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 March 31, 2021

OR

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

For the transition period from to

Commission File Number: 001-39659

BIODESIX, INC.

(Exact Name of Registrant as Specified in its Charter)

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	BDSX	The Nasdaq Global Market

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

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

As of May 7, 2021, the registrant had 26,861,021 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" 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, 2020, which was filed on March 16, 2021. 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" and elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2020, regarding, among other things:

- our inability to achieve or sustain profitability;
- 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 COVID-19 and antibody 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;
- the impact of a pandemic, epidemic, or outbreak of an infectious disease in the United States or worldwide, including the COVID-19 pandemic on our business;
- 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;
- cost-containment efforts of our customers, purchasing groups and integrated delivery networks having a material adverse effect on our sales and profitability;
- potential effects of litigation and other proceedings;
- general economic and financial market conditions;
- our ability to attract and retain key personnel;
- current and future debt financing placing restrictions on our operating and financial flexibility;

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

These risks are not exhaustive. Other sections of this Quarterly Report on Form 10-Q may include additional factors that could harm our business and financial performance. New risk factors may emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

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

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

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

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited).

BIODESIX, INC.

Condensed Balance Sheets
(in thousands, except share data)

	March 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 55,329	$ 62,126
Accounts receivable, net	18,367	15,304
Other current assets	7,548	8,710
Total current assets	81,244	86,140
Non-current assets		
Property and equipment, net	3,387	3,178
Intangible assets, net	12,821	13,260
Other long-term assets	3,003	3,461
Goodwill	15,031	15,031
Total non-current assets	34,242	34,930
Total assets	$ 115,486	$ 121,070
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 3,747	$ 8,964
Accrued liabilities	7,262	7,789
Deferred revenue	2,408	3,532
Current portion of notes payable	2,707	11,840
Total current liabilities	16,124	32,125
Non-current liabilities		
Long-term notes payable	30,328	15,926
Contingent consideration	30,915	29,932
Other long-term liabilities	1,687	1,921
Total non-current liabilities	62,930	47,779
Total liabilities	79,054	79,904
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value, 5,000,000 shares authorized; 0 (2021 and 2020) shares issued and outstanding	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized; 26,785,431 (2021) and 26,561,504 (2020) shares issued and outstanding	27	27
Additional paid-in capital	302,180	299,953
Accumulated deficit	(265,775)	(258,814)
Total stockholders' equity	36,432	41,166
Total liabilities and stockholders' equity	$ 115,486	$ 121,070

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

BIODESIX, INC.

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

	Three Months Ended March 31,	
	2021	**2020**
Revenues	$ 28,866	$ 5,096
Operating expenses:		
Direct costs and expenses	18,218	1,581
Research and development	3,321	2,900
Sales, marketing, general and administrative	11,927	8,080
Change in fair value of contingent consideration	983	957
Total operating expenses	34,449	13,518
Loss from operations	(5,583)	(8,422)
Other income (expense):		
Interest expense	(651)	(1,457)
Change in fair value of warrant liability	—	51
Loss on debt extinguishment	(728)	—
Other income, net	1	123
Total other expense	(1,378)	(1,283)
Net loss	$ (6,961)	$ (9,705)
Net loss per share, basic and diluted	$ (0.26)	$ (37.18)
Weighted-average shares outstanding, basic and diluted	26,604	261

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

BIODESIX, INC.

Condensed Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
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

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance - December 31, 2019	118,766	$ 193,959	255	$ 1	$ 2,324	$ (227,464)	$ (225,139)
Exercise of stock options	—	—	20	—	11	—	11
Net loss	—	—	—	—	—	(9,705)	(9,705)
Balance - March 31, 2020	118,766	$ 193,959	275	$ 1	$ 2,335	$ (237,169)	$ (234,833)

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

BIODESIX, INC.

Condensed Statements of Cash Flows
(in thousands)

	Three Months Ended March 31,	
	2021	**2020**
Cash flows from operating activities		
Net loss	$ (6,961)	$ (9,705)
Adjustments to reconcile net loss to net cash, cash equivalents, and restricted cash used in operating activities		
Depreciation and amortization	746	678
Amortization of convertible notes debt discount	—	677
Loss on extinguishment of term loan	728	—
Stock-based compensation expense	1,752	—
Change in fair value of warrant liability	—	(51)
Change in contingent consideration	983	957
Accrued interest on notes payable and convertible notes payable	24	287
Amortization of debt issuance costs	41	36
Provision for doubtful accounts	193	(3)
Changes in operating assets and liabilities:		
Accounts receivable	(3,256)	2,464
Other current assets	1,068	(85)
Other long-term assets and liabilities	224	(82)
Accounts payable and other accrued liabilities	(5,744)	857
Deferred revenue	(1,124)	(567)
Net cash and cash equivalents and restricted cash used in operating activities	(11,326)	(4,537)
Cash flows from investing activities		
Purchases of property and equipment	(466)	(98)
Patent costs and intangible asset acquisition, net	(50)	(44)
Payment to acquire Oncimmune assets	—	(250)
Net cash and cash equivalents and restricted cash used in investing activities	(516)	(392)
Cash flows from financing activities		
Proceeds from exercise of stock options	475	11
Proceeds from term loan and notes payable	30,000	6,409
Repayment of term loan and notes payable	(25,416)	—
Payment of debt issuance costs	(108)	—
Net cash and cash equivalents and restricted cash provided by financing activities	4,951	6,420
Net (decrease) increase in cash and cash equivalents and restricted cash	(6,891)	1,491
Cash, cash equivalents, and restricted cash - beginning of period	62,306	5,468
Cash, cash equivalents, and restricted cash - end of period	$ 55,415	$ 6,959

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

Note 1 – Organization and Description of Business

Biodesix, Inc. (the "Company", "Biodesix", "we" "us" and "our"), formerly Elston Technologies, Inc., was incorporated in Delaware in 2005. The Company's headquarters are in Colorado, 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) authorized performance 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 Emergency Use Authorization (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 four blood-based lung cancer tests across the lung cancer continuum of care:

- *Nodify XL2*® and *Nodify CDT*™ tests, marketed as part of 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.
- *GeneStrat*® and *VeriStrat*® tests, marketed as part of our Biodesix Lung Reflex® 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 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.

COVID-19 Tests

Using the Bio-Rad SARS-CoV-2 ddPCR test and the Platelia SARS-CoV-2 Total Ab tests, we operate and have commercialized the Biodesix WorkSafe™ testing program. The Company offers two SARS-CoV-2 tests:

- *Bio-Rad SARS-CoV-2 ddPCR* test, which is authorized by the FDA 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, authorized by the FDA, intended for detecting a B-cell immune response to SARS-CoV-2, indicating recent or prior infection.

These tests 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 that it believes are important to the development of new targeted therapies, determining clinical trial eligibility and guiding treatment selection.

All of 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, 2020. 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, 2020 was derived from the audited financial statements.

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.

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. Restricted cash consists of deposits related to the Company's corporate credit cards and prior to March 31, 2021, also included a letter of credit related to an operating lease agreement. As of March 31, 2021 and December 31, 2020, the Company had $0.1 million and $0.2 million in restricted cash, respectively, which was included in 'Other current assets' in the accompanying balance sheets.

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 March 31, 2021 and 2020, see Note 9 – *Revenue & Accounts Receivable Credit Concentration.*

Inventory

Inventory consists primarily of material supplies, which are consumed in the performance of testing services and charged to cost of sales. Inventory is stated at cost and reported within 'Other current assets' in the balance sheet and were $3.4 million and $3.2 million as of March 31, 2021 and December 31, 2020, 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.

Note 3 - Recently Issued Accounting Standards

Standards Being Evaluated

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (ASC Topic 842). The new guidance maintains two classifications of leases: finance leases, which replace capital leases, and operating leases. Lessees will need to recognize a right-of-use asset and a lease liability on the balance sheet for those leases previously classified as operating leases under the old guidance. The liability will be equal to the present value of lease payments. The asset will be based on the liability, subject to adjustment, such as for direct costs. The accounting standard will be effective for the Company beginning January 1, 2022. The Company is currently evaluating this guidance and assessing the overall impact on its financial statements.

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, 2022 with early adoption permitted. The Company is currently evaluating this guidance and assessing the overall impact on its 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 fair values of outstanding borrowings, which are classified as Level 2, approximate their carrying values at March 31, 2021 and December 31, 2020, based on interest rates currently available for similar borrowings and were (in thousands):

	As of			
	March 31, 2021		December 31, 2020	
	Carrying Value	Fair Value	Carrying Value	Fair Value
Borrowings	$ 33,035	$ 33,035	$ 27,766	$ 27,766

The financial liabilities that are measured and recorded at estimated fair value on a recurring basis consist of our contingent consideration associated with our acquisition of Integrated Diagnostics, Inc. (Indi), and prior to the completion of our initial public offering in October 2020, the warrant liability, put option liability and contingent value rights granted to certain holders of our convertible preferred stock and debt instruments, which were accounted for as liabilities 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	March 31, 2021	December 31, 2020
Contingent consideration	$ 30,915	$ 29,932

The following table presents the changes in contingent consideration for the three month period ending March 31, 2021 (in thousands):

Level 3 Rollforward	
Beginning balances - January 1, 2021	$ 29,932
Changes in fair value	983
Ending balances - March 31, 2021	$ 30,915

The following table presents the changes in these financial liabilities for the three month period ending March 31, 2020 (in thousands):

	For the Three Months Ended March 31, 2020			
Level 3 Rollforward	**Contingent Consideration**	**Put Option Liability**	**Warrant Liability**	**Contingent Value Rights**
Beginning balances - January 1, 2020	$ 29,114	$ 3,261	$ 372	$ 60
Additions	—	1,996	—	—
Changes in fair value	957	—	(51)	—
Ending balances - March 31, 2020	$ 30,071	$ 5,257	$ 321	$ 60

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 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. If the gross margin target is met, the Company is required to issue 2,520,108 shares of common stock. For the six months following the achievement of the gross margin target, Indi has the option to require the Company to redeem these common shares for $37.0 million in cash over eight equal quarterly installments. If Indi elects to not exercise its option, the Company has 12 months to repurchase the common stock in two equal and consecutive quarterly cash installments totaling $37.0 million.

The significant unobservable inputs used in the measurement of fair value include the probability of successful achievement of the specified product gross margin targets, the period in which the targets are expected to be achieved, and discount rates which ranged from 12.2% to 13.5%. Significant increases or decreases in any of these inputs would result in a significantly higher or lower fair value measurement.

Contingent consideration is recorded in the balance sheets as long-term liabilities. The net change to contingent consideration during the three months ended March 31, 2021 and 2020 was an increase of $1.0 million and $1.0 million, respectively, and are recorded as operating expenses in the statements of operations.

Put Option Liability

The put option liability was valued based on the calculated returns as a result of the various discounts included in the Company’s convertible notes payable and the related probability assessments of the various settlement scenarios. During the three months ended March 31, 2020, the Company recognized an addition to the put option liability of $2.0 million in connection with a favorable conversion rate granted to holders of issued convertible debt. The put option liability was settled upon the closing of the Company’s initial public offering in October 2020 and reclassified to additional paid-in capital.

Warrant Liability

In connection with entering into the 2018 Notes (see Note 6 – *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. The estimated fair value of the warrant on the issuance date of $0.3 million was recorded as a debt discount and as a preferred stock warrant liability. Through the effective date of the Company’s initial public offering 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 initial public offering, 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. During the three months ended March 31, 2020, the Company recorded a decrease in the value of the warrant liability of $0.1 million.

Contingent Value Rights

In addition to the shares of Series F Preferred Stock that were issued in January 2016, investors who purchased more than their pro-rata amount in the financing described above received a calculated number of contingent value rights (CVRs). In connection with the Series F financing, the Company issued 3,999 CVRs originally valued at $0.5 million. One CVR represents 0.00375% of the Company's interest in the drug ficlatuzumab. The initial estimated value of the CVRs were recorded as a liability and as a reduction to the Series F proceeds. Upon receipt by the Company or a milestone, royalty, or any other type of payment from the Company's ownership rights in the drug, the Company was required to make a cash payment to the CVR holders equal to 15% of net proceeds, as defined. In September 2020, the Company exercised its opt-out right with AVEO Oncology (AVEO) for the payment of 50% of development and regulatory costs for ficlatuzumab. As a result, the CVRs were settled effective December 2, 2020. See Note 13 – *Commitments and Contingencies* for a discussion of the Co-Development Agreement with AVEO.

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):

	March 31, 2021	December 31, 2020
Lab equipment	$ 6,292	$ 5,730
Leasehold improvements	2,012	1,845
Computer equipment	871	871
Furniture and fixtures	424	424
Software	655	651
Construction in process	115	381
	10,369	9,902
Less accumulated depreciation	(6,982)	(6,724)
Total property and equipment, net	$ 3,387	$ 3,178

Depreciation expense was $0.3 million and $0.2 million for the three months ended March 31, 2021 and 2020, respectively.

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

	March 31, 2021			December 31, 2020		
	Cost	Accumulated Amortization	Net Carrying Value	Cost	Accumulated Amortization	Net Carrying Value
Intangible assets subject to amortization						
Patents	$ 1,525	$ (515)	$ 1,010	$ 1,474	$ (494)	$ 980
Purchased technology	16,900	(5,164)	11,736	16,900	(4,694)	12,206
Intangible assets not subject to amortization						
Trademarks	75	—	75	74	—	74
Total	$ 18,500	$ (5,679)	$ 12,821	$ 18,448	$ (5,188)	$ 13,260

Amortization expense related to definite-lived intangible assets was $0.5 million and $0.5 million for the three months ended March 31, 2021 and 2020, respectively. Future estimated amortization expense of intangible assets is (in thousands):

	As of March 31, 2021
Remainder of 2021	$ 1,462
2022	1,945
2023	1,941
2024	1,933
2025	1,929
2026	3,536
Total	$ 12,746

Accrued liabilities consist of the following (in thousands):

	March 31, 2021	December 31, 2020
Compensation related accruals	$ 1,831	$ 3,975
Accrued clinical trial expense	791	715
Other expenses	4,640	3,099
Total accrued liabilities	$ 7,262	$ 7,789

Note 6 – Debt

Our long-term debt consists of notes payable associated with our 2021 Term Loan, 2018 Notes and Paycheck Protection Program, each of which is described in further detail below. Long-term notes payable were as follows (in thousands):

	March 31, 2021	December 31. 2020
2021 Term Loan	$ 30,000	$ —
2018 Notes	—	24,972
Paycheck Protection Program	3,125	3,107
Unamortized debt discount and issuance costs	(90)	(313)
	33,035	27,766
Less: current maturities	2,707	11,840
Long-term notes payable	$ 30,328	$ 15,926

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, provided however, if the Company achieves a revenue milestone of at least $65 million on a trailing twelve-month basis as of the end of any calendar month ending on or prior to September 30, 2022, the interest-only period shall automatically be extended 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 Loan based on changes to the prime rate shall be effective on the effective date of any change to the prime rate.

The Company's final payment, due at maturity on March 1, 2026, shall include all outstanding principal and accrued and unpaid interest, lender fees and expenses, of which the majority will include a final payment of $2.4 million, and all other sums, if any, that shall have become due and payable hereunder with respect to the 2021 Term Loan. The $2.4 million final payment will be amortized as interest expense over the term of the loan. 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 has a trailing six month rolling minimum revenue requirement of not less than 70% of the Company's projected revenue for each such quarter. In addition, 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. 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.

2018 Notes

In February 2018, the Company issued long-term debt of $23.0 million to Innovatus Life Sciences Lending Fund (Innovatus or Lender) (the 2018 Notes). Innovatus is also a holder of the Company's common stock.

At the time of issuance, the Company paid a facility fee of $0.2 million and issued a warrant to Innovatus, with an initial estimated fair value of $0.3 million, for the purchase of 613,333 shares of Series G preferred stock. The facility fee and the estimated warrant fair value were recorded as debt discount and is amortized to interest expense over the term of the 2018 Notes. The 2018 Notes bore annual interest at 10%, of which 7.5% was payable in cash, with the remaining 2.5% added to principal through December 31, 2020. Total interest added to principal was $1.7 million as of March 31, 2021 and December 31, 2020.

On March 19, 2021, in connection with entering into the 2021 Term Loan agreement with SVB, the Company repaid all outstanding principal, accrued and unpaid interest, and prepayment fees in the amount of $25.9 million due under the 2018 Notes and contemporaneously terminated the related Loan and Security Agreement, dated as of February 23, 2018, as amended, between Innovatus and the Company. As a result of the extinguishment of the 2018 Notes, the Company recognized a loss on debt extinguishment of $0.7 million during the three months ended March 31, 2021.

Paycheck Protection Program Note Payable

In April 2020, the Company entered into a loan pursuant to the Paycheck Protection Program under the CARES Act, as administered by the U.S. Small Business Administration (the SBA). The loan, in the principal amount of $3.1 million (the PPP Loan), was disbursed by JPMorgan Chase Bank (JPM) pursuant to a Paycheck Protection Program Promissory Note and Agreement (the Note and Agreement).

The PPP Loan matures on the two-year anniversary of the funding date, April 2022, and bears interest at a fixed rate of 1.00% per annum. Monthly principal and interest payments, less the amount of any potential forgiveness (as discussed below), will commence in September 2021. The Company did not provide any collateral or guarantees in connection with the PPP Loan, nor did the Company pay any facility charge to obtain the PPP Loan. The Note and Agreement provides for customary events of default, including those relating to failure to make payment, bankruptcy, breaches of representations and material adverse effects. The Company may prepay the principal of the PPP Loan at any time without incurring any prepayment charges.

All or a portion of the PPP Loan may be forgiven by the SBA and JPM upon application by the Company. Under the CARES Act, loan forgiveness is available for the sum of documented payroll costs, covered rent payments, and covered utilities during the eight-week period beginning on the approval date of the PPP Loan. For purposes of the CARES Act, payroll costs exclude compensation of an individual employee earning more than $100,000, prorated annually. Not more than 40% of the forgiven amount may be for non-payroll costs. Forgiveness is reduced if full-time headcount declines, or if salaries and wages for employees with salaries of $100,000 or less annually are reduced by more than 25%. The Company currently intends to repay the PPP loan in accordance with the underlying terms and conditions. To the extent we elect to seek forgiveness, the Company cannot assure that the PPP Loan will be forgiven, in whole or in part. If the loan is forgiven in part or in whole, and legal release is received, the Company will reduce the liability by the amount forgiven and record a gain on extinguishment in the statements of operations.

Scheduled principal repayments (maturities) of long-term obligations as of March 31, 2021 were as follows (in thousands):

Year Ending December 31,	As of March 31, 2021
Remainder of 2021	$ 2,707
2022	416
2023	8,333
2024	10,000
2025	10,000
Thereafter	1,669
	$ 33,125

Cash paid for interest was $0.6 million and $0.1 million for the three months ended March 31, 2021 and 2020, respectively.

Note 7 - Convertible Preferred Stock

Prior to its initial public offering in October 2020, the Company had issued convertible preferred stock from time to time to fund its operations and to make acquisitions. The Company's convertible preferred stock was reported as temporary equity in the Company's balance sheet because the preferred shareholders held a majority of the Company's Board of Directors seats and as a result could have caused certain events to occur outside of the Company's control, with the result the Company could have been obligated to redeem the convertible preferred stock.

Immediately prior to the Company's initial public offering and as of March 31, 2020, the Company had issued 118,766,273 convertible preferred shares. On October 27, 2020, upon closing of the Company's initial public offering, each outstanding share of Series A-1 Preferred Stock, Series A-2 Preferred Stock, Series A-3 Preferred Stock, Series B Preferred Stock, Series C Preferred Stock, Series D Preferred Stock, Series E Preferred Stock, Series F Preferred Stock, Series G Preferred Stock and Series H Preferred Stock automatically converted into 0.1684664 share of common stock; and each share of Series B-1 Preferred Stock automatically converted into 0.196 shares of common stock. In the aggregate, all series of preferred stock were converted into 20,090,745 shares of common stock. Subsequent to the Company's initial public offering, there are no longer any series of convertible preferred stock outstanding.

Note 8 – Warrants to Purchase Convertible Preferred Stock

The Company issued warrants to purchase shares of convertible preferred stock in conjunction with the sale of certain of the convertible preferred shares and issuance of debt. At March 31, 2020 and through the closing of the Company's initial public offering in October 2020, the preferred warrants were classified as liabilities with estimated fair value remeasured at each reporting date reported within in the accompanying statements of operations.

The following table presents the activity for convertible preferred stock warrants outstanding as of March 31, 2020 (in thousands, except weighted average exercise price):

	Series E		Series G [1]	
	Warrants	Weighted Average Exercise price	Warrants	Weighted Average Exercise price
Outstanding - January 1, 2020	925	$ 5.00	613	$ 0.75
Granted	—	—	—	—
Forfeited/canceled	(91)	(5.00)	—	—
Exercised	—	—	—	—
Outstanding - March 31, 2020	834	$ 5.00	613	$ 0.75

The warrants to purchase Series E convertible preferred stock were not exercised and expired during the three months ended June 2020.

[1] On October 27, 2020, all convertible preferred stock converted to common stock at the completion of our initial public offering, and as a consequence, the warrants to purchase Series G convertible preferred stock were converted to 103,326 warrants to purchase common stock, which have an expiration date of February 23, 2028.

Note 9 – Revenue & Accounts Receivable Credit Concentration

The Company's revenue is generated from (i) diagnostic tests and (ii) assay development and testing 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 March 31,	
	2021	**2020**
Diagnostic tests	$ 27,195	$ 3,603
Services	1,671	1,493
Total revenue	$ 28,866	$ 5,096

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 $3.5 million in deferred revenue recorded at December 31, 2020, $1.2 million was recognized in revenues, and we received additional advance deposits of $0.1 million, during the three months ended March 31, 2021. The deferred revenue of $2.4 million at March 31, 2021 is expected to be recognized in revenues during 2021 as test results are delivered and services are performed.

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

	Three Months ended March 31,	
	2021	**2020**
The Big Ten Conference	58%	—
Pfizer, Inc.	—	16%
Percent of total revenue	58%	16%

In addition to the above table, we collect reimbursement on behalf of customers covered by Medicare, which accounted for 7% and 41% of the Company's total revenue for the three months ended March 31, 2021 and 2020, respectively.

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	
	March 31, 2021	**December 31, 2020**
The Big Ten Conference	66%	35%
Centura Healthcare	7%	24%
Purdue University	10%	—
Percent of total accounts receivable	83%	59%

Note 10 – Share-Based Compensation

The Company's share-based compensation awards are issued under the 2020 Equity Incentive Plan (2020 Plan) and 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 March 31, 2021, 1,112,052 shares of common stock remained available for future issuance under the 2020 Plan.

Share-Base Compensation Expense

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

	Three Months ended March 31,	
	2021	2020 (1)
Research and development	$ 268	$ —
Sales, marketing, general and administrative	1,484	—
Total	$ 1,752	$ —

(1) Includes the reversal of performance condition option expense netted against 2020 expense.

Stock Option Activity

Stock option activity during the three months ended March 31, 2021, excluding the Bonus Option Program described below, was (in thousands, except weighted average exercise price and weighted average contractual life):

	Number of Options	Weighted Average Exercise Price	Weighted Average Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding - January 1, 2021	2,321	$ 1.82	7.4	$ 42,580
Granted	858	20.55	9.9	285
Forfeited/canceled	(62)	0.23	—	—
Exercised	(209)	1.96	—	—
Outstanding - March 31, 2021	2,908	$ 7.36	8.1	$ 37,655
Exercisable - March 31, 2021	1,294	$ 3.97	7.0	$ 21,149

Restricted Stock Units and Restricted Stock Activity

As of March 31, 2021, there were 79,104 restricted stock units outstanding, with a weighted average grant date fair value of $6.83 per share.

The remaining unrecognized stock-based compensation expense for options and RSUs was approximately $8.1 million as of March 31, 2021, and is expected to be amortized to expense over the next 4.8 years.

Bonus-to-Options Program

As of March 31, 2021, there were 424,145 options outstanding under the Bonus-to-Options Program (Bonus Option Program). These options are fully-vested and have a weighted average exercise price of $17.33 per share and an intrinsic value of approximately $1.3 million as of March 31, 2021. During the three months ended March 31, 2021, 265,615 options with a weighted average exercise price of $20.67 and a remaining weighted average contractual life of 9.9 years were granted, and the Company received $65,440 of proceeds upon the exercise of 14,699 options. The Company accrued $0.5 million during the three month period ended March 31, 2021 related to the estimate of the 2021 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 initial offering period began January 1, 2021 and continues through August 31, 2021. As of March 31, 2021, no shares have been issued under the ESPP.

Note 11 – Earnings Per Share

Basic earnings per share (EPS) excludes dilution and is computed by dividing net loss attributable to the Company's 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. The number of common shares issuable upon assumed conversion of convertible debt was based on the Company's estimated common stock price as of March 31, 2020, as determined by the Company's Board of Directors with assistance from a valuation firm.

Basic and diluted loss per share for the three months ended March 31, 2021 and 2020 were (in thousands, except per share amounts):

	Three Months ended March 31,	
	2021	**2020**
Numerator		
Net loss attributable to common stockholders	$ (6,961)	$ (9,705)
Denominator		
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	26,604	261
Net loss per share, basic and diluted	$ (0.26)	$ (37.18)

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

	Three Months ended March 31,	
	2021	**2020**
Options to purchase common stock	2,908	1,645
Convertible preferred stock	—	119,257
Warrants	103	1,448
Restricted stock units	79	26
Convertible debt	—	34,431
Total	3,090	156,807

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 months ended March 31, 2021 and 2020.

Note 13 – Commitments and Contingencies

Leases

The Company leases facilities under non-cancelable operating leases. Rent expense was $0.3 million and $0.6 million for the three months ended March 31, 2021 and 2020, respectively.

Future minimum lease payments for operating lease obligations are as follows (in thousands):

Year Ending December 31,	**As of March 31, 2021**
Remainder of 2021	$ 75
2022	724
2023	112
	$ 911

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). The Company and AVEO will share equally in the costs of the NSCLC POC Trial, and each will 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 with each responsible for 50% of development and regulatory costs.

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 Company had $0.3 million in remaining obligations related to the AVEO agreement as of March 31, 2021. 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.

Expenses related to this agreement for the three months ended March 31, 2021 and 2020 were zero and $0.6 million, respectively.

License Agreement

In August 2019, we entered into a non-exclusive license agreement with Bio-Rad Laboratories, Inc. (Bio-Rad) (the Bio-Rad License). Under the terms of the Bio-Rad License, the Company received a non-exclusive license, without the right to grant sublicenses, to utilize certain of Bio-Rad's intellectual property, machinery, materials, reagents, supplies and know-how necessary for the performance of Droplet Digital PCR™ (ddPCR) in cancer detection testing for third parties in the United States. The Company also agreed to purchase all of the necessary supplies and reagents for such testing exclusively from Bio-Rad, pursuant to a separately executed supply agreement (the Supply Agreement) with Bio-Rad. As further consideration for the non-exclusive license, the Company agreed to pay a royalty of 2.5% on the net revenue received for the performance of such ddPCR testing collected from third parties. 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. Royalty expense under the Bio-Rad License for the three months ended March 31, 2021 and 2020 were not significant.

Revenue Share Agreement

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 revenue share 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. Revenue share expenses of $0.2 million and $74,400 were incurred for the three months ended March 31, 2021 and 2020, 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 March 31, 2021 (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, 2020 (Form 10-K) and the Condensed Financial Statements as of March 31, 2021 and 2020 and for the three months then ended, 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" 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, 2020, which was filed on March 16, 2021.

The following MD&A discussion is provided to supplement the Condensed Financial Statements as of March 31, 2021 and 2020 and for the three 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 months ended March 31, 2021 and 2020 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 agnostic 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 platform, the Diagnostic Cortex®, 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 technology agnostic 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 over 150,000 samples and 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 six 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 and VeriStrat tests, marketed as part of the Biodesix Lung Reflex 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 tumor profiling test and the VeriStrat immune profiling test now have a less than 36-hour average turnaround time, down from the previous 72-hour average turnaround time, providing physicians with timely results to facilitate treatment decisions. 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 Clinical Laboratory Improvement Amendments (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. 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. Using the Bio-Rad SARS-CoV-2 ddPCR test and the Platelia SARS-CoV-2 Total Ab test, we operate and have commercialized the Biodesix WorkSafe testing program.

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 on-boarding 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.

These tests 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. 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. Additionally, we have overseen and managed onsite testing and validating testing for the Big Ten Conference athletic competitions.

In addition to the six 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 50 biopharmaceutical customers and academic partners. All of our diagnostic testing is performed at one of our two accredited, high-complexity clinical laboratories in Boulder, Colorado and De Soto, Kansas.

Since our inception, we have performed over 450,000 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 customers 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.

We have funded our operations to date principally from net proceeds from an initial public offering 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 $55.3 million and $62.1 million as of March 31, 2021 and December 31, 2020, respectively.

Factors Affecting Our Performance

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

- **Testing volume and customer mix.** Our revenues and costs are affected by the volume of testing and mix of customers from period to period. We evaluate both the volume of our commercial tests, or the number of tests that we perform for patients on behalf of clinicians, as well as tests for biopharmaceutical companies. Our performance depends on our ability to retain and broaden adoption with existing customers, as well as attract new customers. We believe that the test volume we receive from clinicians and biopharmaceutical companies are indicators of growth in each of these customer verticals. Customer mix for our tests has the potential to significantly impact our results of operations, as the average selling price for biopharmaceutical sample testing is currently significantly greater than our average selling price for clinical tests since we are not a contracted provider for, or our tests are not covered by all clinical patients' insurance. We evaluate our average selling price for tests that are covered by Medicare, Medicare Advantage and commercial payers to understand the trends in reimbursement and apply those trends to our revenue recognition policies. Our operating revenues and costs significantly increased beginning in 2020 due to the increase in demand for COVID-19 testing.
- **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. 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 fourth quarter 2020, seeks to further demonstrate the efficacy of the Nodify XL2 and Nodify CDT test. A secondary focus of our studies is understanding the economic impact of our tests in guiding treatment choices 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. 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, we expect to support a growing number of investigations and clinical trials. If our relationships expand, we believe we may have opportunities to offer our platform for companion diagnostic development, novel target discovery and validation efforts, and to grow into other commercial opportunities. For example, we believe our multi-omic data including genomic and proteomic data, in combination with clinical outcomes or claims data, has revenue-generating potential, including for novel target identification and companion diagnostic discovery and development.

- **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. As a result of the successful capital raise associated with our initial public offering, we plan to invest heavily in the field sales force to increase the total number of sales representatives 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. Furthermore, as testing volumes increased over the last twelve months for our COVID-19 testing program, we hired additional project support members to assist us in managing testing capacity.

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, 2020 for more information.

COVID-19 Pandemic

The COVID-19 pandemic has disrupted, and we expect will 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. Employees who can perform their duties remotely are asked to work from home and those on site are asked to follow our social distance guidelines. Our sales, marketing and business development efforts have also been constrained by our operational response to the COVID-19

pandemic due to travel restrictions. We expect to continue to adjust our operational norms to help slow the spread of COVID-19 in the coming months, including complying with government directives and guidelines as they are modified and supplemented.

The COVID-19 pandemic negatively affected, and we expect will continue to negatively affect, our lung diagnostic testing-related revenue and our clinical studies. For example, cancer patients may have more limited access to hospitals, healthcare providers and medical resources as they take steps to control the spread of COVID-19. Our biopharmaceutical customers are facing challenges in recruiting patients and in conducting clinical trials to advance their pipelines, for which our tests could be utilized. As a result of the COVID-19 pandemic, beginning in the latter half of March 2020, we saw a decline in business with existing and new biopharmaceutical customers. We began to see recovery during the fourth quarter 2020 as our delivered tests exceeded first quarter 2020 delivered tests and we expect to continue to see the recovery extending through 2021. Further, our clinical studies, such as our ongoing INSIGHT and ALTITUDE studies, as well as our arrangements including contracted clinical trials with our biopharmaceutical customers, are expected to take longer to complete than what we expected before the outbreak of the COVID-19 pandemic. While our biopharmaceutical revenue for the first quarter 2021 grew in comparison to the first quarter 2020, we are continuing to experience delays in clinical trials from across the country and world due to COVID-19 restrictions through the first quarter of 2021; however, we expect further improvement in our biopharmaceutical activities during the latter half of 2021.

Conversely, we are also experiencing a substantial increase in revenues related to an increase in the demand for our Biodesix WorkSafe testing program, our COVID-19 testing program. As expected, our costs to provide testing and services for COVID-19 testing increased for the first quarter of 2021 compared to the fourth quarter 2020 and the revenue that we generated from this expansion represented a significant portion of our revenue for this period. However, 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. If the pandemic were to dissipate, whether due to a significant decrease in new infections, due to acquiring herd immunity based on previous natural infection, and the availability and rapid distribution of vaccines, the evolution of variant strains that impact diagnostic test performance, or otherwise, the need for COVID-19 testing could decrease significantly and this could have an adverse effect on our results of operations and profitability. As a result, the increase in revenue due to any increase in demand for these diagnostic tests may not be indicative of our future revenue. See Part I, Item 1A “Risk Factors” of our Form 10-K for the year ended December 31, 2020 for a description of how the COVID-19 pandemic may adversely affect our business, financial condition and results of operations.

First Quarter 2021 Financial and Operational Highlights

The Company grew revenue in all lines of business as compared to the first quarter 2020. We generated record revenue during the three months ended March 31, 2021 of $28.9 million, representing an increase of 466% as compared to the three months ended March 31, 2020, which was primarily driven from the entry into COVID-19 testing subsequent to the first quarter 2020. The following were significant developments affecting our business, capital structure and liquidity during the three months ended March 31, 2021:

- As of March 31, 2021, we held cash and cash equivalents of $55.3 million, and successfully enhanced our financial flexibility through a new $30 million term loan while contemporaneously extinguished our 2018 Notes for $25.9 million;
- Recorded COVID-19 testing revenue of $23.2 million;
- Recorded 10% revenue growth in lung diagnostic testing for the three months ended March 31, 2021 as compared to the three months ended March 31, 2020;
- Recorded 12% revenue growth in biopharmaceutical service revenue for the three months ended March 31, 2021 as compared to the three months ended March 31, 2020;
- Announced our partnership with GenScript Biotech Corporation. to conduct performance verification in our laboratory, and to commercialize their FDA EUA authorized cPass SARS-CoV-2 Neutralization Antibody test;
- Announced plans to add a blood-based 52 gene Next Generation Sequencing (NGS) test with 72-hour average turnaround time to our portfolio of molecular testing;
- Expanded our COVID-19 testing programs to include Chicago Public Schools to help safely return back to schools.

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) 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 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 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 goods for biopharma 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 Integrated Diagnostics, Inc. (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 is assessed at each balance sheet date and changes, if any, to the fair value are recognized as operating expenses within the statement of operations. The estimated fair value of the contingent consideration is based upon significant assumptions including probability of successful achievement of a product gross margin target, the estimated timing in which the gross margin target is achieved, and discount rates. The estimated fair value could materially differ from actual values or fair values determined using different assumptions.

Non-Operating Expenses

Interest Expense and Interest Income

Interest expense consists of cash and non-cash interest from our 2021 Term Loan, the 2018 Notes, Paycheck Protection Program loan, and convertible debt. Our convertible debt, along with the related accrued interest, was automatically converted to 1,848,280 shares of our common stock upon completion of our initial public offering in October 2020. 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 March 31,		Change	
	2021	2020	$	%
Revenues	$ 28,866	$ 5,096	$ 23,770	466%
Operating expenses:				
Direct costs and expenses	18,218	1,581	16,637	1,052%
Research and development	3,321	2,900	421	15%
Sales, marketing, general and administrative	11,927	8,080	3,847	48%
Change in fair value of contingent consideration	983	957	26	3%
Total operating expenses	34,449	13,518	20,931	155%
Loss from operations	(5,583)	(8,422)	2,839	(34)%
Other income (expense):				
Interest expense	(651)	(1,457)	806	(55)%
Change in fair value of warrant liability	—	51	(51)	(100)%
Loss on debt extinguishment	(728)	—	(728)	100%
Other income, net	1	123	(122)	(99)%
Total other expense	(1,378)	(1,283)	(95)	7%
Net loss	$ (6,961)	$ (9,705)	$ 2,744	(28)%

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):

	Three Months Ended March 31,		Change	
	2021	2020	$	%
Diagnostic revenue	$ 27,195	$ 3,603	$ 23,592	655%
Services revenue	1,671	1,493	178	12%
Total revenue	$ 28,866	$ 5,096	$ 23,770	466%

Total revenue was $28.9 million for the three months ended March 31, 2021 compared to $5.1 million for the three months ended March 31, 2020, an increase of $23.8 million, or 466%.

Diagnostic test revenue increased to $27.2 million for the three months ended March 31, 2021 compared to $3.6 million for the three months ended March 31, 2020, a net increase of $23.6 million or 655%. This increase was due to $23.2 million of revenue from our two COVID-19 diagnostic tests, which were released in the second quarter of 2020, and an increase in our lung diagnostic tests of $0.4 million as health care practitioners, including pulmonologists, were increasingly diverted to pandemic-related care. However, we began to see recovery during the fourth quarter 2020, in lung diagnostic testing as our delivered tests exceeded first quarter 2020 delivered tests and we expect to continue to see the recovery extending through 2021. In addition, company sales efforts continued to be impacted by COVID-19 pandemic related restrictions.

Services revenue increased to $1.7 million for the three months ended March 31, 2021, compared to $1.5 million for the three months ended March 31, 2020, an increase of $0.2 million or 12%, as we scaled up our pharmaceutical collaboration business.

Operating Expenses

Direct costs and expenses

Direct costs and expenses related to revenue were $18.2 million for the three months ended March 31, 2021 compared to $1.6 million for the three months ended March 31, 2020, an increase of $16.6 million or 1,052%. The increase in direct costs and expenses were primarily driven by costs associated with the delivery of our COVID-19 tests, which were not present during the three month period ended March 31, 2020, slightly offset by a decrease of $0.2 million associated with the delivery of our lung diagnostic tests.

Research and Development

Research and development expenses were $3.3 million for the three months ended March 31, 2021 as compared to $2.9 million for the three months ended March 31, 2020, an increase of $0.4 million, or 15%. The increase in cost was due primarily to increased employee compensation and benefits costs as we expanded our research and development personnel.

The following table summarizes our external and internal costs for the three months ended March 31, 2021 and 2020 (in thousands, except percentages).

	Three Months Ended March 31,		Change	
	2021	2020	$	%
External expenses:				
Clinical trials and associated costs	$ 710	$ 345	$ 365	106%
Other external costs	983	1,260	(277)	(22%)
Total external costs	1,693	1,605	88	5%
Internal expenses	1,628	1,295	333	26%
Total research and development expenses	$ 3,321	$ 2,900	$ 421	15%

Sales, Marketing, General and Administrative

Sales, marketing, general and administrative expenses were $11.9 million for the three months ended March 31, 2021 compared to $8.1 million for the three months ended March 31, 2020, an increase of $3.8 million, or 48%. This increase was driven primarily by increases in employee compensation and benefits of $1.6 million associated with expansion of the Company's workforce, increased share-based compensation expense, and increases in non-employee costs, legal and other fees as a result of the transition from private to a public company.

Change in Fair Value of Contingent Consideration

Change in fair value of contingent consideration was approximately $1.0 million for both the three month periods ended March 31, 2021 and 2020, representing only a slight increase year-over-year. The amounts recorded for change in fair value reflect the passage of time, as well as estimates regarding the period in which targets that trigger the payment of contingent consideration will be achieved and subsequently paid.

Interest Expense

Interest expense was $0.6 million for the three months ended March 31, 2021 compared to $1.5 million for the three months ended March 31, 2020, a decrease of $0.9 million, or 55%. This decrease was due primarily to the decrease of interest expense related to convertible notes, which were converted to common stock upon the successful completion of our initial public offering in October 2020. Cash and non-cash interest expense for the three months ended March 31, 2021 and 2020 was $0.6 million and none, and $0.1 million and $1.4 million, respectively.

Loss on Debt Extinguishment

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 debt extinguishment of $0.7 million during the three month period ended March 31, 2021.

Change in Fair Value of Warrant Liability

During the three months ended March 31, 2020, we recognized a charge for the change in estimated fair value of our warrant liability related to warrants issued in connection with our Series G preferred stock. Effective with the closing of our initial public offering in October 2020, the warrants to purchase Series G preferred stock were automatically converted to warrants to acquire common stock and the carrying value of the warrants of $1.6 million were reclassified to additional paid-in capital.

Other Income, net

Other income, net, during the three months ended March 31, 2021 and 2020 was insignificant and $0.1 million, respectively, a decrease of $0.1 million or 99%. The $0.1 million decrease is primarily attributable to a reduction in sublease income from two subleases that expired in the second and third quarter of 2020.

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 operating activities primarily through financing activities, which include both debt and equity offerings. In October 2020, we completed an initial public offering, resulting in net proceeds of approximately $63.8 million after deducting offering costs, underwriting discounts and commissions. 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. In addition, 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 has a trailing six-month rolling revenue requirement of not less than 70% of the Company's projected revenue for each such quarter set forth in the Company's annual projections. As of March 31, 2021 the Company was not in default under the terms of the 2021 Term Loan.

As of March 31, 2021 we held cash and cash equivalents of $55.3 million. We believe that our existing cash, cash equivalents, and cash generated from sales of our products and services will be sufficient to meet our anticipated needs for at least the next 12 months from the date of this Quarterly Report on Form 10-Q, including amounts due under our PPP loan. The Company currently intends to repay the PPP loan in accordance with the underlying terms and conditions.

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. We may raise additional capital through the issuance of additional equity financing, debt financings or other sources. If this financing is not available to us at adequate levels, we may need to reevaluate our operating plans. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Cash Flows

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

	Three Months Ended March 31,	
	2021	**2020**
Net cash flows (used in) provided by:		
Operating activities	$ (11,326)	$ (4,537)
Investing activities	(516)	(392)
Financing activities	4,951	6,420
Net (decrease) increase in cash and cash equivalents and restricted cash	$ (6,891)	$ 1,491

Our cash flows resulted in a net decrease in cash and cash equivalents of $6.9 million during the three months ended March 31, 2021 as compared to the net increase in cash of $1.5 million for the three month period ended March 31, 2020. For the three months ended March 31, 2021, net cash used in operating activities increased by approximately $6.8 million, primarily due to a year-over-year reduction in net loss of $2.7 million and non-cash adjustments to net loss of $1.9 million, offset by an increase in cash used by net operating assets and liabilities of $11.4 million.

Net cash used in investing activities during the three months ended March 31, 2021 totaled $0.5 million, an increase of $0.1 million compared to the same period in 2020. The increase in net cash used in investing activities was primarily due to purchases of property and equipment in support of our operations.

Net cash provided by financing activities during the three months ended March 31, 2021 totaled $5.0 million, a decrease of $1.5 million compared to the same period in 2020. The net cash provided by financing activities for the three months ended March 31, 2021 primarily resulted from the net proceeds from our 2021 Term Loan, offset in part by the extinguishment costs and repayment of our 2018 Notes. The net cash provided by financing activities for the three months ended March 31, 2020 of $6.4 million primarily resulted from proceeds from the issuance of convertible notes.

Contractual Obligations and Commitments

As a result of the closing of our 2021 Term Loan and repayment of our 2018 Notes, our non-cancelable contractual obligations and commitments for borrowings and interest as presented in our Form 10-K have been modified. The following table provides an update as follows as of March 31, 2021 (in thousands):

	Payments due by period				
	Total	Less than 1 year	1 to 3 years	4 to 5 years	More than 5 years
Borrowings and interest [1]	$ 41,854	$ 4,264	$ 4,789	$ 32,801	$ —

[1] Includes the (a) 2021 Term Loan payments of principal, interest and final payment fee of $2.4 million payment due upon loan maturity and (b) principal and interest payable under the Paycheck Protection Program loan.

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, 2020.

In connection with the purchase transaction of Integrated Diagnostics, Inc., (Indi or Seller) we recorded contingent consideration pertaining to the amounts potentially payable to Indi's shareholder pursuant to the terms of the asset purchase agreement. The estimated fair value of contingent consideration is assessed at each balance sheet date and changes, if any, to the fair value are recognized as operating expenses within the statement of operations. The estimated fair value of the contingent consideration is based upon significant assumptions including probability of successful achievement of the performance targets, the estimated timing in which the performance targets is achieved, and discount rates. The estimated fair value could materially differ from actual values or fair values determined using different assumptions. Under the terms of the arrangement, the amount due to the Seller upon exercise of the Seller put option is dependent upon achievement of the specified performance targets. To the extent the performance targets are achieved and the Seller exercises the put option, the Company would be required to repurchase shares of Company common stock for approximately $37.0 million, payable over eight quarters in accordance with the underlying agreement.

Off-Balance Sheet Arrangements

As of March 31, 2021, 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 primarily relate to our fair value estimates, and are described in greater detail in Note 1 to our condensed financial statements in Part 1 of this Quarterly Report on Form 10-Q.

Revenue Recognition

We recognize revenue upon delivery of promised diagnostic test results and testing services, in an amount that reflects the consideration which we expect to receive in exchange for our 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 service 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. Testing services revenues are recognized upon completion of our performance obligation to deliver testing results for assay development and testing services.

Change in Fair Value of Contingent Consideration

In connection with the purchase transaction with Indi, we recorded contingent consideration pertaining to the amounts potentially payable to Indi's shareholder pursuant to the terms of the asset purchase agreement. The fair value of contingent consideration is assessed at each balance sheet date and changes, if any, to the fair value are recognized as operating expenses within the statements of operations.

The estimated fair value of the contingent consideration is based upon significant assumptions including probabilities of successful achievement of product gross margin targets, the estimated timing in which achievement of the product gross margin target is expected, and discount rates. The estimated fair value could materially differ from actual values or fair values determined using different assumptions.

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 unit option awards 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. Following the completion of our initial public offering, our Board of Directors has determined 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.

Prior to our initial public offering in October 2020, the fair value of our common stock was determined by our Board of Directors in accordance with the methodologies outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation Practice Aid (Practice Aid). In doing so, our Board of Directors determined the best estimate of fair value of our common stock, exercising reasonable judgment and considering numerous objective and subjective factors, by first determining the enterprise value of our business, and then allocating the value among the various classes of our equity securities to derive a per share value of our common stock.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (ASC Topic 842). The new guidance maintains two classifications of leases: finance leases, which replace capital leases, and operating leases. Lessees will need to recognize a right-of-use asset and a lease liability on the balance sheet for those leases previously classified as operating leases under the old guidance. The liability will be equal to the present value of lease payments. The asset will be based on the liability, subject to adjustment, such as for direct costs. The accounting standard will be effective for the Company beginning January 1, 2022. The Company is currently evaluating this guidance and assessing the overall impact on its financial statements.

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, 2022 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, marketable securities and our indebtedness. 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.

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. As of March 31, 2021, 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 March 31, 2021, that have materially affected, or are reasonable likely to materially effect, our internal controls over financial reporting.

This Quarterly Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

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.

In addition to the information set forth elsewhere in this Form 10-Q, you should carefully consider the factors we previously disclosed in our Annual Report on Form 10-K, filed with the SEC on March 16, 2021, as of and for the year ended December 31, 2020. These risks could materially and adversely affect our business, financial condition and results of operations.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

† Previously filed.

\+ Management contract or compensatory plan.

SIGNATURE

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

Biodesix, Inc.

Date: May 11, 2021

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

Exhibit 31.1

SECTION 302 CERTIFICATION

I, Scott Hutton, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Biodesix, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [Paragraph omitted in accordance with Exchange Act Rule 13a-14(a)];

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2021

By: /s/ Scott Hutton

Scott Hutton

Chief Executive Officer

Exhibit 31.2

SECTION 302 CERTIFICATION

I, Robin Harper Cowie, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Biodesix, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [Paragraph omitted in accordance with Exchange Act Rule 13a-14(a)];

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2021

By: /s/ Robin Harper Cowie

Robin Harper Cowie

Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO

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

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Biodesix, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2021 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: May 11, 2021

By: /s/ Scott Hutton
Scott Hutton
Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO

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

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Biodesix, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2021 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: May 11, 2021

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