

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

May 11, 2021

Date of Report (Date of earliest event reported)

Biodesix, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39659
(Commission
File Number)

20-3986492
(I.R.S. Employer
Identification No.)

2970 Wilderness Place, Suite 100
Boulder, Colorado
(Address of Principal Executive Office)

80301
(Zip Code)

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

Not Applicable

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

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

Item 2.02. Results of Operations and Financial Condition.

On May 11, 2021, Biodesix, Inc. (the “Company”) issued a press release announcing the financial and operating results of the Company for the first quarter ended March 31, 2021. A copy of the press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

The information contained in Item 2.02 to this Current Report on Form 8-K and Exhibit 99.1 attached hereto is furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such document or filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

No.	Exhibit
99.1	Press Release issued by Biodesix, Inc. dated May 11, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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

Dated: May 11, 2021

BIODESIX, INC.

By: /s/ Robin Harper Cowie

Name: Robin Harper Cowie

Title: Chief Financial Officer



Biodesix Announces First Quarter 2021 Results

*First Quarter 2021 Record Revenue of Approximately \$28.9 Million Representing 466% Growth over First Quarter 2020
Announced Plans to Launch Two New Diagnostic Tests - SARS-CoV-2 Neutralization Antibody Detection Test and Next
Generation Sequencing Test*

BOULDER, CO, May 11, 2021 – [Biodesix, Inc.](#) (Nasdaq: BDSX), a leading data-driven diagnostic solutions company with a focus in lung disease, today announced financial and operating results for the first quarter ended March 31, 2021 and provided a corporate update.

“We were pleased with our strong operating and financial performance in the first quarter and believe we are off to a solid start in 2021,” said Scott Hutton, Chief Executive Officer. “We are encouraged by the trends in our core lung diagnostic testing. Additionally, Biodesix continues to innovate as demonstrated through our announcement of two new products and we are well-positioned for the future.”

First Quarter 2021 Financial Results

- Successfully secured additional liquidity and deferred principal repayments through February 2024 by closing a new \$30.0 million term loan and retiring the prior term loan for \$25.9 million;
 - Total revenue of \$28.9 million, an increase of 466% over first quarter 2020 and 7% over fourth quarter 2020;
 - COVID-19 testing revenue of \$23.2 million, an increase of 8% over fourth quarter 2020;
 - Lung diagnostic revenue of \$4.0 million, representing continued recovery and growth of 10% over first quarter 2020 and 8% over fourth quarter 2020;
 - Services revenue of \$1.7 million, an increase of 12% over first quarter 2020 and 12% decline over fourth quarter 2020;
 - Gross profit of \$10.6 million and gross margin percentage of 37%, both aligned with management expectations, primarily as a result of growth in COVID-19 testing;
 - Operating expenses (excluding direct costs and expenses) of \$16.2 million, which includes an investment in the planned expansion of our salesforce, increased 36% over first quarter 2020 and 8% over fourth quarter 2020;
 - Non-cash stock compensation expense of \$1.8 million, \$0 and \$3.7 million recognized during first quarter 2021, first quarter 2020 and fourth quarter 2020, respectively; and
 - Net loss of \$7.0 million, an improvement of 28% over first quarter of 2020 and a 54% increase over fourth quarter 2020.
-



Business Highlights

Biodesix continues to make significant progress in lung diagnostics testing, including the addition of a new test to the lung cancer testing portfolio as well as new data that continues to support the value and utility of the Biodesix lung diagnostics portfolio. As a result of on-going progress, the Company was pleased to announce the following:

- Plans to add a blood-based 52-gene next generation sequencing (NGS) test to the portfolio were announced in April 2021. The NGS test has unprecedented turnaround time of only 72-hours, according to data presented in a recent publication in *Diagnostics*. The NGS test will complement the improved 36-hour turnaround time that the GeneStrat® ddPCR and VeriStrat® tests currently offer, providing expanded coverage of 52-genes and broader molecular markers. The test will be used for advanced, late-stage, or recurrent cancer mutation detection in non-small cell lung cancer (NSCLC) and is expected to begin to be offered to physicians in the first half of 2022.
- The issuance of two U.S. patents in April 2021 that enhance the Company's ability to develop blood-based immunotherapy and other pipeline testing strategies for cancer patients.
- Presentation of data from three studies at the American Association for Cancer Research (AACR) Annual Meeting in April 2021, including data from VeriStrat® and the Primary Immune Response (PIR) test that further demonstrate the utility of protein biomarker data from blood-based proteomic testing to support targeted and immunotherapy treatment strategies for NSCLC patients.

Beyond advancements in the lung diagnostic portfolio, the Company continued to expand and progress its partnerships and services related to COVID-19 testing, including the following:

- In April 2021, announced a partnership with GenScript Biotech to conduct performance verification of the cPass™ SARS-CoV-2 Neutralization Antibody Detection test in our laboratory, with expected commercial launch in mid-year 2021. The test is the first and only surrogate neutralizing antibody test with FDA Emergency Use Authorization (EUA) to date and uses ELISA technology to qualitatively detect circulating neutralizing antibodies to the receptor binding domain (RBD) in the spike protein of SARS-CoV-2 that are produced in response to vaccination or previous SARS-CoV-2 infection.
 - In February 2021, announced a partnership with the Chicago Public Schools to provide antigen and Droplet Digital PCR (ddPCR)™ testing for Chicago Public School teachers and staff.
 - In January 2021, collaborated with the Purdue University Protect Purdue Health Center, to test students taking classes on the West Lafayette, Indiana Campus living off-campus during the Spring 2021 semester.
-



Conference call and webcast information

Management will host an investor conference call and webcast today, May 11, 2021 at 4:30 p.m. Eastern Time.

Investor dial-in (domestic):	833-665-0678
Investor dial-in (international):	929-517-0173
Conference ID:	4089648
Webcast:	https://edge.media-server.com/mmc/p/366fz

An archived replay of the webcast will be available on the Company's website for a period of 90 days.

About Biodesix

Biodesix is a leading data-driven diagnostic solutions company with a focus in lung disease. The Company develops diagnostic tests addressing important clinical questions by combining multi-omics through the power of artificial intelligence. Biodesix is the first company to offer six non-invasive tests for patients with diseases of the lung. Biodesix launched the SARS-CoV-2 ddPCR™ test and the Platelia SARS-CoV-2 Total Ab in response to the global pandemic and virus that impacts the lung and causes COVID-19. The blood based Biodesix Lung Reflex® strategy for lung cancer patients integrates the GeneStrat® and VeriStrat® tests to support treatment decisions with results in 72 hours, expediting time to treatment. The blood based Nodify Lung™ nodule risk assessment testing strategy, consisting of the Nodify XL2® and the Nodify CDT™ tests, evaluates the risk of malignancy in incidental pulmonary nodules, enabling physicians to better triage patients to the most appropriate course of action. Biodesix also collaborates with many of the world's leading biotechnology and pharmaceutical companies to solve complex diagnostic challenges in lung disease. For more information about Biodesix, visit biodesix.com.

Note Regarding Forward-Looking Statements

This press release may contain forward-looking statements that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements contained in this press release other than statements of historical fact, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "plan," "expect," "predict," "potential," "opportunity," "goals," or "should," and similar expressions are intended to identify forward-looking statements. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors. Biodesix has based these forward-looking statements largely on its current expectations and projections about future events and trends. These forward-looking statements are subject to a number of risks, uncertainties and assumptions. Forward-looking statements may include information concerning the impact of the



COVID-19 pandemic on Biodesix and its operations, it is possible or assumed future results of operations, including descriptions of its revenues, profitability, outlook and overall business strategy. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Factors that could cause actual results to differ materially from those contemplated in this press release can be found in the Risk Factors section of Biodesix's most recent annual report on Form 10-K, filed March 16, 2021. Biodesix undertakes no obligation to revise or publicly release the results of any revision to such forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. All forward-looking statements are qualified in their entirety by this cautionary statement.

Contacts:

Media:

Bobbi Coffin

bobbi.coffin@biodesix.com

(303) 892-3203

Investors:

Chris Brinzey

chris.brinzey@westwicke.com

(339) 970-2843



Biodesix, Inc.
Condensed Balance Sheets (unaudited)
(in thousands)

	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



Biodesix, Inc.
Condensed Statements of Operations (unaudited)
(in thousands, except share data)

	Three Months Ended	
	March 31, 2021	March 31, 2020
Revenues		
COVID-19	\$ 23,232	\$ —
Lung diagnostic	3,963	3,603
Diagnostic testing revenue	27,195	3,603
Biopharma services	1,671	1,493
Total revenues	28,866	5,096
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