UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 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 June 30, 2022

OR

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

For the transition period from to

Commission File Number: 001-39659

BIODESIX, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware (State or other jurisdiction of incorporation or organization)

2970 Wilderness Place, Suite 100 Boulder, Colorado 80301 (Address of principal executive offices) 20-3986492 (I.R.S. Employer Identification No.)

> 80301 (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 Common Stock, par value \$0.001 per share Trading Symbol(s) BDSX

Name of each exchange on which registered 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 \boxtimes No \square

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	\boxtimes
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 August 1, 2022, the registrant had 39,982,048 shares of common stock, \$0.001 par value per share, outstanding.

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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 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, 2021, which was filed on March 14, 2022. 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, 2021, regarding, among other things:

- the impact of a pandemic, epidemic, or outbreak of an infectious disease in the United States or worldwide, including the continuing spread of COVID-19 (including notable and severe mutations of the virus) may have a material adverse effect on our operations, our ability to generate revenues and income, and our ability to maintain compliance with our debt covenants and, under certain circumstances, remain a going concern;
- 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;
- the demand for our Biodesix WorkSafe[™] testing program and our ability to meet such demand;
- 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;
- natural or man-made disasters and other similar events, including the COVID-19 pandemic, 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;

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- 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.

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PART I—FINANCIAL INFORMATION

BIODESIX, INC.

Condensed Balance Sheets (in thousands, except share data)

	Ju	ne 30, 2022	December 31, 2021		
Assets					
Current assets					
Cash and cash equivalents	\$	23,586	\$	32,712	
Accounts receivable, net of allowance for doubtful accounts of \$52 and \$158		5,452		3,656	
Other current assets		6,019		7,245	
Total current assets		35,057		43,613	
Non-current assets					
Restricted cash		5,000		—	
Property and equipment, net		3,950		4,179	
Intangible assets, net		10,688		11,617	
Operating lease right-of-use assets		3,952		—	
Goodwill		15,031		15,031	
Other long-term assets		1,551		1,657	
Total non-current assets		40,172		32,484	
Total assets	\$	75,229	\$	76,097	
Liabilities and Stockholders' Equity					
Current liabilities					
Accounts payable	\$	1,791	\$	1,662	
Accrued liabilities		6,667	•	7,665	
Deferred revenue		2,230		1,850	
Current portion of operating lease liabilities		1,315		_	
Current portion of contingent consideration		8,151		17,764	
Current portion of notes payable		11,771		19	
Other current liabilities		1,149		—	
Total current liabilities		33,074		28,960	
Non-current liabilities					
Long-term notes payable, net of current portion		8,596		9,993	
Long-term operating lease liabilities		2,902		_	
Contingent consideration		22,916		16,028	
Other long-term liabilities		70		1,389	
Total non-current liabilities		34,484		27,410	
Total liabilities		67,558		56,370	
Commitments and contingencies					
Stockholders' equity					
Preferred stock, \$0.001 par value, 5,000,000 shares authorized; 0 (2022 and 2021) shares issued and outstanding		_		_	
Common stock, \$0.001 par value, 200,000,000 shares authorized; 39,978,844 (2022) and 30,789,649 (2021) shares issued and outstanding		40		31	
Additional paid-in capital		341.014		321,669	
Accumulated deficit		(333,383)		(301,973)	
Total stockholders' equity		7,671		19,727	
Total liabilities and stockholders' equity	\$	75,229	\$	76,097	
	Ψ	70,220	Ψ	70,037	

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

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

	Th	Three Months Ended June 30,			Six Months Ended Jun			d June 30,
		2022		2021		2022		2021
Revenues	\$	10,950	\$	11,885	\$	17,498	\$	40,751
Operating expenses:								
Direct costs and expenses		3,980		7,085		7,215		25,303
Research and development		3,361		3,323		6,567		6,644
Sales, marketing, general and administrative		15,235		11,425		29,722		23,352
Change in fair value of contingent consideration		—		639		_		1,622
Impairment loss on intangible assets						81		
Total operating expenses		22,576		22,472		43,585		56,921
Loss from operations		(11,626)		(10,587)		(26,087)		(16,170)
Other (expense) income:								
Interest expense		(1,346)		(815)		(2,483)		(1,466)
Loss on extinguishment of liabilities		(2,952)				(2,952)		(728)
Other income, net		100				112		1
Total other expense		(4,198)		(815)		(5,323)		(2,193)
Net loss	\$	(15,824)	\$	(11,402)	\$	(31,410)	\$	(18,363)
Net loss per share, basic and diluted	\$	(0.40)	\$	(0.41)	\$	(0.89)	\$	(0.68)
Weighted-average shares outstanding, basic and diluted		39,239		27,730		35,177		27,020

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

Condensed Statements of Stockholders' Equity (in thousands)

	Common Stock			L	Additional Paid-In Accumulated			Total Stockholders'	
	Shares		Amount		Capital		Deficit		Equity
Balance - December 31, 2021	30,790	\$	31	\$	321,669	\$	(301,973)	\$	19,727
Issuance of common stock under employee stock purchase plan	99				202				202
Issuance of common stock for deferred offering									
costs	184		—		600		—		600
Issuance of common stock, net	709		1		1,416				1,417
Exercise of stock options	107				75				75
Stock-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				_		_		
Stock-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

	Common Stock			Additional Paid-In Accumulated				Total Stockholders'	
	Shares	hares Amount			Capital		Deficit		Equity
Balance - December 31, 2020	26,562	\$	27	\$	299,953	\$	(258,814)	\$	41,166
Exercise of stock options	223				475		—		475
Stock-based compensation	—		—		1,752		—		1,752
Net loss							(6,961)		(6,961)
Balance - March 31, 2021	26,785		27		302,180		(265,775)		36,432
Exercise of stock options	164				204		—		204
Stock-based compensation	—		—		539		—		539
Net loss							(11,402)		(11,402)
Balance - June 30, 2021	26,949	\$	27	\$	302,923	\$	(277,177)	\$	25,773

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

Condensed Statements of Cash Flows (in thousands)

(in thousands)		
	 Six Months Ended	
	 2022	2021
Cash flows from operating activities		
Net loss	\$ (31,410) \$	(18,363)
Adjustments to reconcile net loss to net cash, cash equivalents, and restricted cash used in operating activities		
Depreciation and amortization	1,806	1,523
Amortization of lease right-of-use assets	728	
Loss on extinguishment of liabilities	2,952	728
Stock-based compensation expense	2,714	2,291
Change in contingent consideration	—	1,622
Provision for doubtful accounts	(39)	193
Accrued interest, amortization of debt issuance costs and other	2,174	502
Inventory excess and obsolescence	535	_
Impairment loss on intangible assets	81	_
Changes in operating assets and liabilities:		
Accounts receivable	(1,757)	9,830
Other current assets	690	1,794
Other long-term assets	933	447
Accounts payable and other accrued liabilities	(1,195)	(9,453)
Deferred revenue	(392)	(1,350)
Current and long-term operating lease liabilities	(513)	—
Net cash, cash equivalents, and restricted cash used in operating activities	 (22,693)	(10,236)
Cash flows from investing activities		
Purchases of property and equipment	(591)	(747)
Patent costs and intangible asset acquisition, net	 (141)	(117)
Net cash, cash equivalents, and restricted cash used in investing activities	(732)	(864)
Cash flows from financing activities		
Proceeds from the issuance of common stock	16,135	_
Proceeds from issuance of common stock under employee stock purchase plan	202	_
Proceeds from exercise of stock options	92	679
Payment of contingent consideration	(6,625)	_
Proceeds from term loan and notes payable	15,102	30,078
Repayment of term loan and notes payable	(3,025)	(25,419)
Payment of debt issuance costs	(2,115)	(109)
Deferred offering costs	(129)	_
Equity financing costs	(323)	
Other	 (15)	
Net cash, cash equivalents, and restricted cash provided by financing activities	 19,299	5,229
Net decrease in cash, cash equivalents, and restricted cash	(4,126)	(5,871)
Cash, cash equivalents, and restricted cash - beginning of period	32,798	62,306
Cash, cash equivalents, and restricted cash - end of period	\$ 28,672 \$	56,435

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

Statements of Cash Flows (in thousands)

(Continued from the previous page)

Supplemental cash flow information:

	5	Six Months Ende	ed June 30,
	20	022	2021
Common stock issued for deferred offering costs	\$	600 \$	_
Deferred offering costs amortized against Additional paid-in capital		18	—
Original issue discount associated with Promissory Note One		1,025	
Debt issuance costs included in Accrued liabilities		118	—
Equity financing costs included in Accrued liabilities		47	—
Operating lease right-of-use assets obtained in exchange for lease liabilities		4,672	—
Finance lease right-of-use assets obtained in exchange for lease liabilities		123	—
Cash paid for interest		344	720
Cash paid for income taxes			

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

Notes to 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, with laboratories in Colorado and Kansas. The Company conducts all of its operations within a single legal entity. Biodesix is a data-driven 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. 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 performs its blood-based diagnostic tests in its laboratory facilities, which are located in Boulder, Colorado and De Soto, Kansas. In May 2020, the Federal Drug Administration (FDA) granted Emergency Use Authorization (EUA) of the Bio-Rad SARS-CoV-2 Droplet Digital[™] polymerase chain reaction (ddPCR) test to detect Coronavirus Disease 2019 (COVID-19) infection. In April 2020, the FDA authorized the Platelia SARS-CoV-2 Total Ab test to detect COVID-19 antibodies. 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.

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 the 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 new 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 36-hour average turnaround time, providing physicians with timely results to facilitate treatment decisions.
- *GeneStrat NGS™* (*NGS*) test, also marketed as part of our new IQLung testing strategy, our 72-hour average turnaround time blood-based 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, 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 operate and have commercialized the Biodesix WorkSafe testing program, under which the Company offers 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 infection by the SARS-CoV-2 virus.
- Platelia SARS-CoV-2 Total Ab test, which is an antibody test, FDA EUA authorized, 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.



Notes to Condensed Financial Statements

These tests under the Biodesix WorkSafe testing program are utilized by healthcare providers, including hospitals and nursing homes, and are also offered to businesses and educational systems to assist in their back-to-work or back-to-school strategies, a crucial element of restarting economic activity.

In developing the Company's products, the Company has built or gained access to unique biorepositories, proprietary technology, 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 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, 2021. 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, 2021 was derived from the audited financial statements.

As of June 30, 2022, we maintained cash and cash equivalents of \$28.7 million, inclusive of \$5.1 million in restricted cash (see *Restricted Cash* below), and we have \$23.2 million in outstanding aggregate principal amount on our 2021 Term Loan and Promissory Note One. 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 include lung diagnostic testing and COVID-19 testing, and (ii) providing biopharmaceutical companies with development and testing services. 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, including the debt and equity funding and amendments to the 2021 Term Loan and Integrated Diagnostics, Inc. (Indi) Agreement, 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 agreements (see *Note* 6 - Debt) or to obtain waivers or amendments that impact the related covenants. Due to the continued uncertainty caused by the COVID-19 pandemic, significant risks remain with respect to our ability to meet these thresholds and any material adverse effect on our revenues, income and expenses could impact our ability to maintain compliance with these covenants.

Based on our current operating plan, unless we continue to raise additional capital (debt or equity) 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 agreements during the next twelve months, which could result in an Event of Default, as defined, causing an acceleration and repayment of the outstanding balances. We have taken steps to improve our liquidity through raising debt and equity capital during 2022, amendments to our 2021 Term Loan, and have also undertaken several proactive measures to mitigate the financial and operational impacts of the COVID-19 pandemic through 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. During the three months ended June 30, 2022, we entered into a \$25.0 million debt facility with funding for up to \$25.0 million in two tranches. On May 9, 2022, we closed on the first tranche for gross proceeds of \$15.0 million (approximately \$12.8 million, net, after deducting debt issuance costs and original issue discounts (OID)). We also amended the Indi Agreement to delay near term cash requirements and extend the period of milestone payments. 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 flex 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 do raise 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 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



Notes to Condensed Financial Statements

operations could include a hiring freeze, reductions in our workforce, reduction in cash compensation, deferring capital expenditures, and reducing other operating costs.

The Company's revenues, results of operations and cash flows have been materially adversely impacted by the items noted above. 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. 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.

Restricted Cash

Restricted cash consists of the \$5.0 million cash collateralized letter of credit for the benefit of the landlord (lessor) to secure the performance of the Company's obligations under an operating lease agreement with Centennial Valley Properties I, LLC (see *Note* 7 - Leases). In addition, \$0.1 million of deposits related to the Company's corporate credit cards are reported within 'Other current assets' in the balance sheets as of June 30, 2022 and December 31, 2021, respectively.

Concentration of Credit Risk and Other Uncertainties

Substantially all of the Company's cash and cash equivalents are deposited with two major financial institutions 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, it 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 June 30, 2022 and December 31, 2021, see *Note 9 – Revenue and Accounts Receivable Credit Concentration*.

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 balance sheet and was \$1.9 million and \$2.9 million as of June 30, 2022 and December 31, 2021, respectively.

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, 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.

Notes to Condensed Financial Statements

Note 3 - Recently Issued Accounting Standards

Recently adopted accounting standards

In February 2016, the FASB issued Account Standard Update (ASU) No. 2016-2, Leases (ASC 842). This ASU intends to make accounting for leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases accounted for as operating leases. In addition to other related amendments, the FASB issued ASU No. 2018-11, Leases (Topic 842): Targeted Improvements, which offers an additional transition method whereby entities may apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings rather than application of the new leases standard at the beginning of the earliest period presented in the financial statements. The Company elected this transition method and adopted ASC 842 on January 1, 2022 and as a result, recorded operating lease right-of-use (ROU) assets of \$1.3 million, including offsetting deferred rent of \$0.1 million, along with the associated operating lease liabilities of \$1.3 million. On January 1, 2022, the Company did not have any finance leases. The adoption of ASC 842 did not result in a cumulative effect adjustment to beginning retained earnings, and did not materially affect the Company's statement of operations, statement of stockholders' equity or statement of cash flows for the six months ended June 30, 2022.

In addition, the Company elected the following practical expedients permitted under the transition guidance within the new standard:

- 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 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." 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 all of the fair 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 new standard are contained in *Note* 7 — *Leases*.

Standards Being Evaluated

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 will become effective for the Company beginning January 1, 2023 with early adoption permitted. The Company is currently evaluating this guidance and assessing the overall impact on its financial statements.



Notes to Condensed Financial Statements

Note 4 - Fair Value

Recurring Fair Value Measurements

Our borrowing instruments are recorded at their carrying values in the balance sheets, which may differ from their respective fair values. The difference between the carrying value and fair value of outstanding borrowings as of June 30, 2022 is due to the debt issuance costs and OID netted against Promissory Note One entered into with Streeterville Capital, LLC, in May 2022. The carrying value of outstanding borrowings as of December 31, 2021, approximates fair value based on interest rates available at that time for similar borrowings. 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								
		June 30, 2022				December 31, 2021				
	С	Carrying Value		Fair Value Carrying Va		ying Value	Fa	air Value		
Borrowings	\$	20,367	\$	23,317	\$	10,012	\$	10,012		

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 which is accounted for as a liability and remeasured through our statements of operations.

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

Description	June 30, 2022	Decer	nber 31, 2021
Current portion of contingent consideration	\$ 8,151	\$	17,764
Contingent consideration	 22,916	_	16,028
Total contingent consideration	\$ 31,067	\$	33,792

The following table presents the changes in contingent consideration for the six months ended June 30, 2022 and 2021 (in thousands):

	For the six months ended June 30,				
Level 3 Rollforward		2022		2021	
Beginning balances - January 1	\$	33,792	\$	29,932	
Changes in fair value				1,622	
Interest expense		966		289	
Loss on extinguishment of liabilities		2,934			
Payments of contingent consideration		(6,625)			
Ending balances - June 30	\$	31,067	\$	31,843	

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. Under the terms of the original agreement, when the gross margin target was met 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.

The Company met the gross margin target of \$2.0 million for three consecutive months during the three months ended June 30, 2021. The Company entered into an amendment to the original agreement in August 2021 in which all parties agreed to forgo the issuance of common stock and agreed that the Company will 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 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



Notes to Condensed Financial Statements

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 are subject to consent from our lender under the 2021 Term Loan and related amendments (see *Note 6 - Debt*). We have obtained lender consent for contractual payments through the third milestone and interest payment of \$2.1 million paid in July 2022.

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 would result in a significantly higher or lower fair value measurement. During the three months ended June 30, 2022, the Company recorded \$1.1 million in interest expense due to the passage of time and fixed payment schedule, partially offset by a reduction to the contingent consideration balance of \$1.0 million due to an increase in the discount rate to reflect current market and Company specific conditions, resulting in \$0.1 million, net recorded as 'Interest expense' in the statements of operations.

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 three months ended June 30, 2022, we recorded a loss on extinguishment of \$2.9 million in the statements of operations.

Contingent consideration expected to be paid in the next twelve months is recorded in the 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 met is recorded as operating expenses in the statements of operations. Subsequent changes to the contingent consideration following the achievement of the gross margin target are recorded as 'Interest expense' in the statements of operations resulting from the passage of time and fixed payment schedule.

Non-Financial Assets and Liabilities

Our non-financial assets, which primarily consist of property and equipment, goodwill, and other intangible assets, are not required to be carried at fair value on a recurring basis and are reported at carrying value. There were no changes to the valuation methods during the periods presented.

Note 5 – Supplementary Balance Sheet Information

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

	June 30, 2022		Dec	ember 31, 2021
Lab equipment	\$	6,725	\$	6,784
Leasehold improvements		2,365		2,339
Computer equipment		703		700
Furniture and fixtures		341		391
Software		325		600
Vehicles		97		97
Construction in process		411		17
		10,967		10,928
Less: accumulated depreciation		(7,017)		(6,749)
Total property and equipment, net	\$	3,950	\$	4,179

Depreciation expense for the three and six months ended June 30, 2022 was \$0.4 million and \$0.8 million, respectively, compared to \$0.2 million and \$0.5 million for the three and six months ended June 30, 2021, respectively.

Notes to Condensed Financial Statements

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

	June 30, 2022					December 31, 2021						
		Cost		Accumulated Amortization		t Carrying Value	Cost		Accumulated Amortization			Net rrying Value
Intangible assets subject to amortization												
Patents	\$	1,785	\$	(599)	\$	1,186	\$	1,755	\$	(566)	\$	1,189
Purchased technology		16,900		(7,512)		9,388		16,900		(6,572)		10,328
Intangible assets not subject to amortization												
Trademarks		114				114		100		—		100
Total	\$	18,799	\$	(8,111)	\$	10,688	\$	18,755	\$	(7,138)	\$	11,617

Amortization expense related to definite-lived intangible assets was \$0.5 million and \$1.0 million for both the three and six months ended June 30, 2022 and 2021, respectively.

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

	As of	June 30, 2022
Remainder of 2022	\$	986
2023		1,970
2024		1,960
2025		1,954
2026		1,941
2027 and thereafter		1,763
Total	\$	10,574

Accrued liabilities consist of the following (in thousands):

	June 3	30, 2022	December 31, 2021		
Compensation related accruals	\$	3,570	\$	4,029	
Accrued clinical trial expense		908		870	
Other expenses		2,189		2,766	
Total accrued liabilities	\$	6,667	\$	7,665	

Note 6 – Debt

Our long-term debt primarily consists of notes payable associated with Promissory Note One and our 2021 Term Loan which is described in further detail below. Long-term notes payable were as follows (in thousands):

	June 30, 2022			December 31, 2021
Promissory Note One	\$	16,164	\$	
2021 Term Loan		7,000		10,000
Other		153		75
Unamortized debt discount and issuance costs		(2,950)		(63)
		20,367		10,012
Less: current maturities		11,771		19
Long-term notes payable	\$	8,596	\$	9,993

Securities Purchase Agreement

On May 9, 2022 (the First Closing Date), the Company entered into a securities purchase agreement (the SPA) with Streeterville Capital, LLC (Lender), pursuant to which, among other things, the Lender: (i) purchased a secured promissory note (Promissory Note One) in the aggregate principal amount totaling \$16.0 million in exchange for \$15.0 million less certain expenses and (ii) agreed to purchase another secured promissory note at the Company's election (Promissory Note Two and, together with Promissory Note One, the Promissory Notes), subject to certain conditions precedent in aggregate principal amount totaling \$10.3 million in exchange for \$10.0



Notes to Condensed Financial Statements

million in cash proceeds. Each of the Promissory Notes may, at the Company's option, be settled in shares of common stock of the Company (the Common Stock), upon the terms and subject to the limitations and conditions set forth in the Promissory Notes. The Company's net proceeds from the issuance of Promissory Note One were approximately \$12.8 million, after deducting debt issuance costs and original issue discount (OID). The Company intends to use the proceeds from such issuance for general corporate purposes.

The Promissory Notes have a stated interest rate of 6% per annum. The maturity date of each Promissory Note is 24 months from the issuance date of such Note (the Maturity Date). Promissory Note One was issued with an OID of \$1.0 million while Promissory Note Two, if issued, will be subject to an OID of \$0.3 million subject to certain contingencies which could increase the OID by an additional \$0.5 million. The Promissory Notes are eligible for early payment for cash, at the Company's election, subject to a prepayment premium of 10% of the outstanding principal balance.

The Company's ability to draw Promissory Note Two is subject to the satisfaction, among other things, of the following conditions: (i) within nine months following the First Closing Date, repayment in full all outstanding obligations under the 2021 Term Loan, (ii) the Company shall have received no less than \$5.6 million in proceeds from the sale (not attributable to Lender or its affiliates) of newly issued equity securities during the period beginning on the First Closing Date and ending on January 31, 2023 (the Second Closing Date), (iii) on or before the Second Closing Date, the Company shall have met or exceeded Revenue Milestone 1 (as defined in the Promissory Notes), (iv) (a) the aggregate market value of the Company's common stock and any other equity securities held by persons that are not affiliates of the Company on the Second Closing Date shall be greater than or equal to \$75.0 million or (b) received no less than \$20.0 million in additional proceeds from the sale (not attributable to Lender or its affiliates) of new equity securities in the Company not counting those proceeds set forth in item (ii) above (for total proceeds of no less than \$25.6 million during the period beginning on the First Closing Date and ending on the Second Closing Date; (v) as of the Second Closing Date, Company is in good standing with Nasdaq Stock Market (the NASDAQ) and has not received any notice of non-compliance; (vi) Company shall be current in its payments to Indi, and (vii) there being no Trigger Event (as defined in the Promissory Notes) under Promissory Note One. If Promissory Note Two is issued, the terms of Promissory Note One and Note Two will be substantively identical.

Under the SPA, the parties provided customary representations and warranties to each other. Also, until all amounts due under the Promissory Notes are paid in full, the Company agreed, among other things, to: (i) timely make all filings under the Securities Exchange Act of 1934, (ii) ensure that its Common Stock continues to be listed on the NASDAQ or the New York Stock Exchange, (iii) not enter into any agreement or otherwise agree to any covenant, condition, or obligation that locks up, restricts in any way or otherwise prohibits Company: (a) from entering into a variable rate transaction with Lender or any affiliate of Lender, or (b) from issuing Common Stock, preferred stock, warrants, convertible notes, other debt securities, or any other Company securities to Lender or any affiliate of Lender, (iv) will not make any Restricted Issuances (as defined in the Promissory Notes) without Lender's prior written consent, which consent may be granted or withheld in Lender's sole and absolute discretion (v) within 9 months following the First Closing Date, the Company will repay in full all outstanding obligations under the 2021 Term Loan, (vi) beginning on April 1, 2023, Company shall maintain a minimum liquidity balance of at least \$3.0 million (which liquidity balance shall only include cash, cash equivalents and accounts receivable), and (vii) offer the Lender the right to purchase up to 30% of future equity and debt securities offerings, subject to certain exceptions and limitations. The Company also agreed under the SPA to reserve with the Company's transfer agent 37.0 million shares of Common Stock for potential issuance under the Promissory Notes for shares that may be delivered in connection with the redemption right, which reservation may be increased and decreased in certain circumstances.

Beginning on the date that is nine months after the issuance date of the applicable Promissory Note, the Lender has the right to redeem up to \$1.4 million and \$1.0 million of the outstanding balance of Promissory Note One and Promissory Note Two per month, respectively. Payments may be made by the Company, at the Company's option, either in (a) in cash, or (b) in the form of shares of Common Stock with the number of redemption shares being equal to the portion of the applicable redemption amount divided by the Redemption Conversion Price or (c) a combination of cash and shares of Common Stock. The Promissory Notes have a 6% exit fee on any redemption amount paid in cash. The Redemption Conversion Price shall equal 85% multiplied by the lowest daily VWAP during the ten trading days immediately preceding the date the Lender delivers notice electing to redeem a portion of the Promissory Note. The Company's right to satisfy the redemption amount in shares of Common Stock is subject to certain limitations, including (i) there not being any Equity Conditions Failure (as defined in the Note), (ii) the Lender and its affiliates together not owning more than 9.99% of the outstanding shares of Common Stock, and (iii) the aggregate shares of Common Stock issued upon redemption of the Promissory Notes not exceeding 19.99% of the outstanding Common Stock unless the Company has obtained stockholder approval under NASDAQ rules for such issuance.

The Promissory Notes contain certain Trigger Events that generally, if uncured within five trading days, may result in an event of default in accordance with the terms of the Promissory Notes (such event, an Event of Default). Upon an Event of Default, the interest rate may also be increased to the lesser of 15% per annum or the maximum rate permitted under applicable law.

The Company evaluated Promissory Note One in accordance with applicable accounting standards under U.S. GAAP and determined the classification of the instrument as a debt obligation. In addition, the Company evaluated the instrument for embedded derivatives

Notes to Condensed Financial Statements

and concluded there were no embedded features that require bifurcation and separate accounting. The Company will record interest expense over the term of Promissory Note One, using the interest method, to amortize the debt issuance costs and OID.

On May 9, 2022, the Company recorded OID and debt issuance costs of \$3.2 million as a reduction to Promissory Note One to be amortized over the term of Promissory Note One. For the period from May 9, 2022 to June 30, 2022, the Company recorded \$0.3 million for amortization of the OID and debt issuance costs to interest expense in the accompanying statements of operations.

For the period from May 9, 2022 to June 30, 2022, the Company recorded interest expense of \$0.1 million in the accompanying statements of operations and as of June 30, 2022, recorded \$0.1 million in accrued interest in 'Current portion of notes payable' in the accompanying balance sheets.

2021 Term Loan

On March 19, 2021 (Effective Date), the Company entered into a Loan and Security Agreement (the 2021 Term Loan) by and between Silicon Valley Bank, a California corporation (SVB or Lender) and the Company, as borrower, whereby subject to the terms and conditions of the 2021 Term Loan, SVB advanced to the Company an original principal amount of \$30 million.

The 2021 Term Loan provides for an "interest-only" period from the Effective Date through February 28, 2023, with interest due and payable monthly on the first calendar day of each month. However, the Company achieved a revenue milestone of at least \$65 million on a trailing twelve-month basis during the three months ended March 31, 2021 which automatically extended the interest-only period through February 28, 2024. Beginning on the first calendar day of the month following the end of the interest-only period, the 2021 Term Loan shall be payable in (i) consecutive equal installments of principal through March 1, 2026, plus (ii) monthly payments of accrued interest. The principal amount outstanding under the 2021 Term Loan shall accrue interest at a floating per annum rate equal to the greater of (i) 2.00% above the prime rate, or (ii) 5.25%, which interest, in each case, shall be payable monthly. Changes to the interest rate applicable to the 2021 Term Loan based on changes to the prime rate shall be effective on the effective date of any change to the prime rate.

The Company has the option to prepay, prior to maturity, the total outstanding principal amount plus accrued and unpaid interest, subject to a prepayment penalty of 3% of the principal amount if paid prior to the first anniversary of the Effective Date, 2% of the principal amount if paid on or after the first anniversary but prior to the second anniversary of the Effective Date, 1% of the principal amount if paid on or after the second anniversary but prior to October 19, 2025, and 0% thereafter.

The Company granted the Lender a security interest in substantially all of the Company's assets. The 2021 Term Loan requires the Company to comply with a minimum liquidity ratio covenant (as defined) by the 2021 Term Loan of not less than 0.95 to 1.00, and had a trailing six month rolling minimum revenue requirement of not less than 70% of the Company's projected revenue performed at the end of each reporting period. On September 30, 2021, we entered into the Consent and First Amendment to Loan and Security Agreement (the 2021 Term Loan Amendment) to, among other things, amend our 2021 Term Loan to eliminate the revenue covenant for the period ended September 30, 2021 and modify the revenue covenant threshold for the three months ended December 31, 2021. In addition, we agreed to establish a restricted cash collateral account for \$15 million for the benefit of our lender if the balance of our cash and cash equivalents declined below \$40 million. On December 31, 2021, we entered into the Consent and First Amendment to Loan and Security Agreement (the 2021 Term Loan and Security Agreement (the 2021 Term Loan Second Amendment) to, among other things, amend our 2021 Term Loan and First Amendment to Loan and Security Agreement (the 2021 Term Loan and First Amendment to Loan and Security Agreement (the 2021 Term Loan Second Amendment) to, among other things, amend our 2021 Term Loan and First Amendment to: (i) obtain consent for the \$4.6 million January 2022 milestone payment under the Indi APA, (ii) repay \$20 million in outstanding principal on December 31, 2021, and (v) modify the minimum revenue requirement to not less than 75% for the three months ended March 31, 2022 and not less than 75% on a trailing six month rolling basis for each quarter thereafter of the Company's projected revenue performed at the end of each reporting period. The Lender agreed to apply the full amount of funds previously established within the restricted cash collateral account to partially repay the \$20 million in outstanding principal,

On April 7, 2022, the Company entered into the Consent and Third Amendment to Loan and Security Agreement (the 2021 Term Loan Third Amendment). Under the terms of the 2021 Term Loan Third Amendment, the Company agreed to the repayment of \$3.0 million in outstanding principal in April 2022 with an additional \$2.0 million to be paid on September 30, 2022, in exchange for: (i) consent for a \$2.0 million April 2022 milestone payment under the Indi APA, as amended, (ii) waiver of minimum revenue requirement for the three months ended March 31, 2022 and adjustment of remaining revenue milestones for 2022, and (iii) waiver and elimination of the prepayment fee on the \$3.0 million 2021 Term Loan partial repayment in April 2022 and subsequent \$2.0 million principal repayment. The Company recorded a loss on extinguishment of \$18,000 resulting from the write-off of debt issuance costs associated with the \$3.0 million repayment of our 2021 Term Loan in April 2022.

In association with entering into the SPA with the Lender on May 9, 2022 (as described above), the Company has the election to issue Promissory Note Two subject to the Company satisfying, among other things, repaying in full all outstanding obligations under the 2021

Notes to Condensed Financial Statements

Term Loan within nine months following the First Closing Date. As of June 30, 2022, the Company intends to repay all outstanding obligations under the 2021 Term Loan within nine months of the inception of Promissory Note One. The Company's final payment to SVB shall include all outstanding principal and accrued and unpaid interest, lender fees and expenses, which will include a final payment of \$2.7 million, and all other sums, if any, that shall have become due and payable hereunder with respect to the 2021 Term Loan. The \$2.7 million final payment is being amortized as interest expense over the expected remaining term of the loan.

The 2021 Term Loan contains certain covenants limiting the ability of the Company to, among other things, incur future debt, transfer assets except for the ordinary course of business, make acquisitions, pay dividends or make other certain restricted payments, or sell assets, subject to certain exceptions, without the prior written consent of the Lender. Failure to comply with the covenants and loan requirements may result in an event of default. As of June 30, 2022, the Company was in compliance with all restrictive and financial covenants associated with its borrowings. In the event of a default, including, among other things, our failure to make any payment when due or our failure to comply with any covenant under the 2021 Term Loan, the Lender may elect to declare all amounts outstanding to be immediately due and payable, and may proceed against the collateral granted to them to secure such indebtedness, including a royalty-free license or other right to use all of our intellectual property without charge.

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

	As of J	une 30, 2022
Remainder of 2022	\$	7,023
2023		14,616
2024 2025		1,647
2025		25
2026		6
2027 and thereafter		
Total	\$	23,317

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 was set to expire in January 2023. In January 2022, the Company amended the agreement to extend the lease agreement through January 2024, resulting in an additional \$1.2 million in ROU assets and lease liabilities recorded during the three months ended March 31, 2022. 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 expires in October 2023. The Company also holds various copier and storage facility leases under non-cancelable lease agreements that expire in the next one to four 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 located at 919 West Dillion Road; Louisville, Colorado (the Leased Premises). The purpose of the Lease is to replace the Company's current leased premises at 2970 Wilderness Place, Suite 100 in Boulder, Colorado and the Company intends to move its corporate headquarters to the Leased Premises by mid-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 Commencement Date), unless earlier terminated in accordance with the Lease. 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.

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), commencing as of the day after the award the the award the 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



Notes to Condensed Financial Statements

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 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 \$25.7 million by March 2024.

The Lease includes various covenants, indemnities, defaults, termination rights, and other provisions customary for lease transactions of this nature, including maintaining a \$5.0 million letter of credit (subject to contingent reduction over the term of the lease) to secure the performance of the Company's obligations under the Lease. The \$5.0 million letter of credit has to be cash collateralized by the Company through a restricted cash account for the benefit of the Landlord, which we recognized contemporaneously with the commencement of the Lease for accounting purposes.

Operating lease expense was \$0.5 million and \$0.8 million for the three and six months ended June 30, 2022, respectively, compared to \$0.3 million and \$0.6 million for the three and six months ended June 30, 2021, respectively. As of June 30, 2022, the weighted-average remaining lease term and discount rate associated with our operating leases were 7.0 years and 11.40%, respectively.

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

	As of J	une 30, 2022
Remainder of 2022 ⁽¹⁾	\$	(9,732)
2023 ⁽¹⁾		(8,121)
2024		2,619
2025		3,710
2026		3,979
2027 and thereafter		36,327
Total future minimum lease payments		28,782
Less amount representing interest		(24,565)
Total lease liabilities	\$	4,217

⁽¹⁾ Includes \$20.8 million of tenant improvement allowances expected to be received during these periods.

Future minimum lease payments, which do not include amounts for common area maintenance, insurance, or taxes, for operating lease obligations in accordance with ASC 840 - *Leases* were as follows (in thousands):

	As of December 31, 2021
2022	\$ 775
2022 2023	149
2024 2025	9
2025	3
2026	1
2027 and thereafter	
Total	\$ 937

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 offering and our common stock purchase agreement with Lincoln Park Capital Fund, LLC (the LPC facility). 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 Shares), subject to terms and conditions. The Shares will be offered and sold by the Company pursuant to its previously filed and currently effective registration statement on Form S-3. The Shares may only be offered and sold by means of a prospectus, including a prospectus supplement, forming part of the effective registration statement. 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.



Notes to Condensed Financial Statements

On March 7, 2022 (the Effective Date), the Company entered into a purchase agreement with Lincoln Park Capital Fund, LLC (Lincoln Park), pursuant to which Lincoln Park has committed to purchase up to \$50.0 million of the Company's common stock (the Purchase Agreement). 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 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 Capital 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 to advance its growth strategy and for general corporate purposes. On the 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 are included on the balance sheet in 'Other long-term assets'. In addition to the Initial Commitment Shares, the Company recorded \$129,000 of due diligence expenses and legal fees as deferred offering costs. 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 six months ended June 30, 2022, \$18,000 of deferred offering costs were charged against 'Additional paid-in capital', respectively. As of June 30, 2022, \$711,000 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.

During the three and six months ended June 30, 2022, the Company raised approximately \$2.9 million and \$4.5 million, respectively (\$2.8 million and \$4.0 million, respectively, after deducting underwriting discounts and commissions and offering expenses payable), in gross proceeds from the sale of 1,419,139 and 2,127,891 common shares at a weighted average price per share of \$2.03 and \$2.11, respectively, under these programs. As of June 30, 2022, the Company had remaining available capacity for share issuances of approximately \$29.9 million under the at-the-market facility and up to \$49.2 million under the LPC facility, each subject to the restrictions and limitations of the underlying facilities, as applicable.

Subscription Agreements

On April 7, 2022, the Company entered into subscription agreements (the Subscription Agreements) with a consortium of investors (the 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 6,508,376 shares of the Company's common stock (the Shares) in an offering (the Private Placement). The three members of our Board of Directors acquired an aggregate of 3,631,284 shares pursuant to the form of a Subscription Agreement that did not include any registration rights. The remaining 2,877,092 shares were acquired by others pursuant to the form of a Subscription

Notes to Condensed Financial Statements

Agreement whereby the Company agreed to file, subject to certain exceptions, a shelf registration statement with respect to resales of such shares with the Securities and Exchange Commission no later than 60 days from April 7, 2022, which the Company filed on June 6, 2022.

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 \$1.79 per share, which is equal to the closing price of the Company's common stock on April 7, 2022, for an aggregate purchase price of approximately \$11.7 million. The Subscription Agreements include customary representations, warranties and covenants by the parties to the agreement.

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 June 30, 2022.

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 generally provided outside the clinical setting and governed by individual contracts with third parties as well as development and commercialization of companion diagnostics (Services).

Diagnostic test revenues consist of blood-based lung tests and 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 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).

Revenues consisted of the following (in thousands):

	Three Months Ended June 30,				Six Months Ended June 30,				
		2022		2021		2022	2021		
Diagnostic tests	\$	10,206	\$	10,838	\$	15,839	\$	38,033	
Services		744		1,047		1,659		2,718	
Total revenue	\$	10,950	\$	11,885	\$	17,498	\$	40,751	

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 statements of operations. Of the \$1.9 million in 'Deferred revenue' recorded in the balance sheet as of December 31, 2021, \$0.8 million was recognized in revenues during the six months ended June 30, 2022, \$0.3 million was added to 'Deferred revenue' for up-front cash payments received for which the revenue recognition criteria have not been met and \$0.8 million was reclassified from non-current deferred revenue. The 'Deferred revenue' of \$2.2 million recorded in the balance sheet as of June 30, 2022 is expected to be recognized in revenues over the next twelve months as test results are delivered and services are performed. As of June 30, 2022 and December 31, 2021, the Company had zero and \$0.8 million in non-current deferred revenue,



Notes to Condensed Financial Statements

respectively, recorded within 'Other long-term liabilities' in the 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 both pertain to our COVID-19 diagnostic testing services, and their related revenue as a percentage of total revenue were as follows:

	Three Months Ende	d June 30,	Six Months Ended June 30,			
	2022	2021	2022	2021		
The State of Colorado	22 %	_	16%	_		
The Big Ten Conference	_	40 %	_	53%		

In addition to the above table, we collect reimbursement on behalf of customers covered by Medicare, which accounted for 28% and 33% of the Company's total revenue for the three and six months ended June 30, 2022, respectively, compared to 56% for both the three and six months ended June 30, 2021. The Company is subject to credit risk from its accounts receivable related to services provided to its customers. The Company does not perform evaluations of customers' financial condition and does not require collateral.

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				
	June 30, 2022	December 31, 2021			
The State of Colorado	27%				
Medicare	26%	30 %			
Janssen Research and Development, LLC	11 %	14 %			
LabCorp DD (formerly Covance)	4%	11 %			

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 June 30, 2022, 29,740 shares of common stock remained available for future issuance under the 2020 Plan.

Share-Based Compensation Expense

Pre-tax share-based compensation expense reported in the Company's statements of operations was (in thousands):

	Three Months Ended June 30,				Six Months Ended June 30,				
	2022			2021		2022	2021		
Direct costs and expenses	\$	13	\$	18	\$	28	\$	18	
Research and development		192		86		280		354	
Sales, marketing, general and administrative		1,163		435		2,406		1,919	
Total	\$	1,368	\$	539	\$	2,714	\$	2,291	

The remaining unrecognized stock-based compensation expense for options and restricted stock units was approximately \$9.4 million as of June 30, 2022, and is expected to be amortized to expense over the next 3.1 years.



Notes to Condensed Financial Statements

Stock Option Activity

Stock option activity during the six months ended June 30, 2022, 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)	gregate Isic Value
Outstanding - January 1, 2022	2,878	\$ 8.08	7.7	\$ 6,288
Granted	277	3.37		
Forfeited/canceled	(154)	8.89		
Exercised	(130)	0.70	·	
Outstanding - June 30, 2022	2,871	\$ 7.92	7.5	\$ 1,094
Exercisable - June 30, 2022	1,668	\$ 6.11	6.8	\$ 782

Restricted Stock Unit Activity

Restricted stock unit activity during the six months ended June 30, 2022 was (in thousands, except weighted average grant date fair value per share):

	Number of Shares	/eighted Average nt Date Fair Value Per Share
Outstanding - January 1, 2022	151	\$ 5.30
Granted	1,473	2.75
Forfeited/canceled	(11)	3.69
Released	(138)	6.59
Outstanding - June 30, 2022	1,475	\$ 2.64

Bonus-to-Options Program

As part of the Bonus-to-Options Program (Bonus Option Program), the Company recorded the following activity during the six months ended June 30, 2022 (in thousands, excepted weighted average exercise price and weighted average contractual life):

Number of Options	A	verage	Weighted Average Contractual Life (Years)	Aggregate Intrinsic Value	
373	\$	17.00	7.5	\$ 70	6
244		2.29	—	_	-
(14)		20.89		-	-
				_	_
603	\$	10.96	8.3		
603	\$	10.96	8.3		_
	Options 373 244 (14) 603	Number of Options A Exer 373 \$ 244 (14)	Options Exercise Price 373 \$ 17.00 244 2.29 (14) 20.89	Number of OptionsWeighted Average Exercise PriceAverage Contractual Life (Years)373\$ 17.007.52442.29—(14)20.89—603\$ 10.968.3	Number of OptionsWeighted Average Exercise PriceAverage Contractual Life (Years)Aggregate Intrinsic Value373\$ 17.007.5\$ 702442.29——(14)20.89——————603\$ 10.968.3

The Company accrued \$0.4 million and \$0.7 million for the three and six months ended June 30, 2022, respectively, compared to \$0.1 million and \$0.7 million for the three and six months ended June 30, 2021, 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

A total of 338,106 shares of our common stock have been reserved for issuance under the Employee Stock Purchase Plan (ESPP). The ESPP provides for successive six-month offering periods beginning on September 1st and March 1st of each year. As of June 30, 2022, 142,680 shares have been issued under the ESPP leaving 195,426 shares remaining for future issuance.



Notes to Condensed Financial Statements

Note 11 - Net Loss per Common Share

Basic earnings per share (EPS) excludes dilution and is computed by dividing net loss attributable to the common stockholders by the weighted-average shares outstanding during the period. Diluted EPS 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.

In connection with the acquisition of Indi in 2018, the Company recorded contingent consideration (See *Note* 4 - Fair Value) for amounts contingently payable to Indi's selling shareholders pursuant to the terms of the asset purchase agreement. The contingent consideration arrangement requires additional consideration to be paid by the Company to Indi upon attainment of a three-consecutive month gross margin target of \$2.0 million within the seven-year period after the acquisition date. When the gross margin target was met, the Company was required to issue 2,520,108 shares of common stock. The Company met the gross margin target of \$2.0 million for three consecutive months during the three months ended June 30, 2021. As a result of the achievement of the gross margin target, the Company included the 2,520,108 shares of common stock in the calculation of weighted-average shares outstanding used in computing basic and diluted net loss per share for the three and six months ended June 30, 2021. In August 2021, the Company entered into an amendment of the original agreement in which the Company has agreed to forgo the issuance of its Common Stock. Therefore, these shares are not included in the statements of stockholders' equity or shares issued and outstanding in the balance sheets and are not included in our earnings per share calculation subsequent to August 2021.

Basic and diluted loss per share for the three and six months ended June 30, 2022 and 2021 were (in thousands, except per share amounts):

	,	Three Months I	Ende	ed June 30,	Six Months Ended June 30,			
	_	2022		2021		2022		2021
Numerator								
Net loss attributable to common stockholders	\$	(15,824)	\$	(11,402)	\$	(31,410)	\$	(18,363)
Denominator								
Weighted-average shares outstanding used in computing net loss per share, basic and diluted		39,239		27,730		35,177		27,020
Net loss per share, basic and diluted	\$	(0.40)	\$	(0.41)		(0.89)		(0.68)

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 I	Ended June 30,	Six Months Ended June 30,			
	2022	2021	2022	2021		
Options to purchase common stock	3,474	2,874	3,474	2,874		
Shares committed under ESPP	44	—	44			
Warrants	103	103	103	103		
Restricted stock units	1,475	119	1,475	119		
Total	5,096	3,096	5,096	3,096		

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 six months ended June 30, 2022 and 2021.

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



Notes to Condensed Financial Statements

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 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 June 30, 2022. Following the 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 expenses related to this agreement for the three and six months ended June 30, 2022 and 2021.

License Agreements

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 will no longer pay a royalty of 2.5% on the net revenue received for 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 six months ended June 30, 2022 and 2021.

On May 13, 2021 (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 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 for the three and six months ended June 30, 2022 and 2021 was insignificant.

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 \$0.4 million for the three and six months ended June 30, 2022, respectively, compared to \$0.1 million and \$0.3 million for the three and six months ended June 30, 2021, 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 June 30, 2022 (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, 2021 (Form 10-K) and the Condensed Financial Statements as of June 30, 2022 and for the three and six months ended June 30, 2022 and 2021, 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, 2021, which was filed on March 14, 2022.

The following MD&A discussion is provided to supplement the Condensed Financial Statements as of June 30, 2022 and 2021 and for the three and six 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 six months ended June 30, 2022 and 2021 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 data-driven 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 technology 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.

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 eight diagnostic tests 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. 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 36-hour average turnaround time, down from the previous 72-hour average turnaround time, providing physicians with timely results to facilitate treatment decisions. The GeneStrat NGS test is our 72-hour average turnaround time blood-based NGS test, 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 response to the COVID-19 pandemic, through our partnership with Bio-Rad, we commercialized the Biodesix WorkSafe™ testing program. 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. Then U.S. Health and Human Services Secretary Azar declared a public health emergency for COVID-19 in February 2020 which justified the authorization of emergency use of diagnostic tests for the detection and/or diagnosis of COVID-19. The Bio-Rad SARS-CoV-2 ddPCR test and the Platelia SARS-CoV-2 Total Ab test have been granted FDA EUA pursuant to the current emergency declaration. 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. Prior to using the Bio-Rad SARS-CoV-2 tests as part of our testing program, we performed feasibility, verification, and validation studies, including developing software for process automation, sample accessioning, data management and reporting, all required to demonstrate the test operated as claimed by the manufacturer and as required by our certifying regulatory agencies for high complexity laboratory testing. We secured independent reference specimens run with EUA tests to validate these tests as fit for diagnostic use in our laboratories. Post-launch development support for these tests have included improvements in onboarding new personnel, logistics of sample collection, sample receipt and data reporting, all required to support our testing program. Additional releases of the laboratory data management software are ongoing and planned for the foreseeable future. Beginning in the quarter ended June 30, 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 is 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, and we cannot predict how long the EUAs for the SARS-CoV-2 tests will remain in place.

These tests under the Biodesix WorkSafe testing program are utilized by healthcare providers, including hospitals and nursing homes, and are also offered to businesses and educational systems. We have announced multiple partnerships for COVID-19 testing, and maintain an agreement with the State of Colorado to be one of the diagnostic companies to support widespread COVID-19 testing for the State which will expire on August 31, 2022. Additionally, we have overseen and managed onsite testing and validating testing for the Big Ten Conference athletic competitions through the term of our contract which expired on June 30, 2021.

In addition to the eight 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 60 biopharmaceutical companies and academic partners. All of our diagnostic testing is performed at one of our two accredited, highcomplexity clinical laboratories in Boulder, Colorado and De Soto, Kansas.

Since our inception, we have performed over 550,000 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.

The Company continues to address our liquidity needs through improvements to our capital structure. During the three months ended June 30, 2022, the Company entered into: (i) a private placement that raised approximately \$11.7 million in net equity proceeds, (ii) an amendment and partial repayment of our 2021 Term Loan, (iii) modifications to extend payment terms under the Integrated Diagnostics asset purchase agreement (the Indi APA), (iv) common stock sales raising additional funds through our at-the-market facility, and (v) the closing of a \$25.0 million debt facility with funding for up to \$25.0 million occurring in two tranches. On May 9, 2022, we closed on the first tranche for gross proceeds of \$15.0 million (approximately \$12.8 million, net, after deducting debt issuance costs and OID) (Promissory Note One). Each of these strategic initiatives is described in further detail within the Notes to our condensed financial statements in Part 1 of this Quarterly Report on Form 10-Q as well as our Liquidity and Capital Resources section below.

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 \$28.7 million, inclusive of \$5.1 million in restricted cash, and \$32.7 million as of June 30, 2022 and December 31, 2021, respectively.

Factors Affecting Our Performance

We believe there are several important factors that impact 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.

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 which seeks to enroll up to 5,000 patients to continue our clinical understanding of the predictive and prognostic value of the VeriStrat test. 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.

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. For example, 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 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, increasing the total number of sales representatives to drive continued growth, and thereby reduce the geographic footprint each representative must cover. This investment will allow the larger sales force to maximize their education and selling efforts and achieve greater returns. Additionally, we plan to invest in the Boulder-based marketing and customer support teams to continue to provide the field team with the resources to be successful in the field.

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, 2021 for more information.

COVID-19 Pandemic

The COVID-19 pandemic has 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 have also been constrained by our operational response to the COVID-19 pandemic. We will continue to adjust our operational norms, as needed, to help slow the spread of COVID-19, including complying with government directives and guidelines as they are modified and supplemented.

The COVID-19 pandemic and the surge associated with the Delta and Omicron variants have negatively affected our lung diagnostic testing-related revenue and our clinical studies. For example, cancer patients had more limited access to hospitals, healthcare providers and medical resources as steps were taken to control the spread of COVID-19. 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. We do not anticipate the need for COVID testing to be commensurate with the peak demand experienced during the first guarter 2021 and instead expect the demand to moderate as new variants and infections occur. The reduction in demand for COVID-19 diagnostic testing will be a key indicator of continued recovery and is taken as a positive sign for both our Lung Diagnostic and Biopharmaceutical Services during 2022. There is no assurance that our COVID-19 testing program will continue to be accepted by the market or that other diagnostic tests will become more accepted, produce quicker results or are more accurate. Further, the longevity and extent of the COVID-19 pandemic is uncertain and the need for COVID-19 testing could vary which could have a significant effect on our results of operations and profitability. As a result, increases in revenue due to any increase in demand for these diagnostic tests may not be indicative of our future revenue. For example, 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. The Company's sales efforts continued to be impacted by the COVID-19 pandemic during the first half of the first quarter 2022 due to surges associated with variants, which negatively affected the growth rate of our core lung diagnostic testing-related revenue and our clinical studies. However, we began to see further recovery during the latter half of the first quarter and throughout the second quarter 2022 in lung diagnostic testing as health care practitioners, including pulmonologists, increasingly returned to pre-pandemic related care. While the full outcome of the COVID-19 pandemic is unknown, it continues to negatively impact our ability to grow and scale our business in line with our expectations and disclosures at the time of our initial public offering (IPO).

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, 2021, which was filed on March 14, 2022, for a description of how the COVID-19 pandemic may adversely affect our business, financial condition and results of operations.

Second Quarter 2022 Financial and Operational Highlights

The following were significant developments affecting our business, capital structure and liquidity during the three months ended June 30, 2022 as compared to the same period in 2021 unless otherwise noted:

- Total revenue of \$11.0 million, a decrease of 8%, driven primarily by an anticipated year-over-year decline in COVID-19 diagnostic testing revenue, offset by strong year-over-year growth in core lung diagnostics:
 - o Core lung diagnostic revenue of \$7.3 million, reflected a year-over-year increase of 52% that was driven primarily by the increased adoption of Nodify Lung nodule management tests (Nodify CDT & Nodify XL2);
 - COVID-19 testing revenue of \$3.0 million reflected a year-over-year decrease of 51% that was driven by the shift to at-home rapid antigen testing;
 - o Services revenue of \$0.7 million decreased 29% year-over-year. COVID-related delays in clinical study enrollment and sample shipping logistics have begun to recover but are still impacting timelines for existing and new agreements;
- Second quarter 2022 gross margin of \$7.0 million, or 64% as a percentage of revenue as compared to 40% in the comparable prior year period primarily driven by the mix shift of sales to higher-margin core lung diagnostics and away from lower-margin COVID-19 testing;
- Operating expenses (excluding direct costs and expenses) of \$18.6 million, an increase of 21% driven primarily by growth in sales and marketing to drive our growth in core lung diagnostic sales as well as the recent GeneStrat NGS commercial launch;
 - o Includes non-cash stock compensation expense of \$1.4 million as compared to \$0.5 million;
- Net loss of \$15.8 million, an increase of 39%, driven primarily by the loss on extinguishment charge resulting from the restructuring of the contingent consideration agreement with Indi;
- Cash and cash equivalents of \$28.7 million, inclusive of \$5.1 million in restricted cash, as of June 30;
 - o Raised net proceeds of \$27.3 million during the quarter through debt and equity offerings;
 - o Included payment of \$2.0 million for scheduled milestone payment in April 2022 to Indi.

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 (Services).

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) core lung diagnostics testing and (ii) COVID-19 testing.

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, the historical amount of time until payment by a payer and historical price concessions granted to groups of customers.

Services

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.



Operating Expenses

Direct costs and expenses

Cost of diagnostic testing generally consists of cost of materials, direct labor, including bonus, employee benefits, 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 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 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, 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, 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.

Change in Fair Value of Contingent Consideration

In connection with the purchase transaction of Indi, we recorded contingent consideration pertaining to the amounts potentially payable to Indi shareholder pursuant to the terms of the asset purchase agreement. The fair value of contingent consideration was assessed at each balance sheet date and changes, if any, to the fair value were recognized as operating expenses within the statement of operations. The Company met the gross margin target of \$2.0 million for three consecutive months during the three months ended June 30, 2021. Subsequent changes to the contingent consideration following the achievement of the gross margin target are recorded as 'Interest expense' in the statements of operations resulting from the passage of time and fixed payment schedule. The significant unobservable inputs used in the measurement of fair value included 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 significant unobservable input used in the measurement of fair value includes the discount rate since all other inputs became fixed and determinable. During the period ended June 30, 2022, the Company increased the discount rate to reflect current market and Company specific conditions.

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.

Non-Operating Expenses

Interest Expense and Interest Income

For the three and six months ended June 30, 2022, interest expense consists of cash and non-cash interest from Promissory Note One, the 2021 Term Loan 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 six months ended June 30, 2021, interest expense primarily consists of cash and non-cash interest from our 2021 Term Loan. Interest income, which is included in 'Other income, net' in the 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 June 30,		Chai	nge	Six Mont Jun	hs Ended e 30,	Change	
	2022	2021	\$	%	2022	2021	\$	%
Revenues	\$ 10,950	\$ 11,885	\$ (935)	(8)%	5 17,498	\$ 40,751	\$(23,253)	(57)%
Operating expenses:								
Direct costs and expenses	3,980	7,085	(3,105)	(44)%	7,215	25,303	(18,088)	(71)%
Research and development	3,361	3,323	38	1%	6,567	6,644	(77)	(1)%
Sales, marketing, general and administrative	15,235	11,425	3,810	33 %	29,722	23,352	6,370	27 %
Change in fair value of contingent consideration	—	639	(639)	(100)%	—	1,622	(1,622)	(100)%
Impairment loss on intangible assets					81		81	<u> 100</u> %
Total operating expenses	22,576	22,472	104	0%	43,585	56,921	(13,336)	(23)%
Loss from operations	(11,626)	(10,587)	(1,039)	(10)%	(26,087)	(16,170)	(9,917)	(61)%
Other (expense) income:								
Interest expense	(1,346)	(815)	(531)	(65)%	(2,483)	(1,466)	(1,017)	(69)%
Loss on extinguishment of liabilities	(2,952)		(2,952)	(100)%	(2,952)	(728)	(2,224)	(305)%
Other income, net	100		100	100 %	112	1	111	11100 %
Total other expense	(4,198)	(815)	(3,383)	(415)%	(5,323)	(2,193)	(3,130)	(143)%
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Net loss	\$ (15,824)	\$ (11,402)	\$(4,422)	(39)%	5(31,410)	\$ (18,363)	\$(13,047)	(71)%

Revenues

We generate revenue from our diagnostic tests and services that we provide. Our revenues for the periods indicated were as follows (in thousands, except percentages):

		nths Ended e 30,	Cha	inge		ths Ended 1e 30,	Change		
	2022	2021	\$	%	2022	2021	\$	%	
Diagnostic revenue	\$ 10,206	\$ 10,838	\$ (632)	(6)	%\$ 15,839	\$ 38,033	\$ (22,194)	(58)%	
Services revenue	744	1,047	(303)	(29)	% 1,659	2,718	(1,059)	(39)%	
Total revenue	\$ 10,950	\$ 11,885	<u>\$ (935</u>)	(8)	% <u>\$ 17,498</u>	\$ 40,751	\$ (23,253)	(57)%	

Total revenue decreased \$0.9 million or 8%, and \$23.3 million or 57% for the three and six months ended June 30, 2022, respectively, compared to the same periods in 2021.

Diagnostic test revenue decreased \$0.6 million or 6%, and \$22.2 million or 58% for the three and six months ended June 30, 2022, respectively, compared to the same periods in 2021. The decrease for the three and six months ended June 30, 2022 compared to the same periods in 2021 is due to a \$3.1 million and \$25.4 million reduction in COVID-19 revenue, respectively, as the Company focuses its sales effort on the core lung diagnostic product lines. The reduction in Diagnostic test revenue was partially offset by an increase in our core lung diagnostic revenue of \$2.5 million and \$3.2 million for the three and six months ended June 30, 2022, respectively, compared to the same periods in 2021 driven primarily from an increase in Nodify XL2 and CDT, and GeneStrat NGS tests delivered. The Company's sales efforts continued to be impacted by the COVID-19 pandemic during the first half of the first quarter 2022 due to surges associated with variants, which negatively affected the growth rate of our core lung diagnostic testing-related revenue and our clinical studies. However, we began to see further recovery during the latter half of the first quarter and throughout the second quarter 2022 in lung diagnostic testing as health care practitioners, including pulmonologists, increasingly returned to pre-pandemic related care.

Services revenue decreased \$0.3 million or 29%, and \$1.1 million or 39% for the three and six months ended June 30, 2022, respectively, compared to the same periods in 2021 due to lower testing volumes driven by delayed receipt of samples from partner organizations, with an expected increase in volume in the coming months as those samples are delivered. In addition to delayed receipts in samples, 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 the recent Omicron COVID-19 variant spike.

Operating expenses

Direct costs and expenses

Direct costs and expenses related to revenue decreased \$3.1 million or 44%, and \$18.1 million or 71% for the three and six months ended June 30, 2022, respectively, compared to the same periods in 2021 driven primarily by the overall decline in COVID-19 testing, as vaccinations increase as well as broader adoption and availability of at-home testing, partially offset by an increase in direct costs and expenses associated with increased lung diagnostic revenue.

Research and development

Research and development expenses increased \$38,000 or 1%, and decreased \$77,000 or 1% for the three and six months ended June 30, 2022, respectively, compared to the same periods in 2021. The increase in costs for the three months ended June 30, 2022 was due primarily to increased spending on clinical trials and employee compensation and benefit costs, partially offset by decreased other laboratory costs. The decrease in costs for the six months ended June 30, 2022 was due primarily to decreased spending on clinical trials and other laboratory costs, partially offset by employee compensation and benefit costs.

The following table summarizes our external and internal costs for the three and six months ended June 30, 2022 and 2021 (in thousands, except percentages).

	Tł		nths Ended ne 30, Change						ths Ended e 30,		nge	
		2022		2021		\$%		2022	2021	\$		%
External expenses:												
Clinical trials and associated costs	\$	750	\$	596	\$	154	26 %	\$ 1,208	\$ 1,307	\$	(99)	(8)%
Other external costs		803		1,027		(224)	(22)%	6 1,839	2,010		(171)	(9)%
Total external costs		1,553		1,623		(70)	(4)%	6 3,047	3,317		(270)	(8)%
Internal expenses		1,808		1,700		108	6%	3,520	3,327		193	6%
Total research and development expenses	\$	3,361	\$	3,323	\$	38	1%	\$ 6,567	\$ 6,644	\$	(77)	(1)%

Sales, marketing, general and administrative

Sales, marketing, general and administrative expenses increased \$3.8 million or 33%, and \$6.4 million or 27% for the three and six months ended June 30, 2022, respectively, compared to the same periods in 2021. This increase was driven primarily by increases in employee compensation and benefits for both the three and six months ended June 30, 2022. This is also the result of increases in non-employee costs for both the three and six months ended June 30, 2022 associated with increased spending on various sales meetings, training, and campaigns.

Change in fair value of contingent consideration

Change in fair value of contingent consideration decreased \$0.6 million or 100%, and \$1.6 million or 100% for the three and six months ended June 30, 2022, respectively, compared to the same periods in 2021. The net change to contingent consideration through the date the gross margin target was met is recorded as operating expenses in the statements of operations. The decrease of \$0.6 million and \$1.6 million is a result of the gross margin target being met during the three months ended June 30, 2021 and subsequent changes to the contingent consideration following the achievement of the gross margin target are recorded as 'Interest expense' in the statements of operations resulting from the passage of time and fixed payment schedule.

Non-operating expenses

Interest expense

Interest expense increased \$0.5 million or 65%, and \$1.0 million or 69% for the three and six months ended June 30, 2022, respectively, compared to the same periods in 2021. This increase for the three months ended June 30, 2022 is primarily related to the securities purchase agreement with Streeterville Capital, LLC (the Lender), in which the Lender purchased Promissory Note One for which the Company recorded \$0.5 million in interest expense. Additionally, the increase for the six months ended June 30, 2022 is primarily driven by interest related to Promissory Note One and the accelerated accretion of the \$2.7 million SVB final payment as interest expense over the expected remaining term of the loan.

Loss on extinguishment of liabilities

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 three months ended June 30, 2022, we recorded a loss on the extinguishment of \$2.9 million.



On March 19, 2021, the Company entered into a new Loan and Security Agreement (2021 Term Loan) for an original principal amount of \$30 million with a maturity date of March 1, 2026. In connection with entering into the 2021 Term Loan, the Company repaid all outstanding principal and unpaid interest in the amount of \$25.9 million due under the secured promissory note (2018 Notes) and contemporaneously terminated the Loan and Security Agreement, dated as of February 23, 2018, as amended. As a result of the extinguishment of the 2018 Notes, the Company recorded a loss on extinguishment of \$0.7 million during the three months ended March 31, 2021.

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.

During March 2020, a global pandemic was declared by the World Health Organization related to the rapidly growing outbreak of a novel strain of coronavirus (COVID-19). 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. 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. The Company's sales efforts continued to be impacted by the COVID-19 pandemic during the first half of the first quarter 2022 due to surges associated with variants, which negatively affected the growth rate of our core lung diagnostic testing-related revenue and our clinical studies. However, we began to see further recovery during the latter half of the first quarter and throughout the second quarter 2022 in lung diagnostic testing as health care practitioners, including pulmonologists, increasingly returned to pre-pandemic related care. While the full outcome of the COVID-19 pandemic is unknown, it continues to negatively impact our ability to grow and scale our business in line with our expectations and disclosures at the time of our IPO. As a result, the items identified above have had an adverse effect on our revenue, results of operations and cash flows.

In March 2021, we completed the closing of our 2021 Term Loan for a principal amount of \$30 million and extinguished our prior 2018 term loan for \$25.9 million. The 2021 Term Loan contains customary affirmative covenants, including covenants regarding compliance with applicable laws and regulation, payment of taxes, insurance coverage, notice of certain events, and reporting requirements. Further, the 2021 Term Loan contains customary negative covenants limiting the ability to, among other things, incur future debt, transfer assets except for the ordinary course of business, make acquisitions, make certain restricted payments, and sell assets, subject to certain exceptions. The 2021 Term Loan requires the Company to comply with a minimum liquidity ratio covenant (as defined in the 2021 Term Loan) of not less than 0.95 to 1.00, and had a trailing six-month rolling revenue requirement of not less than 70% of the Company's projected revenue performed at the end each reporting period.

On September 30, 2021, we entered into the Consent and First Amendment to Loan and Security Agreement (the 2021 Term Loan Amendment) to, among other things, amend our 2021 Term Loan to eliminate the revenue covenant for the period ended September 30, 2021 and modify the revenue covenant threshold for the three month period ended December 31, 2021. In addition, we agreed to establish a restricted cash collateral account for \$15 million for the benefit of our lender if the balance of our cash and cash equivalents declined below \$40 million.

On December 30, 2021, the Company raised approximately \$16.3 million in gross proceeds from the sale of 3,756,994 common shares at a public offering price of \$4.35 per share in an at-the-market offering. The Company received net proceeds of \$15.7 million after deducting underwriting discounts and commissions and offering expenses payable by the Company.

On December 31, 2021, we entered into the Consent and Second Amendment to Loan and Security Agreement (Second Amendment) to, among other things, amend our 2021 Term Loan and First Amendment to: (i) obtain consent for the \$4.6 million January 2022 milestone payment due under the Indi APA, (ii) repay \$20 million in outstanding principal on December 31, 2021, (iii) waive the \$600,000 prepayment fee on the \$20 million Term Loan repayment, (iv) waive the minimum revenue covenant as of December 31, 2021, and (v) modify the minimum revenue requirement to not less than 75% for the three months ended March 31, 2022 and not less than 75% on a trailing six month rolling basis for each quarter thereafter of the Company's projected revenue performed at the end of each reporting period. The Lender agreed to apply the full amount of funds previously established within the restricted cash collateral account to partially repay the \$20 million in outstanding principal, thereby eliminating the restricted cash collateral account.

On March 7, 2022 (the Effective Date), the Company entered into a purchase agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to \$50.0 million of the Company's common stock (the Purchase Agreement). 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 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 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 Effective Date, the Company 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, the Company entered into subscription agreements (the Subscription Agreements) with a consortium of investors (the 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 the Company's common stock in an offering for an aggregate purchase price of approximately \$11.7 million.

On April 7, 2022, the Company entered into the Consent and Third Amendment to Loan and Security Agreement (Third Amendment) whereby subject to the terms and conditions of the Third Amendment, certain waivers and consents were provided. Under the terms of the Third Amendment to our 2021 Term Loan, the Company agreed to the repayment of \$3.0 million in outstanding principal in April 2022 with an additional \$2.0 million to be paid no later than September 30, 2022, in exchange for the following:

- Consent for a \$2.0 million April 2022 mutually agreed upon milestone payment under the Indi APA, as amended;
- Waiver of minimum revenue requirement for the three months ended March 31, 2022 and adjustment of remaining revenue milestones for 2022; and
- Waiver and elimination of the prepayment fee on the \$3.0 million 2021 Term Loan partial repayment in April 2022 and subsequent \$2.0 million principal repayment.

The Company further 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 are subject to consent from our lender under the 2021 Term Loan and related amendments. We have obtained lender consent for contractual payments through the third milestone and interest payment of \$2.1 million paid in July 2022 and we are in discussions with our lender to obtain consents for future payments.

On May 9, 2022, the Company entered into a securities purchase agreement with Streeterville Capital, LLC (the Lender), pursuant to which, among other things, the Lender: (i) purchased a secured promissory note (Promissory Note One) in the aggregate principal amount totaling \$16.0 million in exchange for \$15.0 million less certain expenses and (ii) agreed to purchase another secured promissory note at the Company's election (Promissory Note Two and, together with Promissory Note One, the Promissory Notes), subject to certain conditions precedent in aggregate principal amount totaling \$10.3 million in exchange for \$10.0 million in cash proceeds. Each of the Promissory Notes may, 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 set forth in the Promissory Notes. On May 9, 2022, the Company closed on the first tranche for gross proceeds of \$15.0 million (approximately \$12.8 million, net, after deducting debt issuance costs and OID), and intends to use the proceeds from such issuance for general corporate purposes.

As mentioned above, the Company maintains two facilities that enable equity financing on an ongoing basis at the Company's sole discretion, our at-themarket offering and our common stock purchase agreement with Lincoln Park Capital Fund, LLC (the LPC facility). During the three and six months ended June 30, 2022, the Company raised approximately \$2.9 million and \$4.5 million, respectively (\$2.8 million and \$4.0 million, respectively, after deducting underwriting discounts and commissions and offering expenses payable), in gross proceeds from the sale of 1,419,139 and 2,127,891 common shares at a weighted average price per share of \$2.03 and \$2.11, respectively, under these programs. As of June 30, 2022, the Company had remaining available capacity for share issuances of approximately \$29.9 million under the at-the-market facility and up to \$49.2 million under the LPC facility, each subject to the restrictions and limitations of the underlying facilities, as applicable.

As of June 30, 2022, we maintained cash and cash equivalents of \$28.7 million, inclusive of restricted cash of \$5.1 million, and we have \$23.2 million in outstanding aggregate principal amount on our 2021 Term Loan and Promissory Note One. 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 include lung diagnostic testing and COVID-19 testing, and (ii) providing biopharmaceutical companies with development and testing services. 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, including the debt and equity funding and amendments to the 2021 Term Loan and Indi APA, 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

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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 agreements or to obtain waivers or amendments that impact the related covenants. As of June 30, 2022, the Company was in compliance with all restrictive and financial covenants associated with its borrowings. However, due to the continued uncertainty caused by the COVID-19 pandemic, significant risks remain with respect to our ability to meet these thresholds and any material adverse effect on our revenues, income and expenses could impact our ability to maintain compliance with these covenants.

Based on our current operating plan, unless we continue to raise additional capital (debt or equity) or obtain waiver from complying with such financial covenants, we expect that we will be unable to maintain our financial covenants under our existing loan agreements during the next twelve months, which could result in an Event of Default, as defined, causing an acceleration of the outstanding balances. We have taken steps to improve our liquidity through the actions noted above and have also undertaken several proactive measures to mitigate the financial and operational impacts of COVID-19 through 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. We plan to raise additional funding 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 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 nor can there be any assurance that the Company will be a beneficiary of the COVID-19 Action Plan. 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.

The Company's revenues, results of operations and cash flows have been materially adversely impacted by the items noted above. We expect to continue to incur significant expenses for the foreseeable future and 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. 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):

	 Six Months Ended June 30,			
	2022	2021		
Net cash flows (used in) provided by:				
Operating activities	\$ (22,693)	\$	(10,236)	
Investing activities	(732)		(864)	
Financing activities	 19,299		5,229	
Net decrease in cash and cash equivalents and restricted cash	\$ (4,126)	\$	(5,871)	

Our cash flows resulted in a net decrease in cash and cash equivalents of \$4.1 million during the six months ended June 30, 2022 as compared to the net decrease in cash of \$5.9 million for the six months ended June 30, 2021. For the six months ended June 30, 2022, net cash used in operating activities increased by approximately \$12.5 million due to a year-over-year increase in net loss from operations of \$13.0 million, primarily driven by an increase in non-cash expenses of approximately \$4.0 million, and unfavorable changes in net working capital of \$3.5 million primarily as a result of a decrease in cash collections from customers and payments to vendors.

Net cash used in investing activities during the six months ended June 30, 2022 totaled \$0.7 million, a decrease of \$0.1 million compared to the same period in 2021. The decrease in net cash used in investing activities was primarily due to decreases in purchases of property and equipment, partially offset by an increase in payments for patents and trademarks.

Net cash provided by financing activities during the six months ended June 30, 2022 totaled \$19.3 million, an increase of \$14.1 million compared to the same period in 2021. The net cash provided by financing activities for the six months ended June 30, 2022 primarily resulted from \$16.1 million net proceeds from the issuance of common stock, \$12.8 million net proceeds from the issuance of Promissory Note One, partially offset by the milestone payments to Indi of \$6.6 million and partial repayment of the 2021 Term Loan of \$3.0 million. The net cash provided by financing activities for the six months ended June 30, 2021 primarily resulted from the net proceeds



from our 2021 Term Loan of \$29.9 million, and proceeds from the exercise of stock options of approximately \$0.7 million, primarily offset by the repayment of \$25.4 million from our 2018 Term Loan.

Contractual Obligations and Commitments

As a result of the entering into additional operating lease agreements, the secured promissory note, and Amendment No. 3 to the Indi APA, our noncancelable contractual obligations and commitments for lease and debt obligations as presented in our Form 10-K have been modified. The following table provides an update as follows as of June 30, 2022 (in thousands):

	 Payments due by period								
	Total	Less than 1 year			1 to 34 to 5yearsyears			More than 5 years	
Borrowings and interest ⁽¹⁾	\$ 27,416	\$	17,126	\$	10,274	\$	16	\$	_
Contingent consideration ⁽²⁾	38,871		8,656		30,215		_		_
Operating lease obligations ⁽³⁾	28,783		(19,084)		5,603		3,938		38,326
Total	\$ 95,070	\$	6,698	\$	46,092	\$	3,954	\$	38,326

- ⁽¹⁾ Includes the Promissory Note One and 2021 Term Loan payments of principal, interest and final payment fee of \$2.7 million due upon loan maturity.
- (2) The gross margin target associated with the purchase transaction of Indi was achieved in the quarter ending June 30, 2021, giving rise to the previously disclosed contingent obligations of \$37.0 million in the aggregate payable through the issuance of Company's shares of common stock subject to a fixed price put option. The Company entered into an amendment in August 2021 to the original agreement in which all parties agreed to forgo the issuance of shares of common stock of the Company that would otherwise be issued, and the Company will instead make six quarterly installment payments of \$4.6 million beginning in January 2022 and a final payment of approximately \$9.3 million in July 2023 for a total of \$37.0 million. 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 all parties agreed to restructure the milestone payments associated with the contingent consideration 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 original payment schedule and the 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.
- ⁽³⁾ Includes \$20.8 million of tenant improvement allowances expected to be received during the remainder of 2022 and the first half of 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, 2021.

Off-Balance Sheet Arrangements

As of June 30, 2022, 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.

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.

Diagnostic test revenues

Diagnostic test revenues are recognized upon completion of our performance obligation to the deliver test results to our customer, either the prescribing physician or third-party to which we contracted for services to be performed. We consider diagnostic testing to be



completed upon the delivery of test results to our customer 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, the historical amount of time until payment by a payer and historical price concessions granted to groups of customers. These estimates require significant judgment by management.

Service revenues

Service revenues are recognized upon completion of our performance obligation to deliver testing results for assay development and testing services. 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.

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 February 2016, the FASB issued ASU No. 2016-2, Leases (Topic 842). This ASU intends to make accounting for leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. In addition to other related amendments, the FASB issued ASU No. 2018-11, Leases (Topic 842): Targeted Improvements, which offers an additional transition method whereby entities may apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings rather than application of the new leases standard at the beginning of the earliest period presented in the financial statements. The Company elected this transition method and adopted ASC 842 on January 1, 2022 and as a result, recorded operating lease right-of-use (ROU) assets of \$1.3 million, including offsetting deferred rent of \$0.1 million, along with the associated operating lease liabilities of \$1.3 million. On January 1, 2022, the Company did not have any finance leases. Additional information and disclosures required by this new standard are contained in Note 3 and Note 7 to our condensed financial statements in Part 1 of this Quarterly Report on Form 10-Q.

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 will become effective for the Company beginning January 1, 2023 with early adoption permitted. The Company is currently evaluating this guidance and assessing the overall impact on its 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 \$1.07 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 and our indebtedness, including our outstanding 2021 Term Loan. As of June 30, 2022, we had \$7 million outstanding on the 2021 Term Loan subject to a floating per annum rate equal to the greater of (i) 2.00% above the prime rate, or (ii) 5.25%. 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 two U.S. financial institutions. 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 June 30, 2022, a hypothetical 100 basis point increase in interest rates would not have a material impact on our investment portfolio, financial position or results of operations.

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 June 30, 2022, that have materially affected, or are reasonable likely to materially effect, our internal controls over financial reporting.

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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, 2021, filed March 14, 2022, 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.

We are subject to certain contractual and regulatory limitations on our ability to consummate future financings.

Pursuant to that certain securities purchase agreement we entered into in May 2022 in connection with the issuance of a promissory note to Streeterville Capital, LLC (Lender), we agreed to be subject to certain restrictions on our ability to issue securities during the term of the notes issued under the agreement. Specifically, we agreed to obtain the Lender's consent prior to issuing any debt securities or certain equity securities where the pricing of such equity securities is tied to the public trading price of our common stock. Furthermore, we also must offer the Lender the right to purchase up to 30% of future equity and debt securities offerings, subject to certain exceptions and limitations, in each case during the term of any note issued to the Lender.

Furthermore, if our public float falls below \$75 million at the next measurement date, we will be subject to the restrictions set forth in General Instruction I.B.6 to Form S-3 that limits our ability to conduct primary offerings under a Form S- 3 registration statement, like issuances under our at-the-market program. Under such limitations, we may not sell, during any 12-month period, securities on Form S-3 having an aggregate market value of more than one-third of our public float. These restrictions may delay or prevent us from entering into funding arrangements or being able to access the capital markets, including under our at-the-market program, on favorable terms or at all.

If we fail to comply with the restrictions and covenants in our May 2022 securities purchase agreement, there could be an event of default under the promissory notes issued thereunder, which could result in an acceleration of payments due under those notes and other consequences.

Failure to meet the restrictions, obligations, and limitations under the May 2022 securities purchase agreement may result in an event of default in accordance with the terms of Promissory Note One issued thereunder and could result in acceleration of obligations under other loan agreements. An event of default would, among other things, provide the noteholder with the right to increase the outstanding balance by 10% for certain major events of default and 5% for others. Additionally, upon an event of default, the noteholder may consider the promissory note immediately due and payable. Furthermore, upon an event of default, the interest rate may also be increased to the lesser of 15% per annum or the maximum rate permitted under applicable law.

The redemption feature under Promissory Note One is dependent upon the market value of our common stock, which could result in significant dilution to our existing stockholders.

Beginning on the date that is nine months after the issuance date of Promissory Note One, the Lender has the right to redeem up to \$1.4 million of the outstanding balance per month. While we have the option to make such payments in either (a) cash, (b) in the form of shares of Common Stock with the number of redemption shares being equal to the portion of the applicable redemption amount divided by the Redemption Conversion Price or (c) a combination of cash and shares of Common Stock. Since the redemption conversion price shall equal 85% multiplied by the lowest daily volume weighted average price of the Common Stock during the ten trading days immediately preceding the date the Lender delivers notice electing to redeem a portion of Promissory Note One, the number of shares to be issued by us in satisfaction of redemption will vary, perhaps considerably. A reduction in our trading value could cause us to issue a greater number of shares under a redemption notice and therefore increase the dilutive effect to other stockholders.

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

On April 7, 2022, the Company entered into subscription agreements (the Subscription Agreements) with a consortium of investors (the 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 the Company's common stock (the Shares) in an offering (the Private Placement). The three members of our Board of Directors acquired an aggregate of 3,631,284 shares pursuant to the form of a Subscription Agreement that did not include any registration rights as they are exempt from registration pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the Securities Act), and Rule 506 promulgated thereunder. The remaining 2,877,092 shares were acquired by



others pursuant to the form of a Subscription Agreement whereby we agreed to file, subject to certain exceptions, a shelf registration statement with respect to resales of such shares with the Securities and Exchange Commission no later than 60 days from April 7, 2022, which the Company filed on June 6, 2022.

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 \$1.79 per share, which is equal to the closing price of the Company's common stock on April 7, 2022, for an aggregate purchase price of approximately \$11.7 million, in order to, among other things, fund the partial repayment of the 2021 Term Loan and for general corporate purposes.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

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Item 6. Exhibits.
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Exhibit Number	Description
10.1+*	Biodesix, Inc. 2021 Senior Management Bonus to Equity Plan
10.2+*	Amendment No. 1 to the Biodesix, Inc. 2021 Senior Management Bonus to Equity Plan
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*	<u>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.</u>
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 h	erewith.

† Previously filed.

+ Management contract or compensatory plan.

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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.

By: ____

Biodesix, Inc.

Date: August 4, 2022

/s/ RYAN H. SIUREK Ryan H. Siurek Chief Accounting Officer

BIODESIX, INC.

2021 Senior Management Bonus to Equity Plan

- 1. **PURPOSES.** The purpose of the Biodesix, Inc. 2021 Senior Management Bonus to Equity Plan (the "*Plan*") is to provide certain designated employees of Biodesix, Inc., a Delaware corporation (the "*Company*"), or its subsidiaries with the opportunity to receive a portion of their annual cash bonus in the form of a Nonstatutory Stock Option (as defined under the Equity Incentive Plan). The Plan is a subplan of the Equity Incentive Plan.
- **2. D**EFINITIONS. For purposes of the Plan:

"Board" means the Board of Directors of the Company.

"Bonus Year" means the calendar year in respect of which an annual cash bonus is earned.

"*Plan*" means this Biodesix, Inc. 2021 Senior Management Bonus to Equity Plan, as set forth herein and as amended from time to time.

"*Committee*" means the Compensation Committee of the Board, or a subcommittee thereof, or such other committee designated by the Board to administer the Plan.

"Company" means Biodesix, Inc., a Delaware corporation, or any successor thereto.

"Eligible Employee" means an employee of the Company or its subsidiaries who the Committee designates as eligible.

"Equity Incentive Plan" means the Biodesix, Inc. 2020 Equity Incentive Plan, as amended from time to time, or any successor equity plan adopted by the Company.

"*Individual Cap*" means the maximum amount of a Participant's annual cash bonus that may be received in the form of a Nonstatutory Stock Option, as determined under Section 5(c) of the Plan.

"Option Election" means an effective election under Section 5 of the Plan.

"Participant" means an Eligible Employee who makes an Option Election under Section 5 of the Plan.

"*Section 409A*" shall mean Section 409A of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder.

3. ADMINISTRATION. The Plan shall be administered by the Committee. The Committee shall, subject to the terms of this Plan, interpret this Plan and the application thereof, and establish, amend and revoke rules and regulations or impose conditions it deems necessary or desirable for the administration of the Plan. All such interpretations, rules, regulations and conditions shall be final, binding and conclusive upon the Participants and all other persons having or claiming any right or interest in the Plan or any Nonstatutory Stock Option granted hereunder.

No member of the Board or Committee, and no officer of the Company to whom the Committee delegates any of its power and authority hereunder, shall be liable for any act, omission, interpretation, construction or determination made in connection with this Plan in good faith, and the members of the Board and the Committee and such officers shall be entitled to

indemnification and reimbursement by the Company in respect of any claim, loss, damage or expense (including attorneys' fees) arising therefrom to the full extent permitted by law (except as otherwise may be provided in the Company's Amended and Restated Certificate of Incorporation) under any indemnification agreement to which such director or officer is then party and under any directors' and officers' liability insurance that may be in effect from time to time.

- 4. ELIGIBILITY. The Committee shall have the authority to determine who is an Eligible Employee under the Plan.
- 5. **Option Election.**
 - a. **ANNUAL ELECTIONS.** Prior to the first day of each Bonus Year, each Eligible Employee may elect, in accordance with rules and procedures established by the Committee, to forgo 25%, 50%, 75% or 100% of such Eligible Employee's annual cash bonus that may be earned in such Bonus Year in exchange for a fully-vested Nonstatutory Stock Option to purchase the number of shares of Common Stock determined under the Conversion Formula set forth in Section 5(d) (an "*Option*"). Notwithstanding the foregoing, any election under this paragraph will be limited by the Individual Cap set forth Section 5(c), or by any maximum dollar amount set forth by the Company or the Eligible Employee in such election. Any election made under this Section 5(a) shall become irrevocable as of December 31 of the year prior to the Bonus Year for which the election is made.
 - b. **INITIAL PARTICIPANT ELECTIONS.** An individual who becomes an Eligible Employee for the first time after a Bonus Year has commenced, and on or prior to September 30 of such year, may elect, not later than the 30th day following the date the individual becomes an Eligible Employee, and in accordance with rules and procedures established by the Committee, to forgo 25%, 50%, 75% or 100% of such Eligible Employee's annual cash bonus that may be earned in such Bonus Year after the date of such election in exchange for an Option. Notwithstanding the foregoing, any election under this paragraph will be limited by the Individual Cap set forth Section 5(c), or by any maximum dollar amount set forth by the Company or the Eligible Employee in such election.
 - c. **INDIVIDUAL CAP.** Each Option Election under this Section 5 shall be limited to an amount equal to the Eligible Employee's target annual bonus for the Bonus Year. If, absent this limitation, a Participant's election would result in such Participant forgoing an amount of the Participant's annual cash bonus in excess of the Participant's target annual bonus for the Bonus Year, the Participant shall be deemed to have elected to forgo an amount equal to 100% of such Participant's target annual bonus for the Bonus Year in exchange for an Option, and any portion of the annual bonus in excess of such amount shall be paid to the Participant in cash, subject to the terms of the annual bonus plan as then in effect.
 - d. **CONVERSION FORMULA.** The number of shares of Common Stock subject to an Option shall be determined using the following formula: (Cash Value * 4)/Average Share Price.

"*Cash Value*" means the value of that portion of the annual cash bonus for the Bonus Year which a Participant has elected to forgo pursuant to a valid Option Election, after application of any applicable maximum dollar amounts or the Individual Cap.

"Average Share Price" means the average share price for the Bonus Year, as determined in good faith by the Committee.

- **6. C**APITALIZATION **A**DJUSTMENTS. In the event of (i) any change in the Common Stock through a merger, consolidation, reorganization, recapitalization or otherwise, (ii) a stock dividend, or (iii) a stock split, combination or other change in the Common Stock, in each case, as described in Section 5.7 of the Equity Incentive Plan, the number of Nonqualified Stock Options held by each Participant shall be increased or decreased proportionately in accordance with Section 5.7 of the Equity Incentive Plan.
- 7. **TERMINATION OF EMPLOYMENT.** In the event that a Participant's employment with the Company or its applicable subsidiary terminates for any reason (including by reason of death, disability, termination by the Company or its subsidiary without cause, voluntary resignation or otherwise), such Participant's Option Election shall be cancelled and shall be of no force and effect, and no portion of any amount paid to the Participant in respect of his or her annual cash bonus shall be eligible for conversion to an Option.
- 8. AMENDMENT AND TERMINATION. The Board may amend or terminate the Plan at any time in whole or in part; provided, however, that no amendment or termination shall adversely affect the rights of a Participant pursuant to a valid Option Election without the consent of the Participant. Notwithstanding the foregoing, the Plan may be amended at any time, without the consent of any Participant (or beneficiary), if necessary or desirable to comply with applicable law.

9. GENERAL PROVISIONS.

- a. **NON-ALIENATION OF BENEFITS.** Neither a Participant nor any other person shall have any rights to sell, assign, transfer, pledge, anticipate, or otherwise encumber the amounts, if any, payable under the Plan. Any attempted sale, assignment, transfer, pledge, anticipation or encumbrance shall be null and void and without any legal effect. No part of the amounts payable under the Plan shall be subject to seizure or sequestration for the payment of any debts, judgments, alimony or separate maintenance owed by a Participant or any other person, nor be transferable by operation of law in the event of a Participant's or any other person's bankruptcy or insolvency.
- b. **No Stockholder Rights.** Neither a Participant nor any other person shall have any rights as a stockholder of the Company with respect to an Option until shares of Common Stock are issued to the Participant in accordance with the terms of such Option under the Equity Incentive Plan.
- c. **SECTION 409A.** It is intended that the Plan and any Nonstatutory Stock Option granted hereunder be exempt from the application of Section 409A and any state law of similar effect. In the event any payment hereunder be deemed to be deferred compensation subject to the requirements of Section 409A, such payment shall be intended to comply with the requirements of Section 409A and the Plan shall be interpreted accordingly. To this end, and notwithstanding any other provision of this Plan to the contrary, if at the time of a Participant's termination of employment with the Company or its subsidiary, (i) the Company's securities are publicly traded on an established securities market, (ii) the Participant is a "specified employee" (as defined in Section 409A), and (iii) the deferral of the commencement of any payments or benefits otherwise payable hereunder as a result of such termination of employment is necessary in order to prevent any accelerated or additional tax under Section 409A, then the Company will defer the commencement of

such payment until the date that is six (6) months following the Participant's termination of employment with the Company or its subsidiary (or the earliest date as is permitted under Section 409A). Any amounts, the payment of which are so deferred, shall be paid in a lump sum payment on the first (1st) day of the seventh (7th) month following the end of such deferral period. If the Participant dies during the deferral period prior to the payment of any deferred amount, then the unpaid deferred amount shall be paid to the personal representative of the Participant's estate within sixty (60) days after the date of the Participant's death. Notwithstanding any provision of this Plan to the contrary, and to the extent necessary to comply with Section 409A with respect to any "deferred compensation" within the meaning of Section 409A, a Participant will be deemed to have a date of termination for purposes of determining the timing of any payments or benefits hereunder only upon a "separation from service" within the meaning of Section 409A. The Company makes no representation that any or all of the payments described in this Plan will be exempt from or comply with Section 409A from applying to any such payment. By making an Option Election, a Participant acknowledges and agrees that the Participant shall be solely responsible for the payment of any taxes, penalties, interest of other expenses incurred by the Participant on account of non-compliance with Section 409A.

- d. **SEVERABILITY.** If any provision of the Plan shall be held illegal or invalid for any reason, such illegality or invalidity shall not affect the remaining provisions of the Plan, and the Plan shall be enforced as if the invalid provisions had never been set forth therein.
- e. **SUCCESSORS IN INTEREST.** The obligation of the Company under the Plan shall be binding upon any successor or successors of the Company, whether by merger, consolidation, sale of assets or otherwise, and for this purpose reference herein to the Corporation shall be deemed to include any such successor or successors.
- f. **GOVERNING LAW.** The Plan shall be construed and enforced in accordance with, and governed by, the laws of the State of Delaware, without giving effect to principles of conflict of laws.

Amendment Number One To The Biodesix, Inc. 2021 Senior Management Bonus to Equity Plan

WHEREAS, Biodesix, Inc., a Delaware corporation (the "*Company*") heretofore has adopted and maintains the Biodesix, Inc. 2021 Senior Management Bonus to Equity Plan (the "*Plan*"), a subplan of the Biodesix, Inc. 2020 Equity Incentive Plan (the "*Equity Incentive Plan*") to provide certain designated employees of the Company or its subsidiaries with the opportunity to receive a portion of their annual cash bonus in the form of a Nonstatutory Stock Option (as defined under the Equity Incentive Plan);

WHEREAS, the Board of Directors of the Company (the "Board") may amend the Plan at any time; and

WHEREAS, the Board desires to amend the Plan to provide for the cancellation of elections thereunder in the event the Company enters into, or announces its intention to enter into, an agreement that, if consummated, would constitute a Change in Control (as defined under the Equity Incentive Plan).

Now, THEREFORE, BE IT RESOLVED, that the Plan hereby is amended, effective for Option Elections (as defined in the Plan) in respect of Bonus Year 2022 and subsequent Bonus Years, to insert a new Section 5(e), to read as follows:

E. CANCELLATION OF OPTION ELECTION. Notwithstanding any other provision of the Plan to the contrary, an Option Election in respect of a Bonus Year shall be automatically cancelled and of no effect in the event that on or after the first day of a Bonus Year, but prior to the date on which Nonstatutory Stock Options in satisfaction of such Option Election have been granted, the Company enters into, or announces its intention to enter into, an agreement that, if consummated, would constitute a Change in Control (as defined under the Equity Incentive Plan) (the "*Option Cancellation*"). The Option Cancellation is irrevocable notwithstanding whether such Change in Control is effectuated and each Participant with respect to whom an Option Election is cancelled pursuant to such Option Cancellation shall again be entitled to receive 100% of such Participant's annual cash bonus earned in such Bonus Year as if no Option Election had been made with respect thereto.

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):

By:

- (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: August 4, 2022

/s/ Scott Hutton

Scott Hutton Chief Executive Officer

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):

By:

- (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: August 4, 2022

/s/ Robin Harper Cowie

Robin Harper Cowie Chief Financial Officer

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 June 30, 2022 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: August 4, 2022

By:

/s/ Scott Hutton Scott Hutton Chief Executive Officer

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 June 30, 2022 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: August 4, 2022

By:

/s/ Robin Harper Cowie Robin Harper Cowie Chief Financial Officer