable maximum accrual caps, in accordance with the Company's paid time off policies as in effect from time to time. You will also be eligible for certain paid holidays pursuant to Company policy. The Company reserves the right to cancel or change its policies regarding vacation, paid time off, paid sick leave and/or holidays from time to time without amendment of this Agreement.

5. At-Will Employment. Your employment relationship is at-will. Either you or the Company may terminate the employment relationship at any time, with or without cause or advance notice.

6. Outside Activities During Employment. Except with the prior written consent of the Company's Chief Executive Officer, you will not during the term of your employment with the Company undertake or engage in any other employment, occupation or business enterprise, other than ones in which you are a passive investor. You may engage in civic and not-for-profit activities so long as such activities do not materially interfere with the performance of your duties hereunder. You agree not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise.

7. Termination.

7.1 Term and Termination. The term of this Agreement shall be the period commencing on the Start Date and ending on the date that this Agreement is terminated by either party pursuant to the provisions of this Agreement. You are employed at-will, meaning that, subject to the terms and conditions set forth herein, either the Company or you may terminate your employment at any time, with or without Cause. Upon termination of your employment for any reason, you shall resign from all positions and terminate any relationships as an employee, advisor, officer or director with the Company and any of its affiliates, each effective on the date of termination.

7.2 Compensation upon Termination. Upon the termination of your employment for any reason, the Company shall pay you all of your accrued and unpaid wages earned through your last day of employment (the "**Separation Date**").

7.3 Severance Benefits upon an Involuntary Termination. If you are subject to an Involuntary Termination (that does not occur within the Change in Control Period (as defined below)), and provided that you remain in compliance with the terms of this Agreement (including the conditions described in Section 7.6 below), the Company shall provide you with the following benefits (the "**Severance Benefits**"):

(a) Cash Severance. The Company shall pay you, as severance, the equivalent of six (6) months (the "**Severance Period**") of your Base Salary in effect as of the Separation Date, subject to standard payroll deductions and withholdings (the "**Severance**"). The Severance will be paid as a continuation on the Company's regular payroll, beginning no later than the first regularly-scheduled payroll date following the sixtieth (60th) day after your Separation from Service, provided the Separation Agreement (as discussed in Section 7.6) has become effective.

(b) Payment of Continued Group Health Plan Benefits. If you are eligible for and timely elect continued group health plan coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 or any state law of similar effect ("**COBRA**") following your Involuntary Termination, the Company will pay your COBRA group health insurance premiums for you and your eligible dependents directly to the insurer until the earliest of (A) the end of the period immediately following your Involuntary Termination that is equal to the Severance Period (the "**COBRA Payment Period**"), (B) the expiration of your eligibility for continuation coverage under COBRA, or (C) the date when you become eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment. For purposes of this Section, references to COBRA premiums shall not include any amounts payable by you under a Section 125 health care reimbursement plan under the Code. Notwithstanding the foregoing, if at any time the Company determines, in its sole discretion, that it cannot pay the COBRA premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then in lieu of providing the COBRA premiums, the Company will instead pay you on the last day of each remaining month of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premiums for that month, subject to applicable tax withholdings (such amount, the "**Special Severance Payment**"), which payments shall continue until the earlier of expiration of the COBRA Payment Period or the date when you become eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment. On the first payroll date following the effectiveness of the Separation Agreement, the Company will make the first payment to the insurer under this clause (and, in the case of the Special Severance Payment, such payment will be to you, in a lump sum) equal to the aggregate amount of payments that the Company would have paid through such date had such payments instead commenced on the Separation Date, with the balance of the payments paid thereafter on the schedule described above. If you become eligible for coverage under another employer's group health plan, you must immediately notify the Company of such event, and all payments and obligations under this subsection shall cease.

(c) Accelerated Vesting. The vesting and exercisability of all outstanding options, restricted stock unit awards, and other equity awards covering the Company's common stock that are held by you as of immediately prior to the Involuntary Termination, to the extent such equity awards would otherwise have vested solely conditioned on your continued services with the Company, shall accelerate vesting in accordance with their applicable vesting schedules as if you had completed an additional number of months of service with the Company equal to the Severance Period as of the Separation Date. For the avoidance of doubt, equity awards which vest wholly or partially subject to the attainment of performance goals are not eligible to accelerate vesting pursuant to this subsection.

7.4 Severance Benefits upon an Involuntary Termination during Change in Control Period. If you are subject to an Involuntary Termination during the Change in Control Period, and provided that you remain in compliance with the terms of this Agreement (including the conditions described in Section 7.6 below), the Company shall provide you with the following change in control severance benefits (the "**Change in Control Severance Benefits**"):

(a) Cash Severance. The Company shall pay you, as severance, the equivalent of twelve (12) months (the "**CIC Severance Period**") of your Base Salary in effect as of the Separation Date, subject to standard payroll deductions and withholdings (the "**CIC Severance**"). The CIC Severance will be paid as a continuation on the Company's regular payroll, beginning no later than the first regularly-scheduled payroll date following the sixtieth (60th) day after your Separation from Service, provided the Separation Agreement (as discussed in Section 7.6) has become effective.

(b) Prorated Annual Bonus. In addition, you will receive a payment equal to the product of (i) the Annual Bonus that you would have been entitled to receive if corporate and/or individual objectives and milestones were fully achieved for the calendar year in which the Separation Date occurs (less standard payroll deductions and applicable withholdings) and (ii) a fraction, the numerator of which is the number of days you were continuously employed by the Company during the year of termination and the denominator of which is the number of days in such year, to be paid periodically in installments during the CIC Severance Period in accordance with the Company's normal payroll practices beginning on the first regularly-scheduled payroll date following the sixtieth (60th) day after your Separation from Service, provided the Separation Agreement (as discussed in Section 7.6) has become effective.

(c) Payment of Continued Group Health Plan Benefits. If you are eligible for and timely elect continued group health plan coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 or any state law of similar effect ("**COBRA**") following your Involuntary Termination, the Company will pay your COBRA group health insurance premiums for you and your eligible dependents directly to the insurer until the earliest of (A) the end of the period immediately following your Involuntary Termination that is equal to the CIC Severance Period (the "**CIC COBRA Payment Period**"), (B) the expiration of your eligibility for continuation coverage under COBRA, or (C) the

date when you become eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment. For purposes of this Section, references to COBRA premiums shall not include any amounts payable by you under a Section 125 health care reimbursement plan under the Code. Notwithstanding the foregoing, if at any time the Company determines, in its sole discretion, that it cannot pay the COBRA premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then regardless of whether you elect continued health coverage under COBRA, and in lieu of providing the COBRA premiums, the Company will instead pay you on the last day of each remaining month of the CIC COBRA Payment Period, a fully taxable cash payment equal to the COBRA premiums for that month, subject to applicable tax withholdings (such amount, the "**Special Severance Payment**"), which payments shall continue until the earlier of expiration of the CIC COBRA Payment Period or the date when you become eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment. On the first payroll date following the effectiveness of the Separation Agreement, the Company will make the first payment to the insurer under this clause (and, in the case of the Special Severance Payment, such payment will be to you, in a lump sum) equal to the aggregate amount of payments that the Company would have paid through such date had such payments instead commenced on the Separation Date, with the balance of the payments paid thereafter on the schedule described above. If you become eligible for coverage under another employer's group health plan, you must immediately notify the Company of such event, and all payments and obligations under this subsection shall cease.

(d) Accelerated Vesting. Effective as of the later of the Separation Date or the effective date of the Change in Control, the vesting and exercisability of all outstanding time-based stock options and other time-based equity awards covering the Company's common stock that are held by you as of immediately prior to the Separation Date shall accelerate vesting in full. For the avoidance of doubt, vesting acceleration under this subsection is conditioned upon the actual consummation of a Change in Control.

For the avoidance of doubt, in no event shall you be entitled to benefits under both Section 7.3 and this Section 7.4. If you are eligible for benefits under both Section 7.3 and this Section 7.4, you shall receive the benefits set forth in this Section 7.4 and such benefits shall be reduced by any benefits previously provided to you under Section 7.3.

7.5 Termination for Cause; Resignation Without Good Reason; Death or Disability. If you resign without Good Reason, or the Company terminates your employment for Cause, upon dissolution or cessation of the Company, or upon your death or disability, then (a) you will no longer vest in any equity awards (including without limitation, the Option), (b) all payments of compensation by the Company to you hereunder will terminate immediately (except as to amounts already earned), and (c) you will not be entitled to any Severance Benefits or Change in Control Severance Benefits.

7.6 Conditions to Receipt of Severance Benefits and Change in Control Severance Benefits. The receipt of the Severance Benefits and Change in Control Severance Benefits will be subject to you signing and not revoking a separation agreement and general release of claims in a form reasonably satisfactory to the Company (the "**Separation Agreement**") by no later than the sixtieth (60th) day after the Separation Date ("**Release Deadline**"). No Severance Benefits or Change in Control Severance Benefits will be paid or provided until the Separation Agreement becomes effective. You shall also resign from all positions and terminate any relationships as an employee, advisor, officer or director with the Company and any of its affiliates, each effective on the Separation Date.

8. Definitions.

8.1 Cause. For purposes of this Agreement, **"Cause"** for termination means: (a) commission of any felony or crime involving dishonesty; (b) participation in any fraud against the Company; (c) material breach of your duties to the Company; (d) persistent unsatisfactory performance of job duties after written notice from the Company and an opportunity to cure (if deemed curable by the Company in its sole discretion); (e) intentional damage to any property of the Company; (f) misconduct, or other violation of Company policy that causes harm; (g) breach of this Agreement, the Confidentiality Agreement (as defined below), or any other written agreement with the Company; or (h) conduct by you which in the good faith and reasonable determination of the Company demonstrates gross unfitness to serve.

8.2 Change in Control. For purposes of this Agreement, a "**Change in Control**" shall have the meaning as set forth in the Company's Amended and Restated 2013 Equity Incentive Plan.

8.3 **Change in Control Period.** For purposes of this Agreement, the "**Change in Control Period**" means the period commencing one (1) month prior to a Change in Control and ending twelve (12) months following a Change in Control.

8.4 **Code.** For purposes of this Agreement, **"Code"** means the U.S. Internal Revenue Code of 1986 (as it has been and may be amended from time to time) and any regulations and guidance that has been promulgated or may be promulgated from time to time thereunder and any state law of similar effect.

8.5 **Good Reason.** For purposes of this Agreement, you shall have "**Good Reason**" for resignation from employment with the Company if any of the following actions are taken by the Company without your prior written consent: (a) a material reduction in your Base Salary, which the parties agree is a reduction of at least 10% of your Base Salary (unless pursuant to a salary reduction program applicable generally to the Company's similarly situated employees); (b) a material reduction in your duties (including responsibilities and/or authorities), *provided*, *however,* that a change in job position (including a change in title) shall not be deemed a "material reduction" in and of itself unless your new duties are materially reduced from the prior duties; or (c) relocation of your principal place of employment to a place that increases your one-way commute by more than fifty (50) miles as compared to your then-current principal place of employment immediately prior to such relocation (disregarding, for this purpose, any required or permitted remote work arrangement due to the impact of COVID-19 or another pandemic, endemic or similar occurrence in connection with which similar restrictions apply, or reestablishment of your principal work location as in effect as of immediately prior to any such pandemic, endemic or similar occurrence and associated remote work arrangement). In order to resign for Good Reason, you must provide written notice to the Company's Board within 30 days after the first occurrence of the event giving rise to Good Reason setting forth the basis for your resignation, allow the Company at least 30 days from receipt of such written notice to cure such event, and if such event is not reasonably cured within such period, you must resign from all positions you then hold with the Company not later than 30 days after the expiration of the cure period.

8.6 **Involuntary Termination.** For purposes of this Agreement, "**Involuntary Termination**" means a termination of your employment with the Company pursuant to either (i) a termination initiated by the Company without Cause, or (ii) your resignation for Good Reason, and provided in either case such termination constitutes a Separation from Service. An Involuntary Termination does not include any other termination of your employment, including a termination due to your death or disability.

8.7 **Separation from Service.** For purposes of this Agreement, "Separation from Service" means a "separation from service", as defined under Treasury Regulation Section 1.409A-1(h).

9. **Proprietary Information Obligations.** As a condition of employment, you shall execute and abide by the Company's standard form of Employee Proprietary Information and Inventions Assignment Agreement (the "**Confidentiality Agreement**"), attached as **Exhibit A**. In your work for the Company, you will be expected not to use or disclose any confidential information, including trade secrets, of any former employer or other person to whom you have an obligation of confidentiality. Rather, you will be expected to use only that information which is generally known and used by persons with training and experience comparable to your own, which is common knowledge in the industry or otherwise legally in the public domain, or which is otherwise provided or developed by the Company. You agree that you will not bring onto Company premises any unpublished documents or property belonging to any former employer or other person to whom you have an obligation of confidentiality. You hereby represent that you have disclosed to the Company any contract you have signed that may restrict your activities on behalf of the Company.

10. **Section 409A.** It is intended that all of the severance benefits and other payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Code Section 409A provided under Treasury Regulations Sections 1.409A 1(b)(4), 1.409A 1(b)(5) and 1.409A 1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. For all purposes of Code Section 409A (including, without limitation, for purposes of Treasury Regulations Sections 1.409A 2(b)(2)(i) and (iii)), your right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this Agreement, if you are deemed by the Company at the time of your Separation from Service to be a "specified employee" for purposes of Code Section 409A(a)(2)(B)(i), and if any of the payments upon Separation from Service set

forth herein and/or under any other agreement with the Company are deemed to be "deferred compensation," then to the extent delayed commencement of any portion of such payments is required in order to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided to you prior to the earliest of (i) the first date following expiration of the six-month period following the date of your Separation from Service with the Company, (ii) the date of your death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Paragraph shall be paid in a lump sum to you, and any remaining payments due shall be paid as otherwise provided herein or in the applicable agreement. No interest shall be due on any amounts so deferred. If the severance benefits are not covered by one or more exemptions from the application of Section 409A and the Release Deadline occurs in the calendar year following the calendar year of your Separation from Service, the Separation Agreement will not be deemed effective any earlier than the Release Deadline for purposes of determining the timing of provision of any severance benefits.

11. Section 280G.

If any payment or benefit you will or may receive from the Company or otherwise (a "**280G Payment**") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then any such 280G Payment pursuant to this Agreement or otherwise (a "**Payment**") shall be equal to the Reduced Amount. The "**Reduced Amount**" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in your receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "**Reduction Method**") that results in the greatest economic benefit for you. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "**Pro Rata Reduction Method**").

Notwithstanding the foregoing, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for you as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (e.g., being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

Unless you and the Company agree on an alternative accounting firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the change in control transaction triggering the Payment shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the change in control transaction, the Company shall appoint a nationally recognized accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder. The Company shall use commercially reasonable efforts to cause the accounting firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to you and the Company within fifteen (15) calendar days after the date on which your right to a 280G Payment becomes reasonably likely to occur (if requested at that time by you or the Company) or such other reasonable time as requested by you or the Company.

If you receive a Payment for which the Reduced Amount was determined pursuant to clause (x) of the first paragraph of this Section and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, you shall promptly return to the Company a sufficient amount of the Payment (after reduction pursuant to clause (x) of the first paragraph of this Section so that no portion of the remaining Payment is subject to the Excise Tax). For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) in the first

paragraph of this Section, you shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

12. Arbitration of All Disputes.

12.1 Agreement to Arbitrate. To ensure the timely and economical resolution of disputes that may arise between you and the Company, both you and the Company mutually agree that pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16, and to the fullest extent permitted by applicable law, you and the Company will submit solely to final, binding and confidential arbitration any and all disputes, claims, or causes of action arising from or relating to: **(i)** the negotiation, execution, interpretation, performance, breach or enforcement of this Agreement; or **(ii)** your employment with the Company (including but not limited to all statutory claims); or **(iii)** the termination of your employment with the Company (including but not limited to all statutory claims). **BY AGREEING TO THIS ARBITRATION PROCEDURE, BOTH YOU AND THE COMPANY WAIVE THE RIGHT TO RESOLVE ANY SUCH DISPUTES THROUGH A TRIAL BY JURY OR JUDGE OR THROUGH AN ADMINISTRATIVE PROCEEDING.**

12.2 Arbitrator Authority. The arbitrator shall have the sole and exclusive authority to determine whether a dispute, claim or cause of action is subject to arbitration under this Section and to determine any procedural questions which grow out of such disputes, claims or causes of action and bear on their final disposition.

12.3 Individual Capacity Only. All claims, disputes, or causes of action under this Section, whether by you or the Company, must be brought solely in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences in this Section are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration.

12.4 Arbitration Process. Any arbitration proceeding under this Section shall be presided over by a single arbitrator and conducted by JAMS, Inc. ("**JAMS**") in San Diego, California, or as otherwise agreed to by you and the Company, under the then applicable JAMS rules for the resolution of employment disputes (available upon request and also currently available at http://www.jamsadr.com/rules-employment-arbitration/). You and the Company both have the right to be represented by legal counsel at any arbitration proceeding, at each party's own expense. The arbitrator shall: **(i)** have the authority to compel adequate discovery for the resolution of the dispute; **(ii)** issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the award; and **(iii)** be authorized to award any or all remedies that you or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS arbitration fees in excess of the amount of court fees that would be required of you if the dispute were decided in a court of law.

12.5 Excluded Claims. This Section shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, claims brought pursuant to the California Private Attorneys General Act of 2004, as amended, the California Fair Employment and Housing Act, as amended, and the California Labor Code, as amended, to the extent such claims are not permitted by applicable law to be submitted to mandatory arbitration and such applicable law is not preempted by the Federal Arbitration Act or otherwise invalid (collectively, the "**Excluded Claims**"). In the event you intend to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be filed with a court, while any other claims will remain subject to mandatory arbitration.

12.6 Injunctive Relief and Final Orders. Nothing in this Section is intended to prevent either you or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any final award in any arbitration proceeding hereunder may be entered as a judgment in the federal and state courts of any competent jurisdiction and enforced accordingly.

13. General Provisions. This Agreement, together with the Confidentiality Agreement, constitutes the entire agreement between you and the Company with regard to this subject matter and is the complete, final, and exclusive embodiment of the parties' agreement with regard to this subject matter. This Agreement is entered into without reliance

on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. Modifications or amendments to this Agreement, other than those changes expressly reserved to the Company's discretion in this letter, must be made in a written agreement signed by you and the Company's Chief Executive Officer. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction to the extent possible in keeping with the intent of the parties. Any waiver of any breach of any provisions of this Agreement must be in writing to be effective, and it shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement. This Agreement is intended to bind and inure to the benefit of and be enforceable by you and the Company, and their respective successors, assigns, heirs, executors and administrators. The Company may freely assign this Agreement, without your prior written consent. You may not assign any of your duties hereunder and you may not assign any of your rights hereunder without the written consent of the Company. This Agreement shall become effective as of the Start Date and shall terminate upon your termination of employment with the Company. The obligations as forth under Sections 7, 8, 9, 10, 11, 12, and 13 will survive the termination of this Agreement. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of California.

This offer is subject to satisfactory proof of your identity and right to work in the United States and other applicable pre-employment screenings.

We look forward to having you join us. If you have any questions about this Agreement, please do not hesitate to call me.

Best regards,

BIOCEPT, INC.

_____

Samuel Riccitelli, Interim President & CEO

Accepted and agreed:

_____

Darrell Taylor, Esq.

Exhibit 10.16

BIOCEPT, INC.
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Each member of the Board of Directors (the "***Board***") of Biocept, Inc. (the "***Company***") who is a non-employee director of the Company (each such member, a "***Non-Employee Director***") will receive the compensation described in this Non-Employee Director Compensation Policy (the "***Director Compensation Policy***").

A Non-Employee Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash is to be paid or equity awards are to be granted, as the case may be.

- Annual Retainer.

  For service as a director: an annual cash retainer of $40,000 (in addition to any annual cash retainers otherwise paid).

- Board Chair.

  For service as Board Chair: an annual cash retainer of $50,000 (in addition to any annual cash retainers otherwise paid).

- Lead Independent Director.

  For service as Lead Independent Director: an annual cash retainer of $50,000 (in addition to any annual cash retainers otherwise paid).

- Audit Committee.

  For service as Chair of the audit committee: an annual cash retainer of $15,000 (in addition to any annual cash retainers otherwise paid).

  For service as member of the audit committee other than as its Chair: an annual cash retainer of $7,500 (in addition to any annual cash retainers otherwise paid).

- Compensation Committee.

  For service as Chair of the compensation committee: an annual cash retainer of $10,000 (in addition to any annual cash retainers otherwise paid).

  For service as member of the compensation committee other than as its Chair: an annual cash retainer of $5,000 (in addition to any annual cash retainers otherwise paid).

- Nominating and Corporate Governance Committee.

  For service as Chair of the nominating and corporate governance committee: an annual cash retainer of $10,000 (in addition to any annual cash retainers otherwise paid).

  For service as member of the nominating and corporate governance committee other than as its Chair: an annual cash retainer of $5,000 (in addition to any annual cash retainers otherwise paid).

- Science, Technology and Clinical Affairs Committee.

  For service as Chair of the science, technology and clinical affairs committee: an annual cash retainer of $10,000 (in addition to any annual cash retainers otherwise paid).

  For service as member of the science, technology and clinical affairs committee other than as its Chair: an annual cash retainer of $5,000 (in addition to any annual cash retainers otherwise paid).

- Initial Awards.

  For each Non-Employee Director who is initially elected or appointed to the Board: an option to purchase 10,000 shares of common stock.

- Annual Awards.

  For each Non-Employee Director who (i) has been serving on the Board for at least six months as of the date of any annual meeting of the stockholders and (ii) will continue to serve as a Non-Employee Director immediately following such meeting: an option to purchase 10,000 shares of common stock.

The annual cash retainers shall be earned and paid on a calendar quarterly basis, subject to proration in the case of service during only a portion of a calendar quarter.

The per share exercise price of each option granted to the Non-Employee Directors shall equal the fair market value of a share of common stock on the date the option is granted. Each such initial award shall vest and become exercisable in substantially equal installments on each of the first three anniversaries of the vesting commencement date, subject to Continuous Service (as defined in the Company's Amended and Restated 2013 Equity Incentive Plan, as amended (the "***Plan***")) on the Board through each such vesting date; provided, that all stock options under the Director Compensation Policy shall vest in full upon the occurrence of a Change in Control (as defined in the Plan). Each such annual award shall fully vest and become exercisable on the first anniversary of the vesting commencement date, subject to Continuous Service on the Board through each such vesting date; provided, that all stock options under the Director Compensation Policy shall vest in full upon the occurrence of a Change in Control. The term of each such stock option shall be 10 years from the date the option is granted. Upon a Non-Employee Director's cessation of Continuous Service on the Board for any reason, his or her stock options granted under this Director Compensation Policy would, to the extent vested on the date of cessation of Continuous Service, remain exercisable for 12 months following the cessation of his or her Continuous Service on the Board (or such longer period as the Board may determine in its discretion on or after the date of such stock options).

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statements (Nos. 333-194930, 333-202656, 333-206347, 333-212960, 333-218018, 333-227267, 333-227900, 333-233285, 333-251676, 333-261093 and 333-264215) on Forms S-8 and Registration Statements (Nos. 333-234459, 333-230797 and 333-228566) on Forms S-1 of Biocept, Inc. ("Company") of our report dated April 5, 2022, relating to our audit of the financial statements as of and for the year ended December 31, 2021, included in this Annual Report on Form 10-K of the Company for the year ended December 31, 2022.

/s/ Mayer Hoffman McCannP.C.

San Diego, CA
April 17, 2023

Exhibit 23.2

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in Registration Statements (No. 333-194930, 333-202656, 333-206347, 333-212960, 333-218018, 333-227267, 333-227900, 333-233285, 333-251676, 333-261093
and 333-264215) on Form S-8 and Registration Statements (No. 333-234459, 333-230797 and
333-228566) on Form S-1 of Biocept,Inc. (the Company)of our report dated April17, 2023, relatingto the financial statements of the Company, which is included in this Annual Report on Form 10-K of Biocept, Inc. for the year ended December 31, 2022.

/s/ RSM US LLP

Dallas, Texas
April 17, 2023

EXHIBIT 31.1

CERTIFICATION

I, Samuel D. Riccitelli, certify that:

1. I have reviewed this Annual Report on Form 10-K of Biocept, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 17, 2023

/s/ Samuel D. Riccitelli

Samuel D. Riccitelli

Interim President and Chief Executive Officer

(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Antonino Morales, certify that:

1. I have reviewed this Annual Report on Form 10-K of Biocept, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 17, 2023

/s/ Antonino Morales

Antonino Morales
Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION

I, Samuel D. Riccitelli, hereby certify pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 as amended (the "Exchange Act"), and 18 U.S.C. Section 1350, that, to my knowledge, the Annual Report on Form 10-K of Biocept, Inc. for the fiscal year ended December 31, 2022 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Biocept, Inc.

Date: April 17, 2023

/s/ Samuel D. Riccitelli

Samuel D. Riccitelli
Interim President and Chief Executive Officer
(Principal Executive Officer)

This certification accompanies the Report pursuant to Rule 13a-14(b) or Rule 15d-14(b) under the Exchange Act and 18 U.S.C. Section 1350 and shall not be deemed filed by the Company for purposes of Section 18 of the Exchange Act.

EXHIBIT 32.2

CERTIFICATION

I, Antonino Morales, hereby certify pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 as amended (the "Exchange Act"), and 18 U.S.C. Section 1350, that, to my knowledge, the Annual Report on Form 10-K of Biocept, Inc. for the fiscal year ended December 31, 2022 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Biocept, Inc.

Date: April 17, 2023

/s/ Antonino Morales

Antonino Morales
Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies the Report pursuant to Rule 13a-14(b) or Rule 15d-14(b) under the Exchange Act of 1934 and 18 U.S.C. Section 1350 and shall not be deemed filed by the Company for purposes of Section 18 of the Exchange Act of 1934.