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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

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: 001-39659

BIODESIX, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**20-3986492**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2970 Wilderness Place, Suite 100 Boulder, Colorado 80301	**80301**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (303) 417-0500

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 $0.001 per share	BDSX	The NASDAQ Global Market

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, smaller reporting company, or an emerging growth company. See the definitions 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 13(a) of the Exchange Act. ☐

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

Indicate by check mark whether the Registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes ☒ No ☐

As of November 1, 2023, the Registrant had 90,476,295 shares of common stock, $0.001 par value per share, outstanding.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements about us and our industry that involve substantial risks and uncertainties, including but not limited to those set forth under the caption "Special Note Regarding Forward-Looking Statements" and Item 1A "Risk Factors" of Part II of this Quarterly Report on Form 10-Q and those discussed in our other filings with the Securities and Exchange Commission (SEC), including the risks described in Item 1A "Risk Factors" of Part I of our Annual Report on Form 10-K for the year ended December 31, 2022, which was filed on March 6, 2023. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future financial condition, results of operations, business strategy and plans, and objectives of management for future operations, as well as statements regarding industry trends, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potentially," "predict," "should," "will" or the negative of these terms or other similar expressions.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties, factors, and assumptions described under the section titled "Risk Factors" in this Report and in the section entitled "Risk Factors" and elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2022, regarding, among other things:

- our inability to achieve or sustain profitability;
- our unaudited financial statements include a statement that there is a substantial doubt about our ability to continue as a going concern, and a continuation of negative financial trends could result in our inability to continue as a going concern;
- our ability to attain significant market acceptance among payers, providers, clinics, patients, and biopharmaceutical companies for our diagnostic tests;
- difficulties managing our growth, which could disrupt our operations;
- failure to retain sales and marketing personnel, and failure to increase our sales and marketing capabilities or develop broad awareness of our diagnostic tests to generate revenue growth;
- failure to maintain our current relationships, or enter into new relationships, with biopharmaceutical companies;
- significant fluctuation in our operating results, causing our operating results to fall below expectations or any guidance we provide;
- product performance and reliability to maintain and grow our business;
- third-party suppliers, including courier services, contract manufacturers and single source suppliers, making us vulnerable to supply problems and price fluctuations;
- the impact of a pandemic, epidemic, or outbreak of an infectious disease in the United States (U.S.) or worldwide, including the COVID-19 pandemic on our business;
- natural or man-made disasters and other similar events negatively impacting our business, financial condition, and results of operations;
- failure to offer high-quality support for our diagnostic tests, which may adversely affect our relationships with providers and negatively impact our reputation among patients and providers;
- our inability to continue to innovate and improve our diagnostic tests and services we offer;
- security or data privacy breaches or other unauthorized or improper access;
- significant disruptions in our information technology systems;
- the incurrence of substantial liabilities and limiting or halting the marketing and sale of our diagnostic tests due to product liability lawsuits;
- our inability to compete successfully with competition from many sources, including larger companies;
- performance issues, service interruptions or price increases by our shipping carriers and warehousing providers;
- cost-containment efforts of our customers, purchasing groups and integrated delivery networks having a material adverse effect on our sales and profitability;
- potential effects of litigation and other proceedings;

- general economic and financial market conditions;
- our ability to attract and retain key personnel;
- current and future debt financing placing restrictions on our operating and financial flexibility;
- our need to raise additional capital to fund our existing operations, develop our platform, commercialize new diagnostic tests, or expand our operations;
- the acquisition of other businesses, which could require significant management attention;
- the uncertainty of the insurance coverage and reimbursement status of newly approved diagnostic tests;
- future healthcare reform measures that could hinder or prevent the commercial success of our diagnostic tests;
- compliance with anti-corruption, anti-bribery, anti-money laundering and similar laws;
- compliance with healthcare fraud and abuse laws;
- our ability to develop, receive regulatory clearance or approval or certification for, and introduce new diagnostic tests or enhancements to existing diagnostic tests that will be accepted by the market in a timely manner;
- failure to comply with ongoing FDA or other domestic and foreign regulatory authority requirements, or unanticipated problems with our diagnostic tests, causing them to be subject to restrictions or withdrawal from the market;
- future product recalls;
- legal proceedings initiated by third parties alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain;
- the volatility of the trading price of our common stock;
- inaccurate estimates or judgments relating to our critical accounting policies, which could cause our operating results to fall below the expectations of securities analysts and investors; and
- other risks, uncertainties and factors, including those set forth under "Risk Factors".

These risks are not exhaustive. Other sections of this Quarterly Report on Form 10-Q may include additional factors that could harm our business and financial performance. New risk factors may emerge from time to time and it is not possible for our management to predict all risk factors, 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, or implied by, any forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Quarterly Report on Form 10-Q or to conform these statements to actual results or to changes in our expectations.

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 Quarterly Report on Form 10-Q, 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.

You should read this Quarterly Report on Form 10-Q and the documents that we reference and have filed as exhibits with the understanding that our actual future results, levels of activity, performance and achievements may be different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited).

BIODESIX, INC.

Condensed Balance Sheets
(in thousands, except share data)

	September 30, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 19,841	$ 43,088
Accounts receivable, net of allowance for doubtful accounts of $57 and $118	5,777	5,065
Other current assets	3,268	5,181
Total current assets	28,886	53,334
Non-current assets		
Property and equipment, net	25,395	5,848
Intangible assets, net	8,416	9,797
Operating lease right-of-use assets	2,093	2,973
Goodwill	15,031	15,031
Other long-term assets	6,965	5,923
Total non-current assets	57,900	39,572
Total assets	$ 86,786	$ 92,906
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities		
Accounts payable	$ 2,904	$ 1,685
Accrued liabilities	6,946	8,218
Deferred revenue	659	962
Current portion of operating lease liabilities	1,113	1,543
Current portion of contingent consideration	19,307	10,341
Current portion of notes payable	50	49
Other current liabilities	1,670	41
Total current liabilities	32,649	22,839
Non-current liabilities		
Long-term notes payable, net of current portion	24,950	25,004
Long-term operating lease liabilities	24,636	5,254
Contingent consideration	5,182	18,645
Other long-term liabilities	815	558
Total non-current liabilities	55,583	49,461
Total liabilities	88,232	72,300
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value, 5,000,000 authorized; 0 (2023 and 2022) issued and outstanding	—	—
Common stock, $0.001 par value, 200,000,000 authorized; 88,315,802 (2023) and 77,614,358 (2022) shares issued and outstanding	88	78
Additional paid-in capital	408,893	387,948
Accumulated deficit	(410,427)	(367,420)
Total stockholders' (deficit) equity	(1,446)	20,606
Total liabilities and stockholders' (deficit) equity	$ 86,786	$ 92,906

The accompanying Notes are an integral part of these unaudited condensed financial statements.

BIODESIX, INC.

Condensed Statements of Operations
(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenues	$ 13,491	$ 11,107	$ 34,419	$ 28,605
Operating expenses:				
Direct costs and expenses	3,229	3,633	9,636	10,848
Research and development	1,938	2,970	8,099	9,537
Sales, marketing, general and administrative	15,496	15,114	51,136	44,836
Impairment loss on intangible assets	—	—	20	81
Total operating expenses	20,663	21,717	68,891	65,302
Loss from operations	(7,172)	(10,610)	(34,472)	(36,697)
Other (expense) income:				
Interest expense	(2,386)	(3,039)	(7,207)	(5,522)
Loss on extinguishment of liabilities, net	—	(52)	—	(3,004)
Change in fair value of warrant liability, net	(1,393)	—	(1,332)	—
Other income, net	2	2	4	114
Total other expense	(3,777)	(3,089)	(8,535)	(8,412)
Net loss	$ (10,949)	$ (13,699)	$ (43,007)	$ (45,109)
Net loss per share, basic and diluted	$ (0.14)	$ (0.34)	$ (0.55)	$ (1.22)
Weighted-average shares outstanding, basic and diluted	79,709	40,448	78,672	36,953

The accompanying Notes are an integral part of these unaudited condensed financial statements.

BIODESIX, INC.

Condensed Statements of Stockholders' (Deficit) Equity
(in thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount			
Balance - December 31, 2022	77,614	$ 78	$ 387,948	$ (367,420)	$ 20,606
Issuance of common stock, net	—	—	(61)	—	(61)
Issuance of common stock under employee stock purchase plan	270	—	420	—	420
Exercise of stock options	9	—	6	—	6
Release of restricted stock units	86	—	—	—	—
Share-based compensation	—	—	2,281	—	2,281
Net loss	—	—	—	(18,702)	(18,702)
Balance - March 31, 2023	77,979	78	390,594	(386,122)	4,550
Exercise of stock options	107	—	81	—	81
Release of restricted stock units	525	1	—	—	1
Issuance of warrants	—	—	674	—	674
Share-based compensation	—	—	1,057	—	1,057
Net loss	—	—	—	(13,356)	(13,356)
Balance - June 30, 2023	78,611	79	392,406	(399,478)	(6,993)
Issuance of common stock, net	9,455	9	15,307	—	15,316
Issuance of common stock under employee stock purchase plan	167	—	223	—	223
Exercise of stock options	6	—	3	—	3
Release of restricted stock units	77	—	—	—	—
Share-based compensation	—	—	954	—	954
Net loss	—	—	—	(10,949)	(10,949)
Balance - September 30, 2023	88,316	$ 88	$ 408,893	$ (410,427)	$ (1,446)

The accompanying Notes are an integral part of these unaudited condensed financial statements.

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders' (Deficit)
	Shares	Amount	Capital	Deficit	Equity
Balance - December 31, 2021	30,790	$ 31	$ 321,669	$ (301,973)	$ 19,727
Issuance of common stock, net	709	1	1,416	—	1,417
Issuance of common stock under employee stock purchase plan	99	—	202	—	202
Issuance of common stock for deferred offering costs	184	—	600	—	600
Exercise of stock options	107	—	75	—	75
Share-based compensation	—	—	1,346	—	1,346
Net loss	—	—	—	(15,586)	(15,586)
Balance - March 31, 2022	31,889	32	325,308	(317,559)	7,781
Issuance of common stock, net	7,928	8	14,321	—	14,329
Exercise of stock options	24	—	17	—	17
Release of restricted stock units	138	—	—	—	—
Share-based compensation	—	—	1,368	—	1,368
Net loss	—	—	—	(15,824)	(15,824)
Balance - June 30, 2022	39,979	40	341,014	(333,383)	7,671
Issuance of common stock under employee stock purchase plan	95	—	153	—	153
Issuance of common stock, net	924	1	1,744	—	1,745
Exercise of stock options	93	—	57	—	57
Release of restricted stock units	95	—	—	—	—
Share-based compensation	—	—	1,170	—	1,170
Net loss	—	—	—	(13,699)	(13,699)
Balance - September 30, 2022	41,186	$ 41	$ 344,138	$ (347,082)	$ (2,903)

The accompanying Notes are an integral part of these unaudited condensed financial statements.

BIODESIX, INC.

Condensed Statements of Cash Flows
(in thousands)

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (43,007)	$ (45,109)
Adjustments to reconcile net loss to net cash, cash equivalents, and restricted cash used in operating activities		
Depreciation and amortization	2,351	2,699
Amortization of lease right-of-use assets	1,851	1,499
Loss on extinguishment of liabilities, net	—	3,004
Share-based compensation expense	4,292	3,884
Change in fair value of warrant liability, net	1,332	—
Provision for doubtful accounts	467	(27)
Accrued interest, amortization of debt issuance costs and other	3,954	5,011
Inventory excess and obsolescence	115	837
Impairment loss on intangible assets	20	81
Changes in operating assets and liabilities:		
Accounts receivable	(1,178)	(765)
Other current assets	1,798	1,868
Other long-term assets	(26)	(3,645)
Accounts payable and other accrued liabilities	(247)	(646)
Deferred revenue	(395)	(985)
Tenant improvement allowances received	18,323	—
Current and long-term operating lease liabilities	(237)	(730)
Net cash and cash equivalents and restricted cash used in operating activities	(10,587)	(33,024)
Cash flows from investing activities		
Purchase of property and equipment	(19,935)	(1,368)
Patent costs and intangible asset acquisition, net	(126)	(179)
Net cash and cash equivalents and restricted cash used in investing activities	(20,061)	(1,547)
Cash flows from financing activities		
Proceeds from the issuance of common stock	15,316	17,966
Proceeds from issuance of common stock under employee stock purchase plan	643	355
Proceeds from exercise of stock options	90	149
Payment of contingent consideration	(7,591)	(8,691)
Proceeds from term loan and notes payable	—	15,102
Repayment of term loan and notes payable	(36)	(5,038)
Payment of debt issuance costs	(833)	(2,249)
Deferred offering costs	—	(129)
Equity financing costs	(61)	(407)
Other	(127)	(24)
Net cash and cash equivalents and restricted cash provided by financing activities	7,401	17,034
Net decrease in cash and cash equivalents and restricted cash	(23,247)	(17,537)
Cash, cash equivalents, and restricted cash - beginning of period	43,174	32,798
Cash, cash equivalents, and restricted cash - end of period	$ 19,927	$ 15,261

The accompanying Notes are an integral part of these unaudited condensed financial statements.

BIODESIX, INC.

Statements of Cash Flows
(in thousands)

(Continued from the previous page)

Supplemental cash flow information:

	Nine Months Ended September 30,	
	2023	**2022**
Common stock issued for deferred offering costs	$ —	$ 600
Deferred offering costs amortized against Additional paid-in capital	—	52
Original issue discount associated with Promissory Note One	—	1,025
Issuance of Perceptive Warrants	674	—
Equity financing costs included in accounts payable and other accrued liabilities	—	14
Operating lease right-of-use assets obtained in exchange for lease liabilities at adoption of ASC 842	—	1,269
Operating lease right-of-use assets obtained in exchange for lease liabilities	867	3,694
Finance lease right-of-use assets obtained in exchange for lease liabilities	773	123
Cash paid for interest	3,241	473
Purchases of property & equipment included in accrued liabilities	824	69
Patent costs included in accrued liabilities	—	10

The accompanying Notes are an integral part of these unaudited condensed financial statements.

Note 1 – Organization and Description of Business

Biodesix, Inc. (the "Company", "Biodesix", "we" "us" and "our"), formerly Elston Technologies, Inc., was incorporated in Delaware in 2005. The Company's headquarters are in Colorado and the Company performs its blood-based diagnostic tests in its laboratory facilities, which are located in Boulder, Colorado and De Soto, Kansas. The Company conducts all of its operations within a single legal entity. Biodesix is a leading diagnostic solutions company leveraging state of the art technologies with its proprietary artificial intelligence platform to discover, develop, and commercialize solutions for clinical unmet needs, with a primary focus in lung disease. The Company develops diagnostic tests addressing important clinical questions by combining multi-omics through the power of artificial intelligence. We derive our revenue from two sources: (i) providing diagnostic testing services associated with (a) blood-based lung tests and (b) prior to May 11, 2023, Coronavirus Disease 2019 (COVID-19) tests (Diagnostic Tests); and (ii) providing biopharmaceutical companies with services that include diagnostic research, clinical research, development and testing services generally provided outside the clinical setting and governed by individual contracts with third parties as well as development and commercialization of companion diagnostics. We also recognize revenue from other services, including amounts derived from licensing our technologies (Services and other). Biodesix offers five Medicare-covered tests for patients with lung diseases. The blood based Nodify Lung® nodule risk assessment testing strategy, consisting of the Nodify XL2® and the Nodify CDT® tests, evaluates the risk of malignancy in incidental pulmonary nodules, enabling physicians to better triage patients to the most appropriate course of action. The blood based IQLung™ strategy for lung cancer patients integrates the GeneStrat® ddPCR test, the GeneStrat NGS™ test and the VeriStrat® test to support treatment decisions across all stages of lung cancer.

In addition to diagnostic tests, the Company provides biopharmaceutical companies with services that include diagnostic research, clinical trial testing, and the discovery, development, and commercialization of companion diagnostics. The Company leverages the proprietary and advanced Diagnostic Cortex® AI (Artificial Intelligence) platform, to collaborate with many of the world's leading biotechnology and pharmaceutical companies to solve complex diagnostic challenges in lung disease. In addition, other revenue includes amounts derived from licensing our digital sequencing technologies to our international laboratory partners.

The Company also offered three SARS-CoV-2 tests. The Bio-Rad SARS-CoV-2 ddPCR test, the cPASS™ neutralization antibody test kit, and the Platelia SARS-CoV-2 Total Ab test have been granted Emergency Use Authorization (EUA) by the Federal Drug Administration (FDA) under Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA). Medical products that are granted an EUA are only permitted to commercialize their products under the terms and conditions provided in the authorization. The FDA may revoke an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, if the conditions for the issuance of the EUA are no longer met, or if other circumstances make revocation appropriate to protect the public health or safety. The EUA declaration under Section 564 of the FDCA is distinct from and independent of the declaration by the Secretary of HHS of a public health emergency under Section 319 of the Public Health Service Act (the PHS Act). On January 30, 2023, the White House issued a Statement of Administration Policy announcing the President's intention to allow the Public Health Emergency declaration under Section 319 to expire on May 11, 2023. Because the EUA declaration from the FDA is distinct from the declaration under Section 319 of the PHS Act, the FDA EUA may remain in effect beyond the duration of the Section 319 declaration. We cannot predict how long the EUAs for the SARS-CoV-2 tests will remain in place. In connection with the expiration of the Public Health Emergency declaration under Section 319, the Company no longer provides commercial COVID-19 diagnostic testing services.

Blood-Based Lung Tests

The Company offers five blood-based lung cancer tests across the lung cancer continuum of care:

Diagnosis

- *Nodify XL2* and *Nodify CDT* tests, marketed as our Nodify Lung Nodule Risk Assessment testing strategy, assess a suspicious lung nodule's risk of lung cancer to help identify the most appropriate treatment pathway. We believe we are the only company to offer two commercial blood-based tests to help physicians reclassify risk of malignancy in patients with suspicious lung nodules.

Treatment & Monitoring

- *GeneStrat ddPCR* and *VeriStrat* tests, marketed as part of our IQLung testing strategy, are used following diagnosis of lung cancer to measure the presence of mutations in the tumor and the state of the patient's immune system to establish the patient's prognosis and help guide treatment decisions. The GeneStrat ddPCR tumor profiling test and the VeriStrat immune profiling test have a turnaround time of two business days, providing physicians with timely results to facilitate treatment decisions.
- *GeneStrat NGS* (NGS) test, also marketed as part of our IQLung testing strategy, is our blood-based NGS test with results in three business days. The NGS test was launched in November 2021 to a select group of physicians, with national launch in January 2022. The 52-gene panel includes guideline recommended mutations to help physicians treating advanced-stage lung

cancer patients identify targeted therapy mutations in genes, such as EGFR, ALK, KRAS, MET, NTRK, ERBB2, and others, and delivers them in an expedited timeframe so patient treatment can begin sooner.

COVID-19 Tests

We operated and commercialized the Biodesix WorkSafe™ testing program, under which the Company offered three SARS-CoV-2 tests:

- *Bio-Rad SARS-CoV-2 ddPCR* test, which is FDA EUA authorized to be performed by Clinical Laboratory Institute Amendments (CLIA) authorized laboratories that perform high complexity tests. The ddPCR test is designed to detect the presence of current infection by the SARS-CoV-2 virus.
- *Platelia SARS-CoV-2 Total Ab* test, which is an antibody test, FDA EUA authorized by the FDA, intended for detecting a B-cell immune response to SARS-CoV-2, indicating recent or prior infection.
- *cPass SARS-CoV-2 Neutralization Antibody* test, which is the first blood-based surrogate neutralizing antibody test with FDA EUA and uses ELISA technology to qualitatively detect circulating neutralizing antibodies to the receptor binding domain (RBD) in the spike protein of SARS-CoV-2 that are produced in response to a previous SARS-CoV-2 infection. This test was commercially introduced in partnership with GenScript Biotech Corporation.

These tests under the Biodesix WorkSafe testing program were utilized by healthcare providers, including hospitals and nursing homes, and were also offered to businesses and educational systems.

On January 30, 2023, the White House issued a Statement of Administration Policy announcing the President’s intention to allow the Public Health Emergency declaration under Section 319 to expire on May 11, 2023. In connection with the expiration of the Public Health Emergency declaration under Section 319, the Company no longer provides commercial COVID-19 diagnostic testing services.

In developing the Company's products, the Company has built or gained access to regulatory approvals, product development know-how, unique biorepositories, proprietary and patented technologies, specimen collection kit manufacturing capabilities, and bioinformatics methods that it believes are important to the development of new targeted therapies, determining clinical trial eligibility and guiding treatment selection. The Company’s testing services are made available through its clinical laboratories.

Note 2 – Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X for interim financial information and reflect all adjustments necessary to state fairly the Company’s financial position, results of operations and cash flows for the interim periods presented. All such adjustments are of a normal recurring nature. Results for interim periods are not indicative of the results for the entire fiscal year. The accompanying unaudited condensed financial statements should be read in conjunction with the audited financial statements included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2022. Certain information and footnote disclosures, including significant accounting policies, normally included in fiscal year financial statements prepared in accordance with accounting principles generally accepted in the U.S. (GAAP) have been condensed or omitted. The condensed balance sheet as of December 31, 2022 was derived from the audited financial statements.

Liquidity and Capital Resources

As of September 30, 2023, we maintained cash and cash equivalents of $19.8 million and we have $30.0 million in outstanding aggregate principal amount on our Perceptive Term Loan Facility (see Note *6 – Debt*). We have incurred significant losses since inception and, as a result, we have funded our operations to date primarily through the sale of common stock, the sale of convertible preferred stock, the issuance of notes payable, and from our two primary revenue sources: (i) diagnostic testing, which includes lung diagnostic testing and, prior to May 11, 2023, COVID-19 testing, and (ii) providing biopharmaceutical companies with development and testing services and licensing our technologies. In accordance with Accounting Standards Update 2014-15 (ASC Topic 205-40), *Presentation of Financial Statements - Going Concern: Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern*, the Company is required to evaluate whether there is substantial doubt about its ability to continue as a going concern each reporting period, including interim periods. In evaluating the Company’s ability to continue as a going concern, management projected its cash flow sources and evaluated the conditions and events that could raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that these financial statements were issued. Management considered the Company’s current projections of future cash flows, current financial condition, sources of liquidity and debt obligations for at least one year from the date of issuance of this Form 10-Q in considering whether it has the ability to meet its obligations.

Our ability to meet our obligations as they come due may be impacted by our ability to remain compliant with financial covenants in our Perceptive Term Loan Facility (see Note 6 – *Debt*) or to obtain waivers or amendments that impact the related covenants. As of September 30, 2023, the Company was in compliance with all restrictive and financial covenants associated with its borrowings.

Based on our current operating plan, unless we continue to raise additional capital (debt or equity) and meet certain agreed upon revenue covenants, or obtain a waiver from complying with such financial covenants, we expect that we will be unable to maintain our financial covenants under our existing loan agreement during the next twelve months, which could result in an Event of Default (as defined in the Perceptive Term Loan Facility), causing an acceleration and repayment of the outstanding balances. We have taken steps to improve our liquidity through raising debt and equity capital and have also undertaken several proactive measures including, among other things, the reduction of planned capital expenditures and certain operating expenses, but we do not expect that these actions alone will be sufficient to maintain our financial covenants. The Perceptive Term Loan Facility requires the Company to recognize revenue in amounts agreed to between the Company and Perceptive as of the last day of each fiscal quarter, which commenced with the fiscal quarter ending March 31, 2023. On May 10, 2023 (the First Amendment Effective Date), the Company entered into the First Amendment to the Credit Agreement (the First Amendment), whereby subject to the terms and conditions of the First Amendment, the Minimum Net Revenue Covenant (as defined in the Credit Agreement) was amended to reduce the relevant threshold through the twelve month period ended March 31, 2024. On August 4, 2023, the Company entered into a second amendment to the Perceptive Term Loan Facility, whereby subject to the terms and conditions of the second amendment, the Minimum Net Revenue Covenant was amended to reduce the relevant threshold through the twelve month period ended December 31, 2025 (see Note 6 - *Debt*) and raised approximately $15.3 million in net proceeds through a private placement equity offering (see Note 8 - *Equity*).

To maintain an adequate amount of available liquidity and execute our current operating plan, we will need to continue to raise additional funds from external sources, such as through the issuance of equity or debt securities; however, we have not secured such funding at the time of this filing and any such financing activities are subject to market conditions. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. There can be no assurance that additional capital will be available to us or, if available, will be available in sufficient amounts or on terms acceptable to us or on a timely basis. If adequate capital resources are not available on a timely basis, we intend to consider limiting our operations substantially. This limitation of operations could include a hiring freeze, reductions in our workforce, reduction in cash compensation, deferring capital expenditures, and reducing other operating costs.

We expect to continue to incur operating losses in the near term while we make investments to support our anticipated growth. Our current operating plan, which is in part determined based on our most recent historical actual results and trends, along with the items noted above, raises substantial doubt about the Company's ability to continue as a going concern for a period beyond one year after these financial statements are issued. Our unaudited financial statements have been prepared assuming we will continue as a going concern and do not include any adjustments that might be necessary should we be unable to continue as a going concern.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the balance sheet date and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates.

Concentrations of Credit Risk and Other Uncertainties

Substantially all of the Company's cash and cash equivalents are deposited with one major financial institution in the United States. The Company continually monitors its positions with, and the credit quality of, the financial institution with which it holds cash. Periodically throughout the year, the Company has maintained balances in various operating accounts in excess of federally insured limits. The Company has not experienced any losses on its deposits of cash and cash equivalents.

Several of the components for certain of the Company's sample collection kits, test reagents, and test systems are obtained from single-source suppliers. If these single-source suppliers fail to satisfy the Company's requirements on a timely basis, the Company could suffer delays in being able to deliver its diagnostic solutions, a possible loss of revenue, or incur higher costs, any of which could adversely affect its operating results.

For a discussion of credit risk concentration of accounts receivable as of September 30, 2023 and December 31, 2022, see Note 9 – *Revenue and Accounts Receivable Credit Concentration.*

Restricted Cash

Restricted cash consists of deposits related to the Company's corporate credit card. As of September 30, 2023 and December 31, 2022, the Company had $0.1 million and $0.1 million restricted cash, respectively, which was included in 'Other current assets' in the accompanying condensed balance sheets.

Inventory

Inventory consists primarily of material supplies, which are consumed in the performance of testing services and charged to 'Direct costs and expenses'. Inventory is stated at cost and reported within 'Other current assets' in the condensed balance sheets and was $1.3 million and $1.4 million as of September 30, 2023 and December 31, 2022, respectively. The Company recorded a reserve for excess inventory of zero and $0.1 million as of September 30, 2023 and December 31, 2022, respectively. During the nine months ended September 30, 2023 and 2022, the Company recorded $0.1 million and $0.8 million, respectively, to the condensed statement of operations for excess and obsolete inventory.

Leases

The Company acts as a lessee under all its lease agreements and holds various real estate leases for its headquarters and laboratory facilities in Boulder, Colorado and De Soto, Kansas and other various copier leases. The Company also leases a building in Louisville, Colorado for office and laboratory space. The purpose of this lease is to replace the Company's corporate headquarters in Boulder, Colorado. The Company intends to relocate by the end of 2023.

The Company elected the following practical expedients as part of the adoption of ASC 842, *Leases*:

- Package of practical expedients which allows the Company to carry forward the historical lease classification;
- Hindsight practical expedient which allows the Company to use hindsight in determining the lease term, in assessing purchase options, and in assessing impairment of right-of-use (ROU) assets;
- Short-term lease practical expedient which allows the Company to capitalize only those leases with an initial term of twelve months or more; and
- The practical expedient to account for lease and non-lease components (such as common area maintenance, utilities, insurance and taxes) as a single lease component for all classes of underlying assets.

Management determines if an arrangement is a lease at inception or upon modification of a contract. Leases are classified as either financing or operating, with classification affecting the pattern of expense recognition in the statements of operations. When determining whether a lease is a finance lease or an operating lease, ASC 842 does not specifically define criteria to determine the "major part of remaining economic life of the underlying asset" and "substantially all of the fair value of the underlying asset." For lease classification determination, Management continues to use (i) 75% or greater to determine whether the lease term is a major part of the remaining economic life of the underlying asset and (ii) 90% or greater to determine whether the present value of the sum of lease payments is substantially all of the fair value of the underlying asset.

ROU assets represent the Company's right to use an underlying asset for the lease term. Lease liabilities represent the Company's obligation to make lease payments under the lease. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of lease payments, the Company uses either the rate implicit in the lease or its incremental borrowing rate, as applicable, based on the information available at lease commencement date. The Company applies the estimated incremental borrowing rates on a lease-by-lease level based on the economic environment associated with the lease. The operating lease ROU asset also includes any lease prepayments, net of lease incentives. Certain of the Company's leases include options to extend or terminate the lease. As leases approach maturity, the Company considers various factors such as market conditions and the terms of any renewal and termination options that may exist to determine whether we will renew or terminate the lease, as such, we generally do not include renewal or termination options in our lease terms for calculating our lease liability, as the options allow us to maintain operational flexibility and we are not reasonably certain we will exercise these options at the time of the lease commencement. The Company's lease agreements do not contain any material residual value guarantees or restrictive covenants. Lease expense for lease payments of operating leases is recognized on a straight-line basis over the term of the lease. The Company uses the long-lived assets impairment guidance to determine recognition and measurement of an ROU asset impairment, if any. The Company monitors for events or changes in circumstances that require a reassessment.

Additional information and disclosures required by this standard are contained in Note 7 — *Leases*.

Other Assets

As of September 30, 2023 and December 31, 2022, the Company has a $5.0 million cash refundable deposit to secure the performance of the Company's obligations associated with the operating lease agreement with Centennial Valley Properties I, LLC (see Note 7 – *Leases*). The $5.0 million refundable deposit is reported within 'Other long-term assets' in the condensed balance sheets.

Fair Value of Financial Instruments

U.S. GAAP for fair value establishes a hierarchy that prioritizes fair value measurements based on the types of inputs used for the various valuation techniques (market approach, income approach and cost approach). We utilize a combination of market and income approaches to value our financial instruments. Our financial assets and liabilities are measured using inputs from the three levels of the fair value hierarchy. Fair value measurements are categorized within the fair value hierarchy based upon the lowest level of the most significant inputs used to determine fair value.

The three levels of the hierarchy and the related inputs are as follows:

Level	Inputs
1	Unadjusted quoted prices in active markets for identical assets and liabilities.
2	Unadjusted quoted prices in active markets for similar assets and liabilities;
	Unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active; or
	Inputs other than quoted prices that are observable for the asset or liability.
3	Unobservable inputs for the asset or liability.

The carrying amounts of certain financial instruments including cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, other long-term assets, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities.

See Note 4 — *Fair Value* for further discussion related to estimated fair value measurements.

Note 3 - Recent Issued Accounting Standards

Recently adopted accounting standards

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments* (ASC Topic 326). This ASU requires measurement and recognition of expected credit losses for financial assets. This guidance became effective for the Company beginning January 1, 2023. The Company evaluated the guidance and determined the overall impact of the adoption had an immaterial impact on our financial statements.

Note 4 - Fair Value

Recurring Fair Value Measurements

Our borrowing instruments are recorded at their carrying values in the condensed balance sheets, which may differ from their respective fair values. The fair value of borrowings as of September 30, 2023 is primarily associated with the Perceptive Term Loan Facility entered into with Perceptive Credit Holdings IV, LP, in November 2022 and was determined using a discounted cash flow analysis, excluding the fair value of the Perceptive Warrant (as defined below) issued in conjunction with the transaction. The difference between the carrying value and fair value of outstanding borrowings as of September 30, 2023 is due to the issuance of the First Amendment Warrants (see Note 6 - *Debt* and as defined in Note 8 - *Equity* below*)* netted against the Perceptive Term Loan Facility as well as an increase in the fair value of the debt as a result of improved credit markets. The difference between the carrying value and fair value of outstanding borrowings as of December 31, 2022 is due to the debt issuance costs and the fair value of the Perceptive Warrant netted against the Perceptive Term Loan Facility. The table below presents the carrying and fair values of outstanding borrowings, which are classified as Level 2, as of the dates indicated (in thousands):

	As of			
	September 30, 2023		December 31, 2022	
	Carrying Value	Fair Value	Carrying Value	Fair Value
Borrowings	$ 25,000	$ 26,501	$ 25,053	$ 26,785

The financial liabilities that are measured and recorded at estimated fair value on a recurring basis consist of our contingent consideration associated with our previous acquisition of Indi and the warrant liabilities granted as consideration for the Perceptive Term Loan Facility (see Note 6 - *Debt*), which were accounted for as liabilities and remeasured through our condensed statements of operations.

The table below presents the reported fair values of contingent consideration and warrant liabilities, which are classified as Level 3 in the fair value hierarchy, as of the dates indicated (in thousands):

Description	September 30, 2023	December 31, 2022
Current portion of contingent consideration	$ 19,307	$ 10,341
Contingent consideration	5,182	18,645
Total contingent consideration	$ 24,489	$ 28,986
Warrant liabilities	$ 1,393	$ 61

The following table presents the changes in contingent consideration and warrant liabilities for the dates indicated (in thousands):

	For the nine months ended September 30, 2023	
Level 3 Rollforward	Contingent Consideration	Warrant Liabilities
Beginning balances - January 1, 2023	$ 28,986	$ 61
Changes in fair value, net	—	1,332
Interest expense	3,094	—
Payments	(7,591)	—
Ending balances - September 30, 2023	$ 24,489	$ 1,393

The following table presents the changes in contingent consideration as of the date indicated (in thousands):

Level 3 Rollforward	For the nine months ended September 30, 2022
Beginning balances - January 1, 2022	$ 33,792
Interest expense	2,142
Loss on extinguishment of liabilities	2,934
Payments of contingent consideration	(8,691)
Ending balances - September 30, 2022	$ 30,177

Contingent Consideration

In connection with the acquisition of Indi in 2018, the Company recorded contingent consideration for amounts contingently payable to Indi's selling shareholders pursuant to the terms of the asset purchase agreement (the Indi APA). The contingent consideration arrangement requires additional consideration to be paid by the Company to such shareholders upon attainment of a three-consecutive month gross margin target of $2.0 million within the seven-year period after the acquisition date, which was achieved during the three months ended June 30, 2021. Under the terms of the original agreement, when the gross margin target was achieved the Company was required to issue 2,520,108 shares of common stock. For the six months following the achievement of the gross margin target, Indi had the option to require the Company to redeem these common shares for $37.0 million in cash over eight equal quarterly installments. If Indi elected to not exercise its option, the Company had 12 months to repurchase the common stock in two equal and consecutive quarterly cash installments totaling $37.0 million.

In August 2021, the Company entered into an amendment to the original agreement in which all parties agreed to forgo the issuance of common stock and agreed that the Company would, in lieu thereof, make six quarterly installments of approximately $4.6 million each beginning in January 2022 and a final payment of approximately $9.3 million in July 2023 for a total of $37.0 million (the Milestone Payments, and each individually a Milestone Payment). The aggregate amount of payments owed by the Company under this amendment is the same as if Indi had exercised the put right or the Company had exercised the call right provided for in the original agreement.

On April 7, 2022, the Company entered into Amendment No. 3 to the Indi APA in which the parties agreed to restructure the Milestone Payments whereby the Company will make five quarterly installments of $2.0 million each beginning in April 2022, three quarterly installments of $3.0 million beginning in July 2023, one installment of $5.0 million in April 2024, and one installment of approximately $8.4 million in July 2024. In addition, the Company agreed to an exit fee of approximately $6.1 million in October 2024. Interest shall accrue on the difference between the payment schedule as agreed in the August 2021 amendment and the April 2022 amended payment

schedule, at an aggregate per annum rate equal to 10%, with such interest to be payable quarterly on the following installment payment date. Our ability to make these payments is subject to ongoing compliance under the Perceptive Term Loan Facility and commencing January 1, 2024, consent from Perceptive (see Note *6 - Debt*).

The contingent consideration liability is accounted for at fair value and subject to certain unobservable inputs. The significant unobservable inputs used in the measurement of the fair value include the probability of successful achievement of the specified product gross margin targets, the period in which the targets were expected to be achieved, and discount rates which ranged from 11% to 16%. As a result of the achievement of the gross margin target, the only remaining significant unobservable input used in the measurement of fair value includes the discount rate since all other inputs became fixed and determinable. Significant increases or decreases in the discount rate could result in a significantly higher or lower fair value measurement.

During the three and nine months ended September 30, 2023, the Company recorded $1.0 million and $3.1 million, respectively, and $1.2 million and $2.1 million during the three and nine months ended September 30, 2022, respectively, in interest expense due to the passage of time and fixed payment schedule.

Contingent consideration expected to be paid in the next twelve months is recorded in the condensed balance sheets as ‘Current portion of contingent consideration’ while the remaining amount to be paid is recorded as ‘Contingent consideration’ within non-current liabilities. The net change to contingent consideration through the date the gross margin target was achieved is recorded as operating expenses in the condensed statements of operations. Subsequent changes to the contingent consideration following the achievement of the gross margin target are recorded as ‘Interest expense’ in the condensed statements of operations resulting from the passage of time and fixed payment schedule.

Warrant Liabilities

On November 21, 2022, as consideration for the Perceptive Term Loan Facility (see Note 6 - *Debt*), the Company issued Perceptive a warrant to purchase up to 5,000,000 shares of the Company's common stock (the Perceptive Warrant), including Initial Warrants and Additional Warrants (as defined in Note 8 - *Equity* below). The Initial Warrants and First Amendment Warrants are equity classified (see Note 8 - *Equity*) while the Additional Warrants are classified as liabilities within 'Other long-term liabilities' and recognized at fair value. The fair value of the Additional Warrants is determined using a Black-Scholes model and subject to certain unobservable inputs. The significant unobservable inputs used in the measurement of the fair value include the fair value of the Company's common stock, risk-free rate, the volatility of common stock, and the probability of the expected borrowing. Significant increases or decreases in the unobservable inputs could result in a significantly higher or lower fair value measurement. During the three and nine months ended September 30, 2023, the Company recorded a $1.4 million and $1.3 million loss, respectively, as a change in fair value through the condensed statement of operations due to changes in unobservable inputs. This is a result of changes in the probability of our ability to draw on Tranche B and C loans. The $1.4 million warrant liability is reported within 'Other current liabilities' in the condensed balance sheets.

Note 5 – Supplementary Balance Sheet Information

Property and equipment consist of the following (in thousands):

	September 30, 2023	December 31, 2022
Lab equipment	$ 6,070	$ 6,035
Leasehold improvements	2,365	2,365
Computer equipment	1,094	749
Furniture and fixtures	349	349
Software	325	324
Vehicles	97	97
Construction in process	22,971	2,947
	33,271	12,866
Less accumulated depreciation	(7,876)	(7,018)
Total property and equipment, net	$ 25,395	$ 5,848

Depreciation expense for the three and nine months ended September 30, 2023 was $0.3 million and $0.9 million, respectively, compared to $0.4 million and $1.2 million for the three and nine months ended September 30, 2022, respectively.

Intangible assets, excluding goodwill, consist of the following (in thousands):

	September 30, 2023			December 31, 2022		
	Cost	Accumulated Amortization	Net Carrying Value	Cost	Accumulated Amortization	Net Carrying Value
Intangible assets subject to amortization						
Patents	$ 1,986	$ (726)	$ 1,260	$ 1,880	$ (647)	$ 1,233
Purchased technology	16,900	(9,858)	7,042	16,900	(8,450)	8,450
Intangible assets not subject to amortization						
Trademarks	114	—	114	114	—	114
Total	$ 19,000	$ (10,584)	$ 8,416	$ 18,894	$ (9,097)	$ 9,797

Amortization expense related to definite-lived intangible assets was $0.5 million and $1.5 million for both the three and nine months ended September 30, 2023 and 2022, respectively.

Future estimated amortization expense of intangible assets is (in thousands):

	As of September 30, 2023
Remainder of 2023	$ 496
2024	1,978
2025	1,972
2026	1,958
2027	1,007
2028 and thereafter	891
Total	$ 8,302

Accrued liabilities consist of the following (in thousands):

	September 30, 2023	December 31, 2022
Compensation related accruals	$ 3,263	$ 4,671
Accrued clinical trial expense	1,304	1,232
Other expenses	2,379	2,315
Total accrued liabilities	$ 6,946	$ 8,218

Note 6 – Debt

Our long-term debt primarily consists of notes payable associated with our Perceptive Term Loan Facility which is described in further detail below. Long-term notes payable were as follows (in thousands):

	September 30, 2023	December 31, 2022
Perceptive Term Loan Facility	$ 30,000	$ 30,000
Other	90	127
Unamortized debt discount and debt issuance costs	(5,090)	(5,074)
	25,000	25,053
Less: current maturities	50	49
Long-term notes payable	$ 24,950	$ 25,004

Perceptive Term Loan Facility

On November 16, 2022 (the Closing Date), the Company entered into a Credit Agreement and Guaranty (the Credit Agreement) with Perceptive Credit Holdings IV, LP as lender and administrative agent (the Lender). The Credit Agreement provides for a senior secured

delayed draw term loan facility with Perceptive Advisors LLC (Perceptive), in an aggregate principal amount of up to $50.0 million (the Perceptive Term Loan Facility). The initial funding of the Perceptive Term Loan Facility was subject to a capital raise of at least $30.0 million in gross proceeds from an equity offering of the Company's common stock. On November 21, 2022 (the Funding Date), the Company raised approximately $40.6 million in gross proceeds from the sale of common stock. The Tranche A Loan, in an aggregate amount of up to $30.0 million (the Tranche A Loan), was funded under the Perceptive Term Loan Facility substantially and concurrently with the closing of the sale of common stock on the Funding Date. In addition to the Tranche A Loan, the Perceptive Term Loan Facility includes an additional Tranche B Loan, in an aggregate amount of up to $10.0 million, and an additional Tranche C Loan, in an aggregate amount of up to $10.0 million, which will be accessible by the Company so long as the Company satisfies certain customary conditions precedent, including revenue milestones. The Tranche B and C loans have loan commitments dates through December 31, 2023 and September 30, 2024, respectively. The Perceptive Term Loan Facility has a maturity date of November 21, 2027 (the Maturity Date) and provides for an interest-only period during the term of the loan with principal due at the Maturity Date. The Company's net proceeds from the Tranche A Loan were approximately $27.9 million, after deducting debt issuance costs and expenses.

Interest Rate

The Perceptive Term Loan Facility will accrue interest at an annual rate equal to the greater of (a) forward-looking one-month term SOFR as posted by CME Group Inc. and (b) 3.0% per annum, plus an applicable margin of 9.0%. As of September 30, 2023, the stated interest rate was approximately 14.3%.

Amortization and Prepayment

On the Maturity Date, the Company is required to pay the Lender the aggregate outstanding principal amount underlying the Perceptive Term Loan Facility and any accrued and unpaid interest thereon. Prior to the Maturity Date, there will be no scheduled principal payments under the Perceptive Term Loan Facility. The Perceptive Term Loan Facility may be prepaid at any time, subject to a prepayment premium equal to 2% to 10% of the aggregate outstanding principal amount being prepaid, depending on the date of prepayment.

Security Instruments and Warrants

Pursuant to a Security Agreement, dated as of the Funding Date (the Security Agreement), between the Company and the Lender, substantially all of the Company’s obligations under the Credit Agreement are secured by a first lien perfected security interest on all of the Company’s assets, subject to customary exceptions.

As consideration for the Credit Agreement, the Company has issued, on the Funding Date, the Perceptive Warrant of up to 5,000,000 shares of the Company's common stock, including the Initial Warrants which are equity classified at a per share exercise price equal to $1.0648 which is equal to the lower of (A) the 10-day volume weighted average price (VWAP) of the Company’s common stock, on the business day immediately prior to the Closing Date of the Tranche A Loan or (B) the public offering price per share of Common Stock of $1.15 (see Note 8 - *Equity*). In addition to the Initial Warrants, the Additional Warrants will each become exercisable into 1,000,000 shares of common stock concurrently with the borrowing date of the Tranche B and C Loans, respectively. The per share exercise price for the Additional Warrants will be equal to the lower of (A) the Initial Warrant exercise price or (B) the 10-day VWAP ending on the business day immediately preceding the funding date of the Tranche B Loan or the Tranche C loan, respectively. Each warrant will be exercisable, in whole or in part, until the 10th anniversary of the applicable date of issuance. If the Tranche B or C loans are not drawn by the respective loan commitment dates, the associated Additional Warrants expire and will not become exercisable. The Company accounts for the Additional Warrants as liabilities as the Additional Warrants do not meet the criteria for equity treatment (see Note 4 - *Fair Value*).

Representations, Warranties, Covenants, and Events of Default

The Credit Agreement contains certain representations and warranties, affirmative covenants, negative covenants, financial covenants, and conditions that are customarily required for similar financings. The affirmative covenants, among other things, require the Company to undertake various reporting and notice requirements, maintain insurance and maintain in full force and effect all Regulatory Approvals, Material Agreements, Material Intellectual Property (each as defined in the Credit Agreement) and other rights, interests or assets (whether tangible or intangible) reasonably necessary for the operations of the Company’s business. The negative covenants restrict or limit the ability of the Company to, among other things and subject to certain exceptions contained in the Credit Agreement, incur new indebtedness; create liens on assets; engage in certain fundamental corporate changes, such as mergers or acquisitions, or changes to the Company’s business activities; make certain Investments or Restricted Payments (each as defined in the Credit Agreement); change its fiscal year; pay dividends; repay other certain indebtedness; engage in certain affiliate transactions; or enter into, amend or terminate any other agreements that has the impact of restricting the Company’s ability to make loan repayments under the Credit Agreement. In addition, the Company must (i) at all times prior to the Maturity Date maintain a minimum cash balance of $2.5

million; and (ii) as of the last day of each fiscal quarter commencing on the fiscal quarter ending March 31, 2023, recognize revenue in amounts agreed to between the Company and Perceptive.

On May 10, 2023, the Company entered into the First Amendment with the Lender, whereby subject to the terms and conditions of the First Amendment, the Minimum Net Revenue Covenant (as defined in the Credit Agreement) was amended to reduce the relevant threshold of each fiscal quarter commencing on the fiscal quarter ending June 30, 2023 through and including the fiscal quarter ending March 31, 2024. As consideration for the First Amendment, the Company agreed to issue to Perceptive a warrant to purchase up to 500,000 shares of the Company's common stock (the First Amendment Warrants) which are equity classified at a per share exercise price equal to $1.6254 (see Note 8 - *Equity*).

On August 4, 2023 (the Second Amendment Effective Date), the Company entered into the Second Amendment to the Credit Agreement and Guaranty (the Second Amendment) with Perceptive as lender and administrative agent and the Company, as borrower, whereby subject to the terms and conditions of the Second Amendment, the Minimum Net Revenue Covenant (as defined in the Credit Agreement) was amended to reduce the relevant threshold as of the last day of each fiscal quarter commencing on the fiscal quarter ending June 30, 2024 through and including the fiscal quarter ending December 31, 2025.

Under the terms of the Second Amendment, the conditions precedent for drawing on the Tranche B Loan were amended to (i) reduce the trailing-twelve month revenue milestone and (ii) add the receipt of aggregate cash proceeds of at least $27.5 million from an equity offering of the Company's common stock (see Note 8 - *Equity*). During the three months ended September 30, 2023, the Company met the amended trailing-twelve month revenue milestone associated with the Tranche B Loan.

The Credit Agreement also contains certain customary Events of Default which include, among others, non-payment of principal, interest, or fees, violation of covenants, inaccuracy of representations and warranties, bankruptcy and insolvency events, material judgments, cross-defaults to material contracts, certain regulatory-related events and events constituting a change of control. As of September 30, 2023, the Company was in compliance with all restrictive and financial covenants associated with its borrowings. The occurrence of an Event of Default could result in, among other things, the declaration that all outstanding principal and interest under the Perceptive Term Loan Facility are immediately due and payable in whole or in part.

On the Closing Date, the Initial Warrants and Additional Warrants were valued at $2.9 million and $0.1 million, respectively, using the Black-Scholes option-pricing model, estimated settlement probabilities and estimated exercise prices. As a result of the fees paid to Perceptive and the value of the Perceptive Warrant, the Company recognized a discount on the Perceptive Term Loan Facility in the amount of $5.2 million. The First Amendment Warrants were valued at $0.7 million using the Black-Scholes option-pricing model which the recognized as a discount on the Perceptive Term Loan Facility. The Company recorded the discount as a reduction to the principal amount of the debt and is amortized as interest expense over the life of the debt.

Scheduled principal repayments (maturities) of long-term obligations were as follows (in thousands):

	As of September 30, 2023
Remainder of 2023	$ 13
2024	50
2025	21
2026	6
2027	30,000
Total	$ 30,090

Note 7 – Leases

Operating Leases

The Company acts as a lessee under all its lease agreements. The Company leases its headquarters and laboratory facilities in Boulder, Colorado, under a non-cancelable lease agreement for approximately 29,722 square feet that is set to expire in January 2024. The Company also leases laboratory and office space in De Soto, Kansas, under a non-cancelable lease agreement for approximately 9,066 square feet that was set to expire in October 2023. In April 2023, the Company amended the agreement to extend the lease agreement through October 2026. The Company also holds various copier leases under non-cancelable lease agreements that expire in the next one to three years.

Centennial Valley Properties I, LLC Lease Agreement

On March 11, 2022, the Company entered into a Lease Agreement (the Lease) with Centennial Valley Properties I, LLC, a Colorado limited liability company (the Landlord) for office and laboratory space in Louisville, Colorado (the Leased Premises). The purpose of

the Lease is to replace the Company's current leased premises in Boulder, Colorado. The Company intends to move its corporate headquarters to the Leased Premises by the end of 2023.

The initial term of the Lease is twelve years (the Initial Term) from the commencement date, which is the earlier of: (i) the Company conducting revenue generating business (as defined in the Lease), or (ii) April 1, 2023. The Company has two renewal options to extend the term of the Lease for an additional seven- or ten-year terms for each renewal. During the three months ended June 30, 2022, the lease commenced for accounting purposes resulting in $2.0 million in ROU assets and lease liabilities being recorded, however, the Lease commenced for legal purposes on April 1, 2023 (the Commencement Date).

Under the Lease, the Company will lease approximately 79,980 square feet at the Leased Premises. The Company will pay base rent over the life of the Lease beginning at approximately $227,000 per month and escalating, based on fixed escalation provisions, to approximately $326,000 per month, plus certain operating expenses and taxes. The Company's obligation to pay base rent shall be abated, commencing as of the Commencement Date and ending on and including the date that is 12 months after the Commencement Date (the Abated Rent Period). Further, the Company's obligation to pay base rent with respect to a portion of the area of the Lease Premises equal to 19,980 square feet shall be abated (the Partial Abated Rent), commencing as of the day after the end of the Abated Rent Period and ending on and including the date that is 24 months after the Commencement Date (the Partial Abated Rent Period). Pursuant to a work letter entered by the parties in connection with the Lease, the Landlord will contribute an aggregate of $18.8 million toward the cost of construction and improvements for the Leased Premises and the Company exercised its option for an additional tenant improvement allowance of $2.0 million (the Extra Allowance Amount). The Company will repay the Extra Allowance Amount actually funded by the Landlord in equal monthly payments with an interest rate of 6% per year over the Initial Term excluding any part of the Abated Rent Period or Partial Abated Rent Period, which shall start to accrue on the date that the Landlord first disburses the Extra Allowance Amount. The Company made an accounting policy election to reduce the right-of-use asset and lease liability at lease commencement because the Lease specifies a maximum level of reimbursement for tenant improvements which are probable of being incurred and within the Company's control. Due to the tenant improvement allowances at the accounting lease commencement date and rent abatement periods described above, the Company expects the lease liability to accrete to approximately $25.5 million by November 2024 after receiving $20.8 million in lessor reimbursements. As of September 30, 2023, the Company has utilized the total $20.8 million ($5.5 million and $18.3 million during the three and nine months ended September 30, 2023, respectively) in tenant improvement allowances for capital expenditures for leasehold improvements related to the Leased Premises and have been reimbursed from the Landlord.

The Lease includes various covenants, indemnities, defaults, termination rights, and other provisions customary for lease transactions of this nature. During the three months ended September 30, 2022, a $5.0 million cash collateralized letter of credit under the operating lease agreement was released and the funds were subsequently transferred to the Landlord as a refundable deposit (subject to contingent reduction over the term of the lease) to secure the performance of the Company's obligations. The $5.0 million refundable deposit is included within 'Other long-term assets' in the condensed balance sheet as of September 30, 2023.

Operating lease expense for all operating leases was $1.1 million and $3.3 million for the three and nine months ended September 30, 2023, respectively, compared to $0.9 million and $1.7 million for the three and nine months ended September 30, 2022, respectively. As of September 30, 2023, the weighted-average remaining lease term and discount rate associated with our operating leases were 10.7 years and 11.4%, respectively.

Future minimum lease payments associated with our operating leases were as follows (in thousands):

	As of September 30, 2023
Remainder of 2023	$ 1,073
2024	2,406
2025	4,032
2026	4,144
2027	4,063
2028 and thereafter	32,263
Total future minimum lease payments	47,981
Less amount representing interest	(22,232)
Total lease liabilities	$ 25,749

Note 8 – Equity

Equity Financing Programs

The Company maintains two facilities that enable equity financing on an ongoing basis at the Company's sole discretion, our at-the-market (ATM) offering and our common stock purchase agreement with Lincoln Park Capital Fund, LLC (Lincoln Park). In November 2021, the Company entered into a sales agreement with a financial institution, pursuant to which the Company may issue and sell, from time to time, shares of its common stock having an aggregate offering price of up to $50.0 million (the ATM Shares), subject to terms and conditions. The ATM Shares will be offered and sold by the Company pursuant to its previously filed and currently effective registration statement on Form S-3, and sales of the common stock, if any, will be made at market prices by methods deemed to be an "at-the-market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on the NASDAQ Global Market, or any other existing trading market for our common stock.

On March 7, 2022 (the LPC Effective Date), the Company entered into a purchase agreement with Lincoln Park Capital Fund, LLC (the Purchase Agreement), pursuant to which Lincoln Park has committed to purchase up to $50.0 million of the Company's common stock (the LPC Facility). Under the terms and subject to the conditions of the Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $50.0 million of the Company's common stock. Such sales of common stock by the Company, if any, will be subject to certain limitations, and may occur from time to time, at the Company's sole discretion, over the 36-month period commencing on the LPC Effective Date. The number of shares the Company may sell to Lincoln Park on any single business day in a regular purchase is 50,000 shares, but that amount may be increased up to 100,000 shares, depending upon the market price of the Company's common stock at the time of sale and subject to a maximum limit of $1.5 million per regular purchase. The purchase price per share for each such regular purchase will be based on prevailing market prices of the Company's common stock immediately preceding the time of sale as computed under the Purchase Agreement. In addition to regular purchases, the Company may also direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases.

Under applicable rules of the NASDAQ Global Market, in no event may the Company issue or sell to Lincoln Park under the Purchase Agreement more than 19.99% of the shares of the Company's common stock outstanding immediately prior to the execution of the Purchase Agreement (the Exchange Cap), unless (i) the Company obtains stockholder approval to issue shares of common stock in excess of the Exchange Cap or (ii) the average price of all applicable sales of common stock to Lincoln Park under the Purchase Agreement equals or exceeds $2.20 per share, such that issuances and sales of the common stock to Lincoln Park under the Purchase Agreement would be exempt from the Exchange Cap limitation under applicable NASDAQ rules.

Lincoln Park has no right to require the Company to sell any shares of common stock to Lincoln Park, but Lincoln Park is obligated to make purchases as the Company directs, subject to certain conditions. In all instances, the Company may not sell shares of its common stock to Lincoln Park under the Purchase Agreement if doing so would result in Lincoln Park beneficially owning more than 9.99% of its common stock.

Actual sales of shares of common stock to Lincoln Park under the Purchase Agreement will depend on a variety of factors to be determined by the Company from time to time, including, among others, market conditions, the trading price of the common stock and determinations by the Company as to the appropriate sources of funding for the Company and its operations. The net proceeds, if any, under the Purchase Agreement will depend on the frequency and prices at which the Company sells shares of its common stock to Lincoln Park. The Company intends to use any net proceeds from the sale of its common stock to Lincoln Park to advance its growth strategy and for general corporate purposes. On the LPC Effective Date, the Company issued 184,275 shares of common stock to Lincoln Park as a commitment fee (the Initial Commitment Shares) for which the Company did not receive consideration and, upon the available amount being reduced to an amount equal to or less than $20.0 million, the Company will be required to issue 61,425 shares (the Additional Commitment Shares and together with the Initial Commitment Shares, collectively, the Commitment Shares). The Initial Commitment Shares issued were valued at $600,000 and, together with due diligence expenses and legal fees of $129,000, reflect deferred offering costs of $729,000, which are included on the condensed balance sheet in 'Other long-term assets'. The deferred offering costs will be charged against 'Additional paid-in capital' upon future proceeds from the sale of common stock under the Purchase Agreement. During the three and nine months ended September 30, 2023 there were no deferred offering costs charged against 'Additional paid-in capital'. During the three and nine months ended September 30, 2022, $33,000 and $51,000 of deferred offering costs were charged against 'Additional paid-in capital', respectively. As of September 30, 2023, $654,000 of deferred offering costs remain.

The Purchase Agreement may be terminated by the Company at any time, at its sole discretion, without any cost or penalty, by giving one business day notice to Lincoln Park to terminate the Purchase Agreement. Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of the common stock. Although the Company has agreed to reimburse Lincoln Park for a limited portion of the fees it incurred in connection with the Purchase Agreement, the Company did not

pay any additional amounts to reimburse or otherwise compensate Lincoln Park in connection with the transaction, other than the issuance of the Commitment Shares.

As of September 30, 2023, the Company had remaining available capacity for share issuances of approximately $29.5 million under the ATM facility and up to $46.9 million under the LPC facility, each subject to the restrictions and limitations of the underlying facilities, as well as volume limitations under applicable SEC rules and regulations that limit their availability as sources of funding.

Subscription Agreements

On August 3, 2023, the Company entered into subscription agreements (the Subscription Agreements) with all the members of our Board of Directors, all Section 16 officers, and additional members of the Biodesix leadership team (together, the Investors) for the issuance and sale by the Company of an aggregate of 16,975,298 of the Company's common stock (the Shares) in a private equity offering (the Private Placement). The Subscription Agreements did not include any registration rights.

Pursuant to the Subscription Agreements, the Investors purchased shares at a purchase price (determined in accordance with Nasdaq rules relating to the "Minimum Value" of the Company's common stock) of $1.62 per share, which is equal to the closing price of the Company's common stock on August 3, 2023, for an aggregate purchase price of approximately $27.5 million. The Subscription Agreements include customary representations, warranties and covenants by the parties to the agreement. During the three months ended September 30, 2023, the Company received $15.3 million in proceeds and issued 9,454,927 shares of common stock pursuant to the Subscription Agreements. On September 27, 2023, the Company entered into an amendment to delay final closing on one subscription agreement. The remaining $12.2 million in proceeds will be received and 7,520,371 shares of common stock will be issued during the three months ended December 31, 2023.

Warrants

During 2018, the Company issued warrants to purchase shares of convertible preferred stock in conjunction with the sale of certain convertible preferred shares and issuance of debt. The Company issued to the lender a warrant to purchase 613,333 shares of Series G convertible preferred stock, at an exercise price of $0.75 per share, subject to adjustment upon specified dilutive issuances. The warrant was immediately exercisable upon issuance and expires on February 23, 2028. Through the effective date of the Company's initial public offering (IPO) in October 2020, the Series G warrants were remeasured to an estimate of fair value using a Black-Scholes pricing model. As a result of the Company's IPO, the preferred stock warrants were automatically converted to warrants to purchase 103,326 shares of common stock with a weighted average exercise price of $4.46 and were also transferred to additional paid-in capital. All common stock warrants remain outstanding as of September 30, 2023.

On November 21, 2022, as consideration for the Perceptive Term Loan Facility (see Note 6 - *Debt*), the Company issued the Perceptive Warrant to purchase up to 5,000,000 shares of the Company's common stock, including the Initial Warrants. In addition to the Initial Warrants, the Additional Warrants will each become exercisable into 1,000,000 shares of common stock concurrently with the borrowing date of the Tranche B and C Loans, respectively. The Company accounts for the Additional Warrants as liabilities as the Additional Warrants do not meet the criteria for equity treatment (see Note 4 - *Fair Value*). The per share exercise price for the Initial Warrants is equal to $1.0648, which is equal to the lower of (A) the 10-day VWAP of the Company's common stock on the business day immediately prior to the Closing Date of the Tranche A Loan or (B) the public offering price per share of common stock of $1.15. The Initial Warrants are equity classified and were immediately exercisable upon issuance and expire on November 21, 2032. The Initial Warrants were valued at $2.9 million using the Black-Scholes option-pricing model assuming an expected term of 10 years, a volatility of 81.3%, a dividend yield of 0% and a risk-free interest rate of 3.67%. All Initial Warrants remain outstanding as of September 30, 2023.

On May 10, 2023, as consideration for the First Amendment (see Note 6 - *Debt*), the Company agreed to issue to Perceptive a warrant to purchase up to 500,000 shares of the Company's common stock (the First Amendment Warrants) at a per share exercise price equal to $1.6254, which is equal to the 10-day VWAP of the Company's common stock ending on the business day immediately prior to the First Amendment Effective Date. The First Amendment Warrants are equity classified and immediately exercisable upon issuance and expire on May 10, 2033. The First Amendment Warrants were valued at $0.7 million using the Black-Scholes option-pricing model assuming an expected term of 10 years, a volatility of 78.7%, a dividend yield of 0% and a risk-free interest rate of 3.49%. All First Amendment Warrants remain outstanding as of September 30, 2023.

Note 9 – Revenue and Accounts Receivable Credit Concentration

We derive our revenue from two primary sources: (i) providing diagnostic testing in the clinical setting (Diagnostic tests); and (ii) providing biopharmaceutical companies with services that include diagnostic research, clinical research, clinical trial testing, development and testing services provided outside the clinical setting and governed by individual contracts with third parties as well as development and commercialization of companion diagnostics. We also recognize revenue from other services, including amounts derived from licensing our technologies (Services and other).

Diagnostic test revenues consist of blood-based lung tests and, prior to May 11, 2023, COVID-19 tests, which are recognized in the amount expected to be received in exchange for diagnostic tests when the diagnostic tests are delivered. The Company conducts diagnostic tests and delivers the completed test results to the prescribing physician or patient, as applicable. The fees for diagnostic tests are billed either to a third party such as Medicare, medical facilities, commercial insurance payers, or to the patient. The Company determines the transaction price related to its diagnostic test contracts by considering the nature of the payer, test type, and historical price concessions granted to groups of customers. For diagnostic test revenue, the Company estimates the transaction price, which is the amount of consideration it expects to be entitled to receive in exchange for providing services based on its historical collection experience, using a portfolio approach. The Company recognizes revenues for diagnostic tests upon delivery of the tests to the physicians requesting the tests or patient, as applicable.

Services revenue consists of on-market tests, pipeline tests, custom diagnostic testing, and other scientific services for a purpose as defined by any individual customer, which is often with biopharmaceutical companies. The performance obligations and related revenue for these sales is defined by a written agreement between the Company and the customer. These services are generally completed upon the delivery of testing results, or other contractually defined milestone(s), to the customer. Revenue for these services is recognized upon delivery of the completed test results, or upon completion of the contractual milestone(s). In addition, other revenue includes amounts derived from licensing our digital sequencing technologies to our international laboratory partners. We are compensated through royalty-based payments for the licensed technology, and depending on the nature of the technology licensing arrangements and considering factors including but not limited to enforceable right to payment and payment terms, and if an asset with alternative use is created, these revenues are recognized in the period when royalty-bearing sales occur.

Revenues consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Diagnostic tests	$ 12,301	$ 10,443	$ 32,395	$ 26,282
Services and other	1,190	664	2,024	2,323
Total revenue	$ 13,491	$ 11,107	$ 34,419	$ 28,605

Deferred Revenue

Deferred revenue consists of cash payments from customers received in advance of delivery. As test results are delivered, the Company recognizes the deferred revenue in ‘Revenues’ in the condensed statements of operations. Of the $1.0 million in ‘Deferred revenue’ recorded in the condensed balance sheet as of December 31, 2022, $0.9 million was recognized in revenues during the nine months ended September 30, 2023 and $0.6 million was added to ‘Deferred revenue’ for up-front cash payments received for which the revenue recognition criteria have not been met. The ‘Deferred revenue’ of $0.7 million recorded in the condensed balance sheet as of September 30, 2023 is expected to be recognized in revenues over the next twelve months as test results are delivered and services are performed. As of September 30, 2023 and December 31, 2022, the Company had $0.4 million in non-current deferred revenue, respectively, recorded within ‘Other long-term liabilities’ in the condensed balance sheets which represent amounts to be recognized in excess of twelve months from the respective balance sheet date.

The Company’s customers in excess of 10% of total revenue and their related revenue as a percentage of total revenue were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
United Healthcare	10%	—	10%	—
The State of Colorado	—	11%	—	14%

In addition to the above table, we collect reimbursement on behalf of customers covered by Medicare, which accounted for 41% and 45% of the Company’s total revenue for the three and nine months ended September 30, 2023, respectively, compared to 37% and 35% for the three and nine months ended September 30, 2022, respectively.

The Company is subject to credit risk from its accounts receivable related to services provided to its customers. The Company's third-party payors and other customers in excess of 10% of accounts receivable, and their related accounts receivable as a percentage of total accounts receivable were as follows:

	As of	
	September 30, 2023	December 31, 2022
Medicare	28%	23%
AstraZeneca UK	—	18%

Note 10 – Share-Based Compensation

The Company's share-based compensation awards are issued under the 2020 Equity Incentive Plan (2020 Plan), the predecessor 2016 Equity Incentive Plan (2016 Plan) and 2006 Equity Incentive Plan (2006 Plan). Any awards that expire or are forfeited under the 2016 Plan or 2006 Plan become available for issuance under the 2020 Plan. As of September 30, 2023, 772,663 shares of common stock remained available for future issuance under the 2020 Plan.

Stock Option Exchange Program

On June 23, 2023, the Company commenced a voluntary offer to exchange certain eligible options held by eligible employees of the Company for new options (the Exchange Offer). The Exchange Offer expired on July 24, 2023. Pursuant to the Exchange Offer, 83 eligible holders elected to exchange, and the Company accepted for cancellation, eligible options to purchase an aggregate of 757,595 shares of the Company's common stock, representing approximately 99% of the total shares of common stock underlying the eligible options. On July 24, 2023, immediately following the expiration of the Exchange Offer, the Company granted new options to purchase 156,868 shares of common stock, pursuant to the terms of the Exchange Offer and the Company's 2020 Equity Incentive Plan. The exercise price of the new options granted pursuant to the Exchange Offer was $1.20 per share, which was the closing price of the common stock on the Nasdaq Global Market on the grant date of the new options. Each new option granted in exchange for the vested shares underlying an eligible option will fully vest on the first day of the month following the first anniversary of the month in which the Exchange Offer is completed. Each new option granted in exchange for the unvested shares underlying an eligible option will vest under an extended vesting schedule, with vesting commencing on the first day of the month following the first anniversary of the month in which the Exchange Offer is completed, and occurring in a series of equal monthly installments over the number of months that were remaining in the surrendered eligible option's vesting schedule immediately prior to the Exchange Offer. Each new option has a maximum term of ten years.

The exchange of stock options was treated as a modification for accounting purposes. The incremental expense was immaterial for the new options and was calculated using the Black-Scholes option pricing model. The incremental expense and the unamortized expense remaining on the exchanged options as of the modification date will be recognized over the new vesting schedule.

Share-Based Compensation Expense

Share-based compensation expense reported in the Company's condensed statements of operations was (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Direct costs and expenses	$ 17	$ 20	$ 41	$ 48
Research and development	68	30	249	310
Sales, marketing, general and administrative	869	1,120	4,002	3,526
Total	$ 954	$ 1,170	$ 4,292	$ 3,884

The unrecognized remaining share-based compensation expense for options and RSUs was approximately $6.6 million as of September 30, 2023 and is expected to be amortized to expense over the next 2.7 years.

Stock Options

Stock option activity during the nine months ended September 30, 2023, excluding the Bonus Option Program described below, was (in thousands, except weighted average exercise price and weighted average contractual life):

	Number of Options	Weighted Average Exercise Price	Weighted Average Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding - January 1, 2023	2,541	$ 8.40	7.4	$ 1,489
Granted	427	1.85	—	—
Forfeited/canceled	(313)	8.88	—	—
Exercised	(122)	0.74	—	—
Cancelled under the Option Exchange	(589)	20.43	—	—
Granted under the Option Exchange	123	1.20	—	—
Outstanding - September 30, 2023	2,067	$ 3.57	7.2	$ 772
Exercisable - September 30, 2023	1,256	$ 4.36	6.1	$ 600

Restricted Stock Unit Activity

Restricted stock unit activity during the nine months ended September 30, 2023 was (in thousands, except weighted average grant date fair value per share):

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Outstanding - January 1, 2023	1,211	$ 2.36
Granted	2,474	1.92
Forfeited/canceled	(228)	2.57
Released	(688)	2.44
Outstanding - September 30, 2023	2,769	$ 1.93

Bonus-to-Options Program

As part of the Bonus-to-Options Program (Bonus Option Program), the Company recorded the following activity during the nine months ended September 30, 2023 (in thousands, excepted weighted average exercise price and weighted average contractual life):

	Number of Options	Weighted Average Exercise Price	Weighted Average Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding - January 1, 2023	526	$ 10.69	7.6	$ 2
Granted	876	2.00	—	—
Forfeited/canceled	(72)	8.88	—	—
Exercised	—	—	—	—
Cancelled under the Option Exchange	(169)	20.67	—	—
Granted under the Option Exchange	34	1.20	—	—
Outstanding - September 30, 2023	1,195	$ 2.75	8.7	$ 15
Exercisable - September 30, 2023	1,161	$ 2.76	8.6	$ —

The Company recorded an insignificant amount and $0.2 million for the three and nine months ended September 30, 2023, respectively, compared to an insignificant amount and $0.7 million for the three and nine months ended September 30, 2022, respectively, related to the estimate of the Bonus Option Program. Options granted, if any, pertaining to the performance of the Bonus Option Program are typically approved and granted in first quarter of the year following completion of the fiscal year.

Employee Stock Purchase Plan

The ESPP provides for successive six-month offering periods beginning on September 1st and March 1st of each year. During the nine months ended September 30, 2023, 437,135 shares were issued under the ESPP leaving 309,012 shares reserved for future issuance.

Note 11 – Net Loss per Common Share

Basic net loss per share excludes dilution and is computed by dividing net loss attributable to the common stockholders by the weighted-average shares outstanding during the period. Diluted net loss per common share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised, resulting in the issuance of shares of common stock that would then share in the earnings or losses of the Company.

Basic and diluted loss per share for the three and nine months ended September 30, 2023 and 2022 were (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Numerator				
Net loss attributable to common stockholders	$ (10,949)	$ (13,699)	$ (43,007)	$ (45,109)
Denominator				
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	79,709	40,448	78,672	36,953
Net loss per share, basic and diluted	$ (0.14)	$ (0.34)	$ (0.55)	$ (1.22)

The following outstanding common stock equivalents were excluded from diluted net loss attributable to common stockholders for the periods presented because inclusion would be anti-dilutive (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Options to purchase common stock	3,262	3,280	3,262	3,280
Shares committed under ESPP	17	33	17	33
Warrants	5,603	103	5,603	103
Restricted stock units	2,769	1,335	2,769	1,335
Total	11,651	4,751	11,651	4,751

Note 12 – Income Taxes

Since inception, the Company has incurred net taxable losses, and accordingly, no provision for income taxes has been recorded. There was no cash paid for income taxes during the three and nine months ended September 30, 2023 and 2022.

Note 13 – Commitments and Contingencies

Co-Development Agreement

In April 2014 and amended in October 2016, the Company entered into a worldwide agreement with AVEO to develop and commercialize AVEO's hepatocyte growth factor inhibitory antibody ficlatuzumab with the Company's proprietary companion diagnostic test, BDX004, a version of the Company’s serum protein test that is commercially available to help physicians guide treatment decisions for patients with advanced non-small cell lung cancer (NSCLC). Under the terms of the agreement, AVEO will conduct a proof of concept (POC) clinical study of ficlatuzumab for NSCLC in which BDX004 will be used to select clinical trial subjects (the NSCLC POC Trial). Under the agreement, the Company and AVEO would share equally in the costs of the NSCLC POC Trial, and each would be responsible for 50% of development and regulatory costs associated with all future clinical trials agreed upon by the Company and AVEO. The Company and AVEO continue to conduct POC clinical trials of ficlatuzumab in combination with BDX004.

In September 2020, the Company exercised its opt-out right with AVEO for the payment of 50% of development and regulatory costs for ficlatuzumab effective December 2, 2020 (the AVEO Effective Date). In September 2021, AVEO announced that the FDA has granted Fast Track Designation (FTD) to ficlatuzumab for the treatment of patients with relapsed or recurrent head and neck squamous cell carcinoma. In November 2021 AVEO also announced plans to initiate a potential registrational Phase 3 clinical trial for ficlatuzumab in the first half of 2023. The Company had $0.1 million in remaining obligations related to the AVEO agreement as of September 30, 2023. Following the AVEO Effective Date, the Company is entitled to a 10% royalty of net sales of ficlatuzumab and 25% of license income generated from the licensing of ficlatuzumab from AVEO. There were no royalties received or expenses related to this agreement for the three and nine months ended September 30, 2023 and 2022.

License Agreement

In August 2019, we entered into a non-exclusive license agreement with Bio-Rad Laboratories, Inc. (Bio-Rad) (the Bio-Rad License). Under the terms of the Bio-Rad License, the Company received a non-exclusive license, without the right to grant sublicenses, to utilize certain of Bio-Rad's intellectual property, machinery, materials, reagents, supplies and know-how necessary for the performance of Droplet Digital PCR™ (ddPCR) in cancer detection testing for third parties in the United States. The Company also agreed to purchase all of the necessary supplies and reagents for such testing exclusively from Bio-Rad, pursuant to a separately executed supply agreement (the Supply Agreement) with Bio-Rad. As further consideration for the non-exclusive license, the Company agreed to pay a royalty of 2.5% on the net revenue received for the performance of such ddPCR testing collected from third parties. On May 24, 2021, the Company entered into the First Amendment to the Non-Exclusive License Agreement with Bio-Rad which amended the Bio-Rad License such that, effective May 1, 2021, the Company no longer paid a royalty of 2.5% on the net revenue received for the performance of such ddPCR testing collected from third parties. The Bio-Rad License expires in August 2024. Either party may terminate for the other's uncured material breach or bankruptcy events. Bio-Rad may terminate the Bio-Rad License if the Company does not purchase licensed products under the Supply Agreement for a consecutive twelve-month period or for any material breach by us of the Supply Agreement. There were no expenses related to this agreement for the three and nine months ended September 30, 2023 and 2022.

On May 13, 2021 (the CellCarta Effective Date), we reached agreement with CellCarta Biosciences Inc. (formerly "Caprion Biosciences, Inc.") (the CellCarta License) on a new royalty bearing license agreement for the Nodify XL2 test. The parties agreed to terminate all prior agreements and replace with this new arrangement, which has a 1% fee on net sales made from the first commercial sale of the Nodify XL2 test to the CellCarta Effective Date as an upfront make-good payment covering past royalties due and a royalty rate of 0.675% on future Nodify XL2 test net sales worldwide for 15 years from the first commercial sale, ending in 2034. Royalty expense under the CellCarta License was $0.1 million for the three and nine months ended September 30, 2023, respectively, compared to an insignificant amount and $0.1 million for the three and nine months ended September 30, 2022.

As part of the acquisition of the assets of Oncimmune USA, the Company entered into several agreements to govern the relationship between the parties. The Company agreed to a license agreement and royalty payment related to an acquired diagnostic test of 8% of recognized revenue for non-screening tests up to an annual minimum volume and 5% thereafter, with an escalating minimum through the first four years of sales. Royalty expenses were $0.2 million and $0.6 million for both the three and nine months ended September 30, 2023 and 2022, respectively.

Litigation, Claims and Assessments

From time to time, we may become involved in legal proceedings or investigations which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition, or cash flows.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Biodesix, Inc. is referred to throughout this Quarterly Report on Form 10-Q for the period ended September 30, 2023 (Form 10-Q) as "we", "us", "our" or the "Company".

The following Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2022 (Form 10-K) and the Condensed Financial Statements as of September 30, 2023 and for the three and nine months ended September 30, 2023 and 2022, included in Part I, Item 1 of this Form 10-Q, which provide additional information regarding our financial position, results of operations and cash flows. To the extent that the following MD&A contains statements which are not of a historical nature, such statements are forward-looking statements, which involve risks and uncertainties, including but not limited to those set forth under the caption "Special Note Regarding Forward-Looking Statements" and Item 1A "Risk Factors" of Part II in this Quarterly Report on Form 10-Q and those discussed in our other filings with the Securities and Exchange Commission (SEC), including the risks described in Item 1A "Risk Factors" of Part I of our Annual Report on Form 10-K for the year ended December 31, 2022, which was filed on March 6, 2023.

The following MD&A discussion is provided to supplement the Condensed Financial Statements as of September 30, 2023 and 2022 and for the three and nine months then ended included in Part I, Item 1 of this Quarterly Report on Form 10-Q. We intend for this discussion to provide you with information that will assist you in understanding our financial statements, the changes in key items in those financial statements from period to period, and the primary factors that accounted for those changes.

Data for the three and nine months ended September 30, 2023 and 2022 has been derived from our unaudited condensed financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Overview

We are a leading diagnostic solutions company leveraging state of the art technologies with our proprietary AI platform to discover, develop, and commercialize solutions for clinical unmet needs, with a primary focus in lung disease. By combining a multi-omic approach with a holistic view of the patient's disease state, we believe our solutions provide physicians with greater insights to help personalize their patient's care and meaningfully improve disease detection, evaluation, and treatment. Our unique approach to precision medicine provides timely and actionable clinical information, which we believe helps improve overall patient outcomes and lowers the overall healthcare cost by reducing the use of ineffective and unnecessary treatments and procedures. In addition to our diagnostic tests, we provide biopharmaceutical companies with services that include diagnostic research, clinical trial testing, and the discovery, development, and commercialization of companion diagnostics. We also recognize revenue from other services, including amounts derived from licensing our technologies.

Our core belief is that no single technology will answer all clinical questions that we encounter. Therefore, we employ multiple technologies, including genomics, transcriptomics, proteomics, and radiomics, and leverage our proprietary AI-based Diagnostic Cortex® platform to discover innovative diagnostic tests for clinical use. The Diagnostic Cortex is an extensively validated deep learning platform optimized for the discovery of diagnostic tests, which we believe overcomes standard machine learning challenges faced in life sciences research. Our data-driven and multi-omic approach is designed to enable us to discover diagnostic tests that answer critical clinical questions faced by physicians, researchers, and biopharmaceutical companies.

We continuously incorporate new market insights and patient data to enhance our platform through a data-driven learning loop. We regularly engage with our customers, key opinion leaders, and scientific experts to stay ahead of the rapidly evolving diagnostic treatment landscape to identify additional clinical unmet needs where a diagnostic test could help improve patient care. Additionally, we incorporate clinical and molecular profiling data from our commercial clinical testing, research studies, clinical trials, and biopharmaceutical customers or academic partnerships, to continue to advance our platform. We have a variety of samples with associated data in our biobank, including tumor profiles and immune profiles, which are used for both internal and external research and development initiatives.

We have commercialized five diagnostic tests for our lung diagnostic business, each of which have Medicare coverage, which are currently available for use by physicians. Our Nodify XL2 and Nodify CDT tests, marketed as part of the Nodify Lung Nodule Risk Assessment testing strategy, assess the risk of lung cancer to help identify the most appropriate treatment pathway. The Nodify Lung Risk Assessment testing strategy has resulted in a change in the calculated risk of malignancy in 80-85% of the cases. We believe we are the only company to offer two commercial blood-based tests to help physicians reclassify risk of malignancy in patients with suspicious lung nodules. Our GeneStrat ddPCR, GeneStrat NGS, and VeriStrat tests, marketed as the IQLung testing strategy, are used following diagnosis of lung cancer to measure the presence of mutations in the tumor and the state of the patient's immune system to establish the patient's prognosis and help guide treatment decisions. The GeneStrat targeted tumor profiling test and the VeriStrat immune profiling test now have a turnaround time of two business days, down from the previous three business day turnaround time, providing physicians with timely results to facilitate treatment decisions. The GeneStrat NGS test is our blood-based NGS test with results in three business days, which was launched in November 2021 to a select group of physicians, with national launch in January 2022. The 52-gene panel includes guideline recommended mutations to help physicians treating advanced-stage lung cancer patients

identify all four major mutation classes and genes, such as EGFR, ALK, KRAS, MET, NTRK, ERBB2, and others, and delivers them in an expedited timeframe so patient treatment can begin sooner.

In addition to the five diagnostic tests currently on the market, we perform over 30 assays for research use as part of our laboratory services that have been used by over 65 biopharmaceutical companies and academic partners. All of our diagnostic and services testing is performed at one of our two accredited, high-complexity clinical laboratories in Boulder, Colorado and De Soto, Kansas.

Since our inception, we have performed over 600,000 clinical diagnostic tests, and continue to generate a large and growing body of clinical evidence consisting of over 300 clinical and scientific peer-reviewed publications, presentations, and abstracts. Through ongoing study of each of our tests, we continue to grow our depth of understanding of disease biology and the broad utility of each of our tests. We believe we are poised for rapid growth by leveraging our scientific development and laboratory operations expertise along with our commercial infrastructure which includes sales, marketing, reimbursement, and regulatory affairs.

In the United States, we market our tests to clinical customers through our targeted sales organization, which includes sales representatives that are engaged in sales efforts and promotional activities primarily to pulmonologists, oncologists, cancer centers and nodule clinics. We market our tests and services to biopharmaceutical companies globally through our targeted business development team, which promotes the broad utility of our tests and testing capabilities throughout drug development and commercialization which is of value to pharmaceutical companies and their drug-development process.

In response to the COVID-19 pandemic, through our partnership with Bio-Rad, we commercialized the Biodesix WorkSafe™ testing program, which included three commercialized tests. Our scientific diagnostic expertise, technologies, and existing commercial infrastructure enabled us to rapidly commercialize two FDA EUA authorized tests, a part of our customizable program. Both diagnostic tests are owned and were developed by Bio-Rad and Bio-Rad has granted us permission to utilize both tests for commercial diagnostic services. The Bio-Rad SARS-CoV-2 ddPCR test was FDA EUA authorized on May 1, 2020, authorizing performance of the test in laboratories certified under CLIA to perform high complexity tests. The second test is the Platelia SARS-CoV-2 Total Ab test, which is an antibody test intended for detecting a B-cell immune response to SARS-CoV-2, indicating recent or prior infection. The Platelia SARS-CoV-2 Total Ab test was FDA EUA authorized on April 29, 2020. Beginning in second quarter 2021, we began partnering with GenScript Biotech Corporation to commercialize the blood-based cPass SARS-CoV-2 Neutralizing Antibody testing as a service. The test was the first surrogate neutralizing antibody test with FDA EUA and uses ELISA technology to qualitatively detect circulating neutralizing antibodies to the RBD in the spike protein of SARS-CoV-2 that are produced in response to a previous SARS-CoV-2 infection.

Medical products that are granted an EUA are only permitted to commercialize their products under the terms and conditions provided in the authorization. The FDA may revoke an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, if the conditions for the issuance of the EUA are no longer met, or if other circumstances make revocation appropriate to protect the public health or safety. The EUA declaration under Section 564 of the FDCA is distinct from and independent of the declaration by the Secretary of HHS of a public health emergency under Section 319 of the Public Health Service Act (the PHS Act). On January 30, 2023, the White House issued a Statement of Administration Policy announcing the President’s intention to allow the Public Health Emergency declaration under Section 319 to expire on May 11, 2023. Because the EUA declaration from the FDA is distinct from the declaration under Section 319 of the PHS Act, the FDA EUA may remain in effect beyond the duration of the Section 319 declaration. We cannot predict how long the EUAs for the SARS-CoV-2 tests will remain in place. In connection with the expiration of the Public Health Emergency declaration under Section 319, the Company no longer provides commercial COVID-19 diagnostic testing services.

These tests under the Biodesix WorkSafe testing program were utilized by healthcare providers, including hospitals and nursing homes, and were also offered to businesses and educational systems. We announced multiple partnerships for COVID-19 testing and maintained an agreement with the State of Colorado to be one of the diagnostic companies to support widespread COVID-19 testing for the State, which expired on August 31, 2022.

We have funded our operations to date principally from net proceeds from the issuances of our common stock, the sale of convertible preferred stock, revenue from diagnostic testing and services, and the incurrence of indebtedness. We had cash and cash equivalents of $19.8 million and $43.1 million as of September 30, 2023 and December 31, 2022, respectively.

Factors Affecting Our Performance

We believe there are several important factors that have impacted our operating performance and results of operations, including:

- **Testing volume and customer mix.** Our revenues and costs are affected by the volume of testing and mix of customers from period to period. We evaluate both the volume of our commercial tests, or the number of tests that we perform for patients on behalf of clinicians, as well as tests for biopharmaceutical companies. Our performance depends on our ability to retain and broaden adoption with existing customers, as well as attract new customers. We believe that the test volume we receive from clinicians and biopharmaceutical companies are indicators of growth in each of these customer verticals. Customer mix for our tests has the potential to significantly impact our results of operations, as the average selling price for biopharmaceutical

sample testing is currently significantly greater than our average selling price for clinical tests since we are not a contracted provider for, or our tests are not covered by all clinical patients' insurance. We evaluate our average selling price for tests that are covered by Medicare, Medicare Advantage and commercial payers to understand the trends in reimbursement and apply those trends to our revenue recognition policies.

- **Reimbursement for clinical diagnostic testing.** Our revenue depends on achieving broad coverage and reimbursement for our tests from third-party payers, including both commercial and government payers. On June 7, 2022, we announced that WPS Government Health Administrators, the Medicare administrative contractor with jurisdiction for Biodesix's De Soto, Kansas laboratory, has provided coverage for the Nodify CDT lung nodule test. All five Biodesix blood-based lung diagnostic tests within the Nodify Lung Nodule Risk Assessment testing strategy and IQLung strategy for lung cancer patients are now covered by Medicare. Payment from third-party payers differs depending on whether we have entered into a contract with the payers as a "participating provider" or do not have a contract and are considered a "non-participating provider." Payers will often reimburse non-participating providers, if at all, at a lower rate than participating providers.

  Historically, we have experienced situations where commercial payers proactively reduced the amounts they were willing to reimburse for our tests, and in other situations, commercial payers have determined that the amounts they previously paid were too high and have sought to recover those perceived excess payments by deducting such amounts from payments otherwise being made. When we contract to serve as a participating provider, reimbursements are made pursuant to a negotiated fee schedule and are limited to only covered indications. Becoming a participating provider generally results in higher reimbursement for covered indications and lack of reimbursement for non-covered indications. As a result, the impact of becoming a participating provider with a specific payer will vary. If we are not able to obtain or maintain coverage and adequate reimbursement from third-party payers, we may not be able to effectively increase our testing volume and revenue as expected. Additionally, retrospective reimbursement adjustments can negatively impact our revenue and cause our financial results to fluctuate.

  On October, 17, 2022, the Company announced that the U.S. Department of Veterans Affairs (the VA), the largest integrated health care system in the United States, awarded a Federal Supply Schedule Contract for the Company's entire portfolio of lung cancer diagnostic tests. The VA provides care at 1,298 health care facilities, including 171 VA Medical Centers and 1,113 outpatient sites of care of varying complexity to over 9 million veterans enrolled in the VA health care program. All of our existing lung diagnostic tests will be payable when performed and partnering with the VA represents a large opportunity for Biodesix to help improve care for our Veterans by integrating our five diagnostic products and testing strategies into our country's largest health system.

  On December 19, 2022, the Company announced the signing of our first four private payer commercial policies covering our Nodify XL2 test. These contracts included three Blue Cross Blue Shield plans in North Carolina, South Carolina, and Kansas City, and a contract with Capital District Physician's Health Plan in New York. In total, these new private pay contracts add approximately 4.5 million covered lives and are in geographic regions of the country where the incidence of lung cancer is high.

  On July 6, 2023, the Company announced that the Centers for Medicare & Medicaid Services (CMS) has designated the Nodify CDT Test as an Advanced Diagnostic Laboratory Test (ADLT) effective June 30, 2023. Obtaining ADLT status is a recognition that the Nodify CDT test meets the stringent criteria established under the Protecting Access to Medicare Act of 2014. ADLT status is reserved for innovative tests with Medicare coverage that provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests.

- **Investment in clinical studies and product innovation to support growth.** A significant aspect of our business is our investment in research and development, including the development of new products and our investments in clinical utility studies. We have invested heavily in clinical studies for our on market and pipeline products. Our studies focus primarily on the clinical utility of our tests including the ongoing INSIGHT study to continue our clinical understanding of the predictive and prognostic value of the VeriStrat test. On June 27, 2023, we completed enrollment of 5,000 patients with non-small cell lung cancer. The ALTITUDE study, launched during the fourth quarter 2020, seeks to further demonstrate the efficacy of the Nodify XL2 and Nodify CDT tests. A secondary focus of our studies is understanding the economic impact of our tests in assisting with decisions related to patient management and the potential impact of our tests in reducing overall healthcare costs. On July 12, 2023, we announced the prospective, real-world ORACLE study (An Observational Registry Study to Evaluate the Performance of the Nodify XL2 Test) achieved the primary endpoint of a statistically significant change in the proportion of benign lung nodules managed by Nodify XL2 experiencing invasive procedures. The ORACLE study showed patients with benign nodules managed with the Nodify XL2 test were 74% less likely to undergo an unnecessary invasive procedure compared to the control group. Additionally, the proportion of patients sent to CT surveillance with malignant nodules did not differ between the Nodify XL2 group and the control group.

  Our clinical research has resulted in approximately 90 peer-reviewed publications for our tests. In addition to clinical studies, we are collaborating with investigators from multiple academic cancer centers. On June 3, 2022, we announced the intent to

develop a new novel molecular minimal residual disease (MRD) test as a part of a master sponsored research agreement (MSRA) with Memorial Sloan Kettering Cancer Center (MSK). In addition, the MSRA between MSK and the Company also includes the potential future development of other diagnostic tests aimed at improving the treatment of cancer. We believe these studies are critical to gaining physician adoption and driving favorable coverage decisions by payers and expect our investments in research and development to increase. Further we also expect to increase our research and development expenses to fund further innovation and develop new clinically relevant tests.

- **Ability to attract new biopharmaceutical customers and maintain and expand relationships with existing customers**. Our business development team promotes the broad utility of our products for biopharmaceutical companies in the United States and internationally. Our revenue, business opportunities and growth depend in part on our ability to attract new biopharmaceutical customers and to maintain and expand relationships with existing biopharmaceutical customers. We expect to increase our sales and marketing expenses in furtherance of this as we continue to develop these relationships, and we expect to support a growing number of investigations and clinical trials. If our relationships expand, we believe we may have opportunities to offer our platform for companion diagnostic development, novel target discovery and validation efforts, and to grow into other commercial opportunities. For example, we believe our multi-omic data including genomic and proteomic data, in combination with clinical outcomes or claims data, has revenue-generating potential, including for novel target identification and companion diagnostic discovery and development.

  On June 30, 2022, the Company announced an arrangement with Royal Philips, a global leader in health care technology, in which our Nodify Lung blood-based lung nodule risk assessment testing will be incorporated into Philips Lung Cancer Orchestrator lung cancer patient management system. The incorporation of proteomics data – along with the radiologic and patient history data currently used to determine treatment decisions – can help create diagnostic efficiency for cancer care centers in the management of a growing number of lung nodule cases, via the contextual launch of Biodesix Nodify Lung application within Lung Cancer Orchestrator. Philips Lung Cancer Orchestrator solution is designed to enable health systems to operationalize lung cancer screening and lung nodule management programs at scale.

- **Motivating and expanding our field sales force and customer support team**. Our field sales force is the primary point of contact in the clinical setting. These representatives of the Company must cover expansive geographic regions which limits their time for interaction and education of our products in the clinical setting. We plan to continue investing in the field sales force through select expansion and provide them with tools that maximize their education and selling efforts in order to achieve greater returns. Additionally, we plan to invest in the marketing and customer support teams to continue to provide the field sales force with the resources to be successful.

While each of these areas present significant opportunities for us, they also pose significant risks and challenges that we must address. See Part II, Item 1A “Risk Factors” within this Form 10-Q and Item 1A “Risk Factors” of Part I of our Annual Report on Form 10-K for the year ended December 31, 2022 for more information.

COVID-19 Pandemic

The COVID-19 pandemic disrupted, and may continue to disrupt, our lung diagnostic testing operations. To protect the health and well-being of our workforce, partners, vendors and customers, we provide voluntary COVID-19 testing for employees working on-site, implemented social distance and building entry policies at work, restricted travel and facility visits, and followed the States of Colorado and Kansas’ public health orders and the guidance from the Centers for Disease Control and Prevention (CDC). Employees who can perform their duties remotely have the option to work from home. Our sales, marketing and business development efforts may be constrained by our operational response to future COVID-19 variant outbreaks. We will continue to adjust our operational norms, as needed, including complying with government directives and guidelines as they are modified and supplemented.

The COVID-19 pandemic and the surge associated with multiple variants negatively affected our lung diagnostic testing-related revenue and our clinical studies. Beginning in the third quarter 2020, the Company’s COVID-19 testing services began to experience rapid growth with a peak in the first quarter 2021; however, subsequent to this peak, we experienced a rapid decline in COVID-19 testing revenue primarily as a result of a few significant contracts that expired as well as the ongoing increase in COVID-19 vaccination rates across the U.S. and the adoption and availability of at-home testing. On January 30, 2023, the White House issued a Statement of Administration Policy announcing the President’s intention to allow the Public Health Emergency declaration under Section 319 to expire on May 11, 2023. In connection with the expiration of the Public Health Emergency declaration under Section 319, the Company no longer provides commercial COVID-19 diagnostic testing services.

See Item 1A “Risk Factors” of Part II in this Quarterly Report on Form 10-Q and those discussed in our other filings with the SEC, including the risks described in Item 1A “Risk Factors” of Part I of our Annual Report on Form 10-K for the year ended December 31, 2022, which was filed on March 6, 2023, for a description of how the COVID-19 pandemic may adversely affect our business, financial condition and results of operations.

Third Quarter 2023 Financial and Operational Highlights

The following were significant developments affecting our business, capital structure and liquidity during the three months ended September 30, 2023 as compared to the same period in 2022 unless otherwise noted:

- Total revenue of $13.5 million, an increase of 21% including COVID testing revenue in third quarter 2022, driven primarily by strong year-over-year growth in lung diagnostics, and a 37% year-over-year increase excluding COVID testing revenues from the prior year comparison;
    - *Lung diagnostic revenue of $12.3 million reflected a year-over-year increase of 34% driven primarily by the continued adoption of Nodify Lung nodule risk assessment tests, and approximately 60% when excluding one-time cash revenue from tests performed in prior periods primarily from Medicare coverage of the Nodify CDT test;*
    - *Services and other revenue of $1.2 million increased 79% year-over-year, a result of the ongoing recovery in testing volumes from clinical studies, services and new agreements;*
    - *COVID-19 testing revenue decreased by 100% year-over-year, as the Company no longer provides COVID-19 diagnostic testing services;*
- Third quarter 2023 gross profit of $10.3 million, or 76% gross margin compared to 67% gross margin in the comparable prior year period, primarily driven by growth in Lung diagnostic testing and optimization of testing workflows that resulted in improvements in costs per test, the ongoing recovery of our Services business, and the commercial discontinuation of our lower-margin COVID-19 diagnostic testing;
- Operating expenses (excluding direct costs and expenses) of $17.4 million, a decrease of approximately $0.7 million, or 4% as compared to the third quarter 2022 (includes non-cash stock compensation expense of $1.0 million as compared to $1.2 million). This decrease is primarily attributable to a decrease in research and development costs, partially offset by increased sales and marketing costs to support lung diagnostic sales growth to enhance product awareness and drive adoption;
- Net loss of $10.9 million, a decrease of approximately $2.8 million, or 20%;
- Cash and cash equivalents of $19.8 million as of September 30, 2023, an increase of $2.4 million from June 30, 2023;
    - *The Company plans to draw down an additional $10 million from the second tranche of its $50 million term loan facility with Perceptive Advisors in the fourth quarter of 2023;*
    - *Cash balance includes $15.3 million of the $27.5 million private placement announced in August. The remaining $12.2 million will be received in the fourth quarter of 2023.*

Components of Operating Results

Revenues

We derive our revenue from two primary sources: (i) providing diagnostic testing in the clinical setting (Diagnostic Tests); and (ii) providing biopharmaceutical companies with services that include diagnostic research, clinical research, clinical trial testing, development and testing services generally provided outside the clinical setting and governed by individual contracts with third parties as well as development and commercialization of companion diagnostics. We also recognize revenue from other services, including amounts derived from licensing our technologies (Services and other).

Diagnostic Tests

Diagnostic test revenue is generated from delivery of results from our diagnostic tests. In the United States, we performed tests as both an in-network and out-of-network service provider depending on the test performed and the contracted status of the insurer. We provide diagnostic tests in two primary categories: (i) lung diagnostics testing and (ii) COVID-19 testing. On January 30, 2023, the White House issued a Statement of Administration Policy announcing the President’s intention to allow the Public Health Emergency declaration under Section 319 to expire on May 11, 2023. In connection with the expiration of the Public Health Emergency declaration under Section 319, the Company no longer provides commercial COVID-19 diagnostic testing services.

We consider diagnostic testing to be completed upon the delivery of test results to our customer, either the prescribing physician or third-party to which we contracted for services to be performed, which is considered the performance obligation. The fees for such services are billed either to a third party such as Medicare, medical facilities, commercial insurance payers, or to the patient. We determine the transaction price related to our contracts by considering the nature of the payer, test type, the historical amount of time until payment by a payer and historical price concessions granted to groups of customers.

Services and other

Services revenue is generated from the delivery of our on-market tests, pipeline tests, custom diagnostic testing, and other scientific services for a purpose as defined by any individual customer. At times we collaborate with large biopharmaceutical companies in an attempt to discover biomarkers that would be helpful in their drug development or marketing. The performance obligations and related revenue for these sales is defined by a written agreement between us and our customer. These services are generally completed upon the delivery of testing results, or other contractually defined milestone(s), to the customer, which is considered the performance obligation. Customers for these services are typically large pharmaceutical companies where collectability is reasonably assured and therefore revenue is accrued upon completion of the performance obligations. Revenue derived from services is often unpredictable and can cause dramatic swings in our overall net revenue line from quarter to quarter.

In addition, other revenue includes amounts derived from licensing our digital sequencing technologies to our international laboratory partners. We are compensated through royalty-based payments for the licensed technology, and depending on the nature of the technology licensing arrangements, and considering factors including, but not limited to: enforceable right to payment and payment terms, and if an asset with alternative use is created, these revenues are recognized in the period when royalty-bearing sales occur.

Operating Expenses

Direct costs and expenses

Cost of diagnostic testing generally consists of cost of materials, direct labor, including bonuses, employee benefits, share-based compensation, equipment and infrastructure expenses associated with acquiring and processing test samples, including sample accessioning, test performance, quality control analyses, charges to collect and transport samples; curation of test results for physicians; and in some cases, license or royalty fees due to third parties. Costs associated with performing our tests are recorded as the tests are processed regardless of whether revenue was recognized with respect to the tests. Infrastructure expenses include depreciation of laboratory equipment, rent costs, amortization of leasehold improvements and information technology costs. Royalties for licensed technology are calculated as a percentage of revenues generated using the associated technology and recorded as expense at the time the related revenue is recognized. One-time royalty payments related to signing of license agreements or other milestones, such as issuance of new patents, are amortized to expense over the expected useful life of the patents. While we do not believe the technologies underlying these licenses are necessary to permit us to provide our tests, we do believe these technologies are potentially valuable and of possible strategic importance to us or our competitors. Under these license agreements, we are obligated to pay aggregate royalties ranging from 1% to 8% of sales in which the patents or know-how are used in the product or service sold, sometimes subject to minimum annual royalties or fees in certain agreements.

We expect the aggregate cost of diagnostic testing to increase in line with the increase in the number of tests we perform, but the cost per test to decrease modestly over time due to the efficiencies we may gain as test volume increases, and from automation and other cost reductions. Cost of services includes costs incurred for the performance of development services requested by our customers. Costs of development services will vary depending on the nature, timing and scope of customer projects.

Research and development

Research and development expenses consist of costs incurred to develop technology and include salaries, share-based compensation and benefits, reagents and supplies used in research and development laboratory work, infrastructure expenses, including allocated facility occupancy and information technology costs, contract services, clinical studies, other outside costs and costs to develop our technology capabilities. Research and development expenses account for a significant portion of our operating expenses and consist primarily of external and internal costs incurred in connection with the discovery and development of our product candidates.

External expenses include: (i) payments to third parties in connection with the clinical development of our product candidates, including contract research organizations and consultants; (ii) the cost of manufacturing products for use in our preclinical studies and clinical trials, including payments to contract manufacturing organizations (CMOs) and consultants; (iii) scientific development services, consulting research fees and for sponsored research arrangements with third parties; (iv) laboratory supplies; and (v) allocated facilities, depreciation and other expenses, which include direct or allocated expenses for IT, rent and maintenance of facilities. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the level of service that has been performed at each reporting date. We track external costs by the stage of program, clinical or preclinical.

Internal expenses include employee-related costs, including salaries, share-based compensation and related benefits for employees engaged in research and development functions. We do not track internal costs by product candidate because these costs are deployed across multiple programs and, as such, are not separately classified.

Research and development costs are expensed as incurred. Payments made prior to the receipt of goods or services to be used in research and development are deferred and recognized as expense in the period in which the related goods are received or services are rendered. Costs to develop our technology capabilities are recorded as research and development.

We expect our research and development expenses to increase as we continue to innovate and develop additional products and expand our data management resources. As our services revenue grows, an increasing portion of research and development dollars are expected to be allocated to cost of services for biopharmaceutical service contracts. This expense, though expected to increase in dollars, is expected to decrease as a percentage of revenue in the long term, though it may fluctuate as a percentage of our revenues from period to period due to the timing and extent of these expenses.

Sales, marketing, general and administrative

Our sales and marketing expenses are expensed as incurred and include costs associated with our sales organization, including our direct sales force and sales management, client services, marketing and reimbursement, as well as business development personnel who are focused on our biopharmaceutical customers. These expenses consist primarily of salaries, commissions, bonuses, employee benefits, share-based compensation, and travel, as well as marketing and educational activities and allocated overhead expenses. We expect our sales and marketing expenses to increase in dollars as we expand our sales force, increase our presence within the United States, and increase our marketing activities to drive further awareness and adoption of our tests and our future products. These expenses, though expected to increase in dollars, are expected to decrease as a percentage of revenue in the long term, though they may fluctuate as a percentage of our revenues from period to period due to the timing and extent of these expenses.

Our general and administrative expenses include costs for our executive, accounting, finance, legal and human resources functions. These expenses consist principally of salaries, bonuses, employee benefits, share-based compensation, and travel, as well as professional services fees such as consulting, audit, tax and legal fees, and general corporate costs and allocated overhead expenses. We expect that our general and administrative expenses will continue to increase in dollars, primarily due to increased headcount and costs associated with operating as a public company, including expenses related to legal, accounting, regulatory, maintaining compliance with exchange listing and requirements of the SEC, director and officer insurance premiums and investor relations. These expenses, though expected to increase in dollars, are expected to decrease as a percentage of revenue in the long term, though they may fluctuate as a percentage from period to period due to the timing and extent of these expenses.

Non-Operating Expenses

Interest Expense and Interest Income

For the three and nine months ended September 30, 2023, interest expense consists of cash and non-cash interest from the Perceptive Term Loan Facility and changes in the value of our contingent consideration associated with the passage of time subsequent to the achievement of the gross margin target in the second quarter 2021. For the three and nine months ended September 30, 2022, interest expense primarily consists of cash and non-cash interest from Promissory Note One and the 2021 Term Loan (both as defined below) as well as changes in the value of our contingent consideration associated with the passage of time subsequent to the achievement of the contingency in the second quarter 2021. Interest income, which is included in ‘Other income, net’ in the condensed statements of operations consists of income earned on our cash and cash equivalents.

Results of Operations

The following table sets forth the significant components of our results of operations for the periods presented (in thousands, except percentages):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2023	2022	$	%	2023	2022	$	%
Revenues	$ 13,491	$ 11,107	$ 2,384	21%	$ 34,419	$ 28,605	$ 5,814	20%
Operating expenses								
Direct costs and expenses	3,229	3,633	(404)	(11)%	9,636	10,848	(1,212)	(11)%
Research and development	1,938	2,970	(1,032)	(35)%	8,099	9,537	(1,438)	(15)%
Sales, marketing, general and administrative	15,496	15,114	382	3%	51,136	44,836	6,300	14%
Impairment loss on intangible assets	—	—	—	0%	20	81	(61)	(75)%
Total operating expenses	20,663	21,717	(1,054)	(5)%	68,891	65,302	3,589	5%
Loss from operations	(7,172)	(10,610)	3,438	32%	(34,472)	(36,697)	2,225	6%
Other (expense) income								
Interest expense	(2,386)	(3,039)	(653)	(21)%	(7,207)	(5,522)	1,685	31%
Loss on extinguishment of liabilities, net	—	(52)	52	100%	—	(3,004)	3,004	100%
Change in fair value of warrant liability, net	(1,393)	—	(1,393)	(100)%	(1,332)	—	(1,332)	(100)%
Other income, net	2	2	—	0%	4	114	110	96%
Total other expense	(3,777)	(3,089)	688	22%	(8,535)	(8,412)	123	1%
Net loss	$ (10,949)	$ (13,699)	$ 2,750	20%	$ (43,007)	$ (45,109)	$ 2,102	5%
Share-based compensation [1]	$ 954	$ 1,170	$ (216)	(18)%	$ 4,292	$ 3,884	$ 408	11%

[1] Amounts represent share-based compensation expense reported in the Company's results of operations above.

Revenues

We generate revenue by providing laboratory testing of our diagnostic tests and services. Our revenues for the periods indicated were as follows (in thousands, except percentages):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2023	2022	$	%	2023	2022	$	%
Revenues								
Lung Diagnostic	$ 12,301	$ 9,157	$ 3,144	34%	$ 32,382	$ 21,058	$ 11,324	54%
COVID-19	—	1,286	(1,286)	(100)%	13	5,224	(5,211)	(100)%
Diagnostic testing revenue	12,301	10,443	1,858	18%	32,395	26,282	6,113	23%
Services and other revenue	1,190	664	526	79%	2,024	2,323	(299)	(13)%
Total revenues	$ 13,491	$ 11,107	$ 2,384	21%	$ 34,419	$ 28,605	$ 5,814	20%

Total revenue increased $2.4 or 21%, and increased $5.8 million or 20% for the three and nine months ended September 30, 2023, respectively, compared to the same periods in 2022.

Diagnostic test revenue increased $1.9 million or 18%, and increased $6.1 million or 23% for the three and nine months ended September 30, 2023, respectively, compared to the same periods in 2022 due to an increase in our lung diagnostic testing revenue of $3.1 million and $11.3 million, respectively, driven by an increase in our Nodify XL2 and CDT diagnostic tests delivered. The Company's lung diagnostic sales efforts continued to gain momentum during the three and nine months ended September 30, 2023 as the number of tests delivered reached the highest in Company history for three consecutive quarters. Partially offsetting this increase was a $1.3 million and $5.2 million reduction in COVID-19 testing revenue for the three and nine months ended September 30, 2023, respectively, resulting from the expiration of significant COVID-19 testing contracts and the recession of the COVID-19 pandemic. Additionally, on January 30, 2023, the White House issued a Statement of Administration Policy announcing the President's intention to allow the Public Health Emergency declaration under Section 319 to expire on May 11, 2023. In connection with the expiration of the Public Health Emergency declaration under Section 319, the Company no longer provides COVID-19 diagnostic testing services commercially.

Services and other revenue increased $0.5 million or 79%, and decreased $0.3 million or 13% for the three and nine months ended September 30, 2023, respectively, compared to the same periods in 2022. The increase in revenue for the three months ended September 30, 2023 was primarily due to recovery in testing volumes from clinical studies and services. The decrease in revenue for the nine months ended September 30, 2023 was due to lower testing volumes driven by delayed enrollment in clinical trials and the completion of a material contract in 2022. In addition, service revenue can fluctuate due to several factors including contract timing, which can be long under normal circumstances, and currently reflects the slower pace of overall prospective clinical trial enrollment recovering from disruptions put forth by COVID-19.

Operating Expenses

Direct costs and expenses

Direct costs and expenses related to revenue decreased $0.4 million or 11%, and decreased $1.2 million or 11% for the three and nine months ended September 30, 2023, respectively, compared to the same periods in 2022. The decrease in costs for the three and nine months ended September 30, 2023 was driven primarily by the overall decline in COVID-19 testing revenue, partially offset by an increase in direct costs and expenses associated with increased lung diagnostic and services testing volume.

Research and development

Research and development expenses decreased $1.0 million or 35%, and decreased $1.4 million or 15% for the three and nine months ended September 30, 2023, respectively, compared to the same periods in 2022. The decrease in costs for both the three and nine months ended September 30, 2023 was due primarily to a decrease in internal expenses associated with compensation and benefit costs and other external costs associated with contracted services and laboratory costs.

The following table summarizes our external and internal costs for the three and nine months ended September 30, 2023 and 2022 (in thousands, except percentages):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2023	2022	$	%	2023	2022	$	%
External expenses:								
Clinical trials and associated costs	$ 393	$ 433	$ (40)	(9)%	$ 1,609	$ 1,641	$ (32)	(2)%
Other external costs	563	846	(283)	(33)%	2,230	2,685	(455)	(17)%
Total external costs	956	1,279	(323)	(25)%	3,839	4,326	(487)	(11)%
Internal expenses	982	1,691	(709)	(42)%	4,260	5,211	(951)	(18)%
Total research and development expenses	$ 1,938	$ 2,970	$ (1,032)	(35)%	$ 8,099	$ 9,537	$ (1,438)	(15)%

Sales, marketing, general and administrative

Sales, marketing, general and administrative expenses increased $0.4 million or 3%, and increased $6.3 million or 14% for the three and nine months ended September 30, 2023, respectively, compared to the same periods in 2022. The increase for the three and nine months ended September 30, 2023 was driven primarily by increases in employee compensation and benefits associated with an increase in sales team headcount and variable compensation as well as increases in non-employee costs associated with increased spending on various sales meetings, training, and campaigns during 2023 as compared to 2022. During the nine months ended September 30, 2022 the Company’s sales efforts continued to be impacted by the COVID-19 pandemic due to surges associated with multiple variants, restricting and delaying the Company's ability to execute our lung diagnostic sales strategy, resulting in lower sales and marketing costs in the first half of 2022.

Non-operating Expenses

Interest expense

Interest expense decreased $0.7 million or 21%, and increased $1.7 million or 31% for the three and nine months ended September 30, 2023, respectively, compared to the same periods in 2022. The interest expense for the three months ended September 30, 2023 is primarily related to the Perceptive Term Loan Facility of $1.4 million and interest associated with the contingent consideration of $1.0 million. The interest expense for the three months ended September 30, 2022, is associated with the contingent consideration of $1.3 million as well as the 2021 Term Loan with Silicon Valley Bank of $0.9 million and securities purchase agreement with Streeterville Capital, LLC of $0.8 million, both of which were refinanced by the Perceptive Term Loan Facility.

The interest expense for the nine months ended September 30, 2023 is primarily related to interest associated with the Perceptive Term Loan Facility of $3.9 million and interest associated with the contingent consideration of $3.1 million. The interest expense for the nine months ended September 30, 2022 is primarily related to interest associated with is associated with the contingent consideration of $2.3 million as well as the 2021 Term Loan with Silicon Valley Bank of $1.8 million and securities purchase agreement with Streeterville Capital, LLC of $1.4 million in 2022.

Loss on extinguishment of liabilities, net

On April 7, 2022, the Company entered into Amendment No. 3 to the Indi APA in which all parties agreed to restructure the milestone payments. During the three months ended June 30, 2022, the Company evaluated Amendment No. 3 to the Indi APA in accordance with applicable accounting standards under U.S. GAAP which resulted in the extinguishment of the original instrument due to the substantially different terms. As a result, during the nine months ended September 30, 2022, we recorded a loss on the extinguishment of $3.0 million.

Change in fair value of warrant liability, net

On November 21, 2022, as consideration for the Perceptive Term Loan, the Company issued the Perceptive Warrant, with warrants exercisable into 3,000,000 shares of the Company's common stock issued on the funding date of the Tranche A Loan which are equity classified (the Initial Warrants). In addition to the Initial Warrants and to the extent the Company has the ability to exercise its right to borrow the remaining availability under the Perceptive Term Loan, additional warrants will become exercisable into 1,000,000 shares of common stock concurrently with the borrowing of the Tranche B Loan, and additional warrants will become exercisable into 1,000,000 shares of common stock concurrently with the borrowing of the Tranche C Loan (together, the Additional Warrants). The Company accounts for the Additional Warrants as liabilities as the Additional Warrants do not meet the criteria for equity classification. During the three and nine months ended September 30, 2023, the Company recorded a $1.4 million and $1.3 million net loss, respectively, as a change in fair value through the condensed statement of operations due to changes in unobservable inputs. This is a result of changes in the probability of our ability to draw on Tranche B and C loans.

Liquidity and Capital Resources

We are an emerging growth company and, as such, have yet to generate positive cash flows from operations. We have funded our operations to date principally from net proceeds from the sale of our common stock, the sale of convertible preferred stock, revenue from diagnostic testing and services, and the incurrence of indebtedness.

As a result of the pandemic, the Company diversified its diagnostic testing beyond lung diagnostic testing to include the critical service of COVID-19 diagnostic testing. Beginning in the third quarter 2020, the Company's COVID-19 testing services began to experience rapid growth with a peak in the first quarter 2021; however, subsequent to this peak, we experienced a rapid decline in COVID-19 testing revenue primarily as a result of a few significant contracts that expired as well as the ongoing increase in COVID-19 vaccination rates across the U.S. and the adoption and availability of at-home testing. On January 30, 2023, the White House issued a Statement of Administration Policy announcing the President's intention to allow the Public Health Emergency declaration under Section 319 to expire on May 11, 2023. In connection with the expiration of the Public Health Emergency declaration under Section 319, the Company no longer provides commercial COVID-19 diagnostic testing services. In addition, the COVID-19 pandemic negatively affected our lung diagnostic testing-related revenue and our clinical studies. We began to see recovery during the fourth quarter 2020 in our core lung diagnostic testing as our delivered tests exceeded first quarter 2020 delivered tests and have continued to grow thereafter. The Company's sales efforts were impacted by the COVID-19 pandemic due to surges associated with variants, which negatively affected the growth rate of our core lung diagnostic testing-related revenue and our clinical studies. While we have seen recovery in delivered tests in lung diagnostic testing as health care practitioners, including pulmonologists, increasingly returned to pre-pandemic related care, we experienced more variability as compared to pre-pandemic levels as physician practices are adjusting to post-pandemic levels of care. As a result, the items identified above have had an adverse effect on our revenue, results of operations and cash flows.

On March 7, 2022 (the LPC Effective Date), we entered into a purchase agreement with Lincoln Park (the Purchase Agreement), pursuant to which Lincoln Park has committed to purchase up to $50.0 million of our common stock (the LPC Facility). Under the terms and subject to the conditions of the Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $50.0 million of our common stock. Such sales of common stock by us, if any, will be subject to certain limitations, and may occur from time to time, at our sole discretion, over the 36-month period commencing on the LPC Effective Date. As consideration for Lincoln Park's irrevocable commitment to purchase our common stock upon the terms of and subject to satisfaction of the conditions set forth in the purchase agreement, on the LPC Effective Date, we issued 184,275 shares of common stock to Lincoln Park as a commitment fee valued at $600,000 for which no consideration was received.

On April 7, 2022, we entered into subscription agreements with a consortium of investors, including three members of our Board of Directors and other existing shareholders of the Company, for the issuance and sale by the Company of an aggregate of 6,508,376 shares of our common stock in an offering for an aggregate purchase price of approximately $11.7 million.

The Company amended the Indi APA agreement in April 2022 in which all parties agreed to restructure the Milestone Payments whereby the Company will make five quarterly installments of $2.0 million each beginning in April 2022, three quarterly installments of $3.0 million beginning in July 2023, one installment of $5.0 million in April 2024, and one installment of approximately $8.4 million in July 2024. In addition, the Company agreed to an exit fee of approximately $6.1 million in October 2024. Interest shall accrue on the difference between the payment schedule as agreed in the August 2021 amendment and the April 2022 amended payment schedule, at an aggregate per annum rate equal to 10%, with such interest to be payable quarterly on the following installment payment date. Our

ability to make these payments is subject to ongoing compliance under the Perceptive Term Loan and commencing January 1, 2024, consent from Perceptive.

On May 9, 2022, the Company entered into a securities purchase agreement with Streeterville, pursuant to which, among other things, Streeterville: (i) purchased Promissory Note One in the aggregate principal amount totaling $16.0 million in exchange for $15.0 million less certain expenses. Promissory Notes One could, at the Company's option, be settled in cash or shares of common stock of the Company, upon the terms and subject to the limitations and conditions. On May 9, 2022, the Company closed on Promissory Note One for gross proceeds of $15.0 million (approximately $12.8 million, net, after deducting debt issuance costs and OID).

On November 21, 2022, the Company funded and/or closed various financing transactions, including: (i) a term loan facility for up to $50.0 million, with funding of $30.0 million and the issuance of warrants exercisable into 3,000,000 shares of the Company’s common stock occurring on November 21, 2022, and two additional contingently issuable tranches of $10.0 million each subject to certain terms and conditions, including revenue milestones, (ii) a follow-on equity offering of common stock and (iii) a subscription agreement for the issuance of common stock to certain members of the Company’s management team. Collectively, the Company raised gross proceeds of approximately $70.7 million ($65.7 million after deducting commissions, fees and expenses payable). Approximately $23.9 million of the net proceeds were used to retire outstanding debt of the Company and the remaining proceeds of approximately $42.0 million will be used for commercial expansion of sales, supporting the Company’s product pipeline, research and development and for general corporate purposes.

On April 7, 2023, the Company entered into a limited waiver under which the Lender agreed to waive the minimum revenue requirement for the three months ended March 31, 2023 (Limited Waiver). In addition, on May 10, 2023, the Company entered into the First Amendment to the Credit Agreement (First Amendment) with Perceptive as lender and administrative agent and the Company, as borrower, whereby subject to the terms and conditions of the First Amendment, the Minimum Net Revenue Covenant, as defined in the Credit Agreement, was modified to reduce the threshold through the twelve month period ended March 31, 2024.

On August 3, 2023, the Company entered into subscription agreements (the Subscription Agreements) with all of the members of our Board of Directors, all Section 16 officers, and additional members of the Biodesix leadership team for the issuance and sale by the Company of an aggregate of 16,975,298 of the Company’s common stock for an aggregate purchase price of approximately $27.5 million. During the three months ended September 30, 2023, the Company received $15.3 million in proceeds and issued 9,454,927 shares of common stock. On September 27, 2023, the Company entered into an amendment to delay final closing on one subscription agreement. The remaining $12.2 million in proceeds will be received and 7,520,371 shares of common stock will be issued during the three months ended December 31, 2023.

On August 4, 2023 (the Second Amendment Effective Date), the Company entered into the Second Amendment to the Credit Agreement and Guaranty (the Second Amendment) with Perceptive as lender and administrative agent and the Company, as borrower, whereby subject to the terms and conditions of the Second Amendment, the Minimum Net Revenue Covenant (as defined in the Credit Agreement) was amended to reduce the relevant threshold as of the last day of each fiscal quarter commencing on the fiscal quarter ending June 30, 2024 through and including the fiscal quarter ending December 31, 2025.

Pursuant to the original terms of the Credit Agreement and Guaranty entered into on November 21, 2022, the Perceptive Term Loan Facility includes an additional Tranche B Loan, in an aggregate amount of up to $10.0 million, which is accessible by the Company so long as the Company satisfies certain customary conditions precedent, including revenue milestones. Under the terms of the Second Amendment, the conditions precedent for drawing on the Tranche B Loan were amended to (i) reduce the trailing-twelve month revenue milestone and (ii) add the receipt of aggregate cash proceeds of at least $27.5 million from an equity offering of the Company's common stock. During the three months ended September 30, 2023, the Company met the amended trailing-twelve month revenue milestone associated with the Tranche B Loan.

As of September 30, 2023, the Company had remaining available capacity for share issuances of approximately $29.5 million under the ATM facility and up to $46.9 million under the LPC Facility, each subject to the restrictions and limitations of the underlying facilities, as well as volume limitations under applicable SEC rules and regulations that limit their availability as sources of funding.

As of September 30, 2023, we maintained cash and cash equivalents of $19.8 million and we have $30.0 million in outstanding aggregate principal amount on our Perceptive Term Loan. We have incurred significant losses since inception and, as a result, we have funded our operations to date primarily through the sale of common stock, the sale of convertible preferred stock, the issuance of notes payable, and from our two primary revenue sources: (i) diagnostic testing, which includes lung diagnostic testing and, prior to May 11, 2023, COVID-19 testing, and (ii) providing biopharmaceutical companies with development and testing services and licensing our technologies. In accordance with Accounting Standards Update 2014-15 (ASC Topic 205-40), *Presentation of Financial Statements - Going Concern: Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern*, the Company is required to evaluate whether there is substantial doubt about its ability to continue as a going concern each reporting period, including interim periods. In evaluating the Company’s ability to continue as a going concern, management projected its cash flow sources and evaluated the conditions and events that could raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that these financial statements were issued. Management considered the Company’s current projections of future cash

flows, current financial condition, sources of liquidity and debt obligations for at least one year from the date of issuance of this Form 10-Q in considering whether it has the ability to meet its obligations.

Our ability to meet our obligations as they come due may be impacted by our ability to remain compliant with financial covenants in our loan agreement or to obtain waivers or amendments that impact the related covenants. As of September 30, 2023, the Company was in compliance with all restrictive and financial covenants associated with its borrowings.

Based on our current operating plan, unless we continue to raise additional capital (debt or equity) and meet certain agreed upon revenue covenants, or obtain waivers from complying with such financial covenants, we expect that we will be unable to maintain our financial covenants under our existing loan agreement during the next twelve months, which could result in an Event of Default, as defined in the Perceptive Term Loan Facility, causing an acceleration of the outstanding balances. We have taken steps to improve our liquidity through raising debt and equity capital and have also undertaken several proactive measures including, among other things, the reduction of planned capital expenditures and certain operating expenses but we do not expect that these actions alone will be sufficient to maintain our financial covenants.

To maintain an adequate amount of available liquidity and execute our current operating plan, we will need to continue to raise additional funds from external sources, such as through the issuance of equity or debt securities and any such financing activities are subject to market conditions. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. There can be no assurance that additional capital will be available to us or, if available, will be available in sufficient amounts or on terms acceptable to us or on a timely basis. If adequate capital resources are not available on a timely basis, we intend to consider limiting our operations substantially. This limitation of operations could include a hiring freeze, reductions in our workforce, reduction in cash compensation, deferring capital expenditures, and reducing other operating costs.

We expect to continue to incur operating losses in the near term while we make investments to support our anticipated growth. Our current operating plan, which is in part determined based on our most recent historical actual results and trends, along with the items noted above, raises substantial doubt about the Company's ability to continue as a going concern for a period beyond one year from when the September 30, 2023 financial statements are issued. Our unaudited financial statements have been prepared assuming we will continue as a going concern and do not include any adjustments that might be necessary should we be unable to continue as a going concern.

Cash Flows

The following summarizes our cash flows for the periods indicated (in thousands):

	Nine Months Ended September 30,	
	2023	**2022**
Net cash flows (used in) provided by:		
Operating activities	$ (10,587)	$ (33,024)
Investing activities	(20,061)	(1,547)
Financing activities	7,401	17,034
Net decrease in cash and cash equivalents and restricted cash	$ (23,247)	$ (17,537)

Our cash flows resulted in a net decrease in cash and cash equivalents and restricted cash of $23.2 million during the nine months ended September 30, 2023 as compared to the net decrease in cash of $17.5 million for the nine months ended September 30, 2022. For the nine months ended September 30, 2023, net cash used in operating activities totaled $10.6 million, a decrease of approximately $22.4 million compared to the same period in 2022 primarily due to the $18.3 million in tenant improvement allowances received for capital expenditures and leasehold improvements related to the CVP Lease which have been reimbursed from the CVP landlord (see cash used in investing activities below). Subsequent to the use of the tenant improvement allowance, the CVP Lease will result in a negative cash flow within operations due to normal rental payments. Additionally, the Company had favorable changes in working capital that contributed to the improvement in net cash used in operating activities compared to the same period in 2022. During the nine months ended September 30, 2022, our $5.0 million cash collateralized letter of credit under the operating lease agreement with CVP was released and the funds were subsequently transferred to the landlord as a refundable deposit to secure the performance of the Company's obligations.

Net cash used in investing activities during the nine months ended September 30, 2023 totaled $20.1 million, an increase of $18.5 million compared to the same period in 2022. The increase in net cash used in investing activities was primarily due to increases in purchases of property and equipment and capital expenditures for leasehold improvements related to the CVP Lease. These leasehold improvements are tenant improvements and have been reimbursed from the Landlord, as described above in net cash used in operating activities.

Net cash provided by financing activities during the nine months ended September 30, 2023 totaled $7.4 million, a decrease of $9.6 million compared to the same period in 2022. The net cash provided by financing activities for the nine months ended September 30, 2023 primarily resulted from $15.3 million net proceeds from the issuance of common stock from the Subscription Agreements, partially offset by milestone payments to Indi of $7.6 million and payments of debt issuance costs of $0.8 million. The net cash provided by financing activities for the nine months ended September 30, 2022 primarily resulted from $18.0 million net proceeds from the issuance of common stock from the November 2022 follow-on equity offering and subscription agreements, $12.8 million net proceeds from the issuance of Promissory Note One, partially offset by the milestone payments to Indi of $8.7 million and partial repayment of the 2021 Term Loan of $5.0 million.

Contractual Obligations and Commitments

The following table summarizes our non-cancelable contractual obligations and commitments, including finance lease obligations entered into during the nine months ended September 30, 2023 (in thousands):

	Payments due by period [1]				
	Total	Less than 1 year	1 to 3 years	4 to 5 years	More than 5 years
Borrowings and interest [2]	$ 48,265	$ 4,426	$ 8,755	$ 35,084	$ —
Contingent consideration	26,887	20,812	6,075	—	—
Operating lease obligations	47,980	2,706	7,948	8,170	29,156
Finance lease obligations	858	356	502	—	—
Total	$ 123,990	$ 28,300	$ 23,280	$ 43,254	$ 29,156

(1) Royalty payments that we may owe are not included as the amount and timing of such payments is uncertain.

(2) Includes the Perceptive Term Loan payments of principal and interest. Interest amounts associated with the Perceptive Term Loan are variable and estimated based on the interest rate in effect on September 30, 2023.

There have been no other significant changes to our future contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022.

Off-Balance Sheet Arrangements

As of September 30, 2023, we have not entered into any off-balance sheet arrangements.

Critical Accounting Policies and Significant Judgments and Estimates

In accordance with accounting principles generally accepted in the United States, we are required to make estimates and assumptions that affect the amounts reported in the condensed financial statements and accompanying notes. Certain of these estimates significantly influence the portrayal of our financial condition and results of operations and require us to make difficult, subjective or complex judgments. Our critical accounting policies are described in greater detail below and in Note 2 to our condensed financial statements in Part 1 of this Quarterly Report on Form 10-Q as well as Part II, Item 8 of our Annual Report on Form 10-K for the year ended December 31, 2022, which was filed on March 6, 2023.

Revenue Recognition

We recognize revenue when our customers obtain control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for our goods or services. To determine revenue recognition for our arrangements with our customers, we perform a five-step process, which includes: (i) identifying the contract(s) with a customer; (ii) identifying the performance obligations in the contract; (iii) determining the transaction price; (iv) allocating the transaction price to the performance obligations in the contract; and (v) recognizing revenue when (or as) we satisfy our performance obligations. The Company generates revenues from (i) diagnostic tests and (ii) assay development, testing services, and licensing our technologies (Services and other revenue).

The Company recognizes revenues related to blood-based lung diagnostic billings based on estimates of the amounts ultimately expected to be collected from customers on a portfolio approach. In determining the amount to accrue for a delivered test, the Company considers factors such as test type, payment history, payer coverage, whether there is a reimbursement contract between the payer and the Company, payment as a percentage of agreed upon rate (if applicable), amount paid per test and any current developments or changes that could impact reimbursement. Variable consideration, if any, is estimated based on an analysis of historical experience and adjusted as better estimates become available. These estimates require significant judgment by management.

The Company also provides services to patients with whom the Company does not have contracts as defined in Financial Accounting Standards Board (FASB) Accounting Standards Codification 606 (ASC 606). The Company recognizes revenue for these patients when contracts, as defined in ASC 606, are established at the amount of consideration to which it expects to be entitled, or when the Company receives substantially all of the consideration subsequent to satisfaction and delivery of the performance obligations.

In addition, other revenue includes amounts derived from licensing our digital sequencing technologies to our international laboratory partners. We are compensated through royalty-based payments for the licensed technology, and depending on the nature of the technology licensing arrangements and considering factors including but not limited to enforceable right to payment and payment terms, and if an asset with alternative use is created, these revenues are recognized in the period when royalty-bearing sales occur.

Share-based Compensation and Grant Date Fair Value

Share-based compensation related to stock options granted to our employees, directors and non-employees is measured at the grant date based on the fair value of the award. For our service-based awards, the fair value of each award is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards. Compensation expense for share-based awards with performance conditions is recognized based upon the probability the performance conditions will be met as defined in the grant. Restricted stock units are measured at their grant date fair value using the closing price of our common stock on the date of grant and recognized to expense on a straight-line basis over the vesting period of each award. We estimate forfeitures and adjust these estimates to actual forfeitures as they occur.

We use the Black-Scholes option-pricing model to estimate the fair value of our share-based option awards, which requires assumptions to be made related to expected term of an award, expected volatility, the risk-free rate and expected dividend yield. The fair value of our common stock is based on our closing price as reported on the date of grant on the primary stock exchange on which our common stock is traded. Changes in these subjective assumptions can materially affect the estimated value of equity grants and the share-based compensation that we record in our financial statements.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments* (ASC Topic 326). This ASU requires measurement and recognition of expected credit losses for financial assets. This ASU requires measurement and recognition of expected credit losses for financial assets. This guidance became effective for the Company beginning January 1, 2023. The Company evaluated the guidance and determined the overall impact of the adoption had an immaterial impact on our financial statements.

Implications of Being an Emerging Growth Company and Smaller Reporting Company

We are an “emerging growth company” within the meaning of the Jumpstart Our Business Startups Act (JOBS Act). As an emerging growth company, we may take advantage of certain exemptions from various public company reporting requirements, including the requirement that our internal control over financial reporting be audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”), certain requirements related to the disclosure of executive compensation in our periodic reports and proxy statements, the requirement that we hold a nonbinding advisory vote on executive compensation and any golden parachute payments. We may take advantage of these exemptions until we are no longer an emerging growth company. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of our financials to those of other public companies more difficult.

We will remain an emerging growth company until the earliest to occur of (i) the last day of the fiscal year in which we have more than $1.24 billion in annual revenue; (ii) the date we qualify as a “large accelerated filer,” with at least $700 million of equity securities held by non-affiliates; (iii) the date on which we have issued, in any three-year period, more than $1.0 billion in non-convertible debt securities; and (iv) until December 31, 2025 (the year ended December 31st following the fifth anniversary of our initial public offering).

Additionally, we are a “smaller reporting company” as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which: (i) the market value of our common shares held by non-affiliates exceeds $250 million as of the end of that year’s second fiscal quarter, or (ii) our annual revenues exceeded $100 million during such completed fiscal year and the market value of our common shares held by non-affiliates exceeds $700 million as of the end of that year’s second fiscal quarter.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates.

Interest Rate Risk

We are exposed to market risk for changes in interest rates related primarily to our cash and cash equivalents, marketable securities and our indebtedness, including our outstanding Perceptive Term Loan. As of September 30, 2023, we had $30.0 million outstanding on the Perceptive Term Loan Facility which has an annual rate equal to the greater of (a) forward-looking one-month term SOFR as posted by CME Group Inc. and (b) 3.0% per annum, plus an applicable margin of 9.0%. Historically, we have not entered into derivative agreements such as interest rate caps and swaps to manage our floating interest rate exposure.

Periodically throughout the year, we have maintained balances in various operating accounts in excess of federally insured limits. Our cash and cash equivalents are funds held in checking and bank savings accounts, primarily at one U.S. financial institution. We consider all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. We continually monitor our positions with, and the credit quality of, the financial institutions with which we invest.

As of September 30, 2023, a hypothetical 100 basis point increase in interest rates would have an estimated $0.3 million impact per year on our financial position and results of operations, based on the current Perceptive Term Loan principal remaining outstanding through maturity.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, or Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures 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.

Based on their evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

There were no changes to our internal control over financial reporting during the three months ended September 30, 2023 that have materially affected, or are reasonable likely to materially effect, our internal controls over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings or investigations which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition, or cash flows.

Item 1A. Risk Factors.

"Item 1A. Risk Factors" of our Annual Report on Form 10-K as of and for the year ended December 31, 2022, filed March 6, 2023, and subsequent quarterly reports on Form 10-Q, if applicable, include a discussion of our risk factors. The information presented below updates, and should be read in conjunction with, the risk factors and information we previously disclosed and, except as presented below, there have been no material changes from the risk factors described in our Annual Report on Form 10-K and subsequent quarterly reports on Form 10-Q. These risks could materially and adversely affect our business, financial condition and results of operations.

FDA may end its general policy of enforcement discretion and regulate laboratory developed tests as medical devices.

On September 29, 2023, the Food and Drug Administration (FDA) announced a proposed rule to amend its regulations to explicitly regulate laboratory developed tests (LDTs) as in vitro diagnostic (IVD) tests in accordance with the agency's regulatory authority over medical devices. If this rule is finalized, our tests that are currently offered as LDTs would become subject to statutory and regulatory provisions that are applicable to medical devices, including but not limited to, medical device reporting and correction and removal reporting requirements, quality systems regulations, registration and listing requirements, and premarket review requirements. Failure to comply with applicable requirements under the relevant timeframes could cause us to lose the ability to perform our tests, experience disruptions to our business, or become subject to administrative or judicial enforcement actions, which in turn may have an adverse impact on our business, financial condition, and results of operations. For more information regarding these risks, see Item 1A "Risk Factors" of Part I of our Annual Report on Form 10-K for the year ended December 31, 2022, which was filed on March 6, 2023, under the heading "—Risks Related to our Governmental Regulation—*Our current line of diagnostic tests is covered under CLIA and CMS, however, changes in the way that the FDA regulates tests performed by laboratories like ours could result in delay or additional expense in offering our tests and tests that we may develop in the future. In addition, our COVID testing program and select partnerships we may enter into may cause us to be subject to additional FDA requirements.*"

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

On August 3, 2023, the Company entered into subscription agreements (the Subscription Agreements) with all of the members of our Board of Directors, all Section 16 officers, and additional members of the Biodesix leadership team (together, the Investors) for the issuance and sale by the Company of an aggregate of 16,975,298 of the Company's common stock (the Shares) in a private equity offering (the Private Placement). The Subscription Agreements did not include any registration rights.

Pursuant to the Subscription Agreements, the Investors purchased shares at a purchase price (determined in accordance with Nasdaq rules relating to the "Minimum Value" of the Company's common stock) of $1.62 per share, which is equal to the closing price of the Company's common stock on August 3, 2023, for an aggregate purchase price of approximately $27.5 million. The Subscription Agreements include customary representations, warranties and covenants by the parties to the agreements. During the three months ended September 30, 2023, the Company received $15.3 million in proceeds and issued 9,454,927 shares of common stock. On September 27, 2023, the Company entered into an amendment to delay final closing on one subscription agreement. The remaining $12.2 million in proceeds will be received and 7,520,371 shares of common stock will be issued during the three months ended December 31, 2023. The Company intends to use the proceeds for the commercial expansion of sales, research and development, and for general corporate purposes.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None of our directors or officers adopted, modified, or terminated a Rule 10b5-1 trading arrangement during the quarter ended September 30, 2023.

Item 6. Exhibits.

Exhibit Number	Description
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal 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 Principal 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 Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** Furnished herewith.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Biodesix, Inc.

Date: November 7, 2023

By: /s/ CHRISTOPHER C. VAZQUEZ

Christopher C. Vazquez
Chief Accounting Officer
(Principal Accounting Officer)

Exhibit 31.1

SECTION 302 CERTIFICATION

I, Scott Hutton, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Biodesix, 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(s) 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 annual 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(s) 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: November 7, 2023

By: /s/ Scott Hutton

Scott Hutton

Chief Executive Officer

Exhibit 31.2

SECTION 302 CERTIFICATION

I, Robin Harper Cowie, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Biodesix, 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(s) 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 annual 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(s) 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: November 7, 2023

By: /s/ Robin Harper Cowie

Robin Harper Cowie

Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Biodesix, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2023 By: /s/ Scott Hutton

Scott Hutton
Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Biodesix, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2023 By: /s/ Robin Harper Cowie

Robin Harper Cowie
Chief Financial Officer