

**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**

November 15, 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 November 15, 2021, Biodesix, Inc. (the “Company”) issued a press release announcing the financial and operating results of the Company for the third quarter ended September 30, 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 November 15, 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: November 15, 2021

BIODESIX, INC.

By: /s/ Robin Harper Cowie

Name: Robin Harper Cowie

Title: Chief Financial Officer



Biodesix Announces Third Quarter 2021 Results and Highlights

Third Quarter 2021 Lung Diagnostic Revenue of \$4.5 Million Increased 51% over Third Quarter 2020

Company launches 72-hour Next Generation Sequencing (NGS) test

Conference Call and Webcast Today at 9:00 a.m. ET

BOULDER, CO, November 15, 2021 – [Biodesix, Inc.](#) (Nasdaq: BDSX), a leading data-driven diagnostic solutions company with a focus in lung disease, today announced its financial and operating results for the third quarter ended September 30, 2021 and provided a corporate update.

“The third quarter was highlighted by the growth of our core lung diagnostics and biopharma service product offerings, which grew year-over-year 51% and 133% respectively, despite the headwinds from the COVID-19 Delta variant, offset by expected reductions in COVID-19 testing from increased vaccination rates and adoption of non-laboratory testing,” said Scott Hutton, CEO of Biodesix. “Driven by the productivity from our growing sales force, and expanding body of clinical evidence supporting the value of our tests, we expect growth in core lung diagnostics testing to continue through the remainder of the year and into 2022. We are very pleased with the initial results from the ORACLE study recently presented at CHEST as they demonstrate that the Nodify XL2® test is performing as expected in the clinic, is changing physician decisions, and reducing unnecessary interventions on benign nodules. In addition to the CHEST and other data releases this quarter, we are pleased to announce that we have launched our 72-hour liquid NGS test ahead of schedule to a select group of physicians, with broad US launch still anticipated for the first quarter of 2022. Given the material progress made across all aspects of our base business this past quarter, we look forward to finishing strong through the end of 2021.”

Third Quarter 2021 Financial Results

For the three-month period ended September 30, 2021, as compared to the same period of 2020 (where applicable):

- Total revenue of \$6.5 million was driven by our core lung diagnostic revenue of \$4.5 million, an increase of 51%;
 - *Continued lung diagnostic year over year growth despite recent surges in COVID-19 Delta variant;*
 - *Lung diagnostic growth driven primarily from sales of Nodify nodule management tests and sales force expansion;*
- Services revenue of \$1.5 million, an increase of 133%;

- *Clinical trial services showed improvement and we expect further recovery in clinical trial enrollments in remainder of 2021;*
- COVID-19 testing revenue of \$0.5 million, a decline of 91%;
 - *Decline commensurate with our prior commentary on the expectation of COVID-19 testing declines, excluding any potential impact of the Biden administration COVID-19 Action Plan;*
- Gross margin was \$3.8 million or 58% as a percentage of revenue as compared to 40% in the quarter ended June 30, 2021, primarily as a result of the mix shift of sales to higher margin lung diagnostic and services;
- Operating expenses (excluding direct costs and expenses) of \$16.9 million, which includes an investment in the planned expansion of our sales force, increased 46%;
 - *Remain on track to double size of lung focused direct and dedicated sales force in 2021;*
 - *Includes non-cash stock compensation expense of \$1.4 million;*
- Recorded a non-cash gain of \$3.1 million in the period associated with our PPP loan forgiveness from the Small Business Administration;
- Net loss of \$11.5 million, an increase of 30%; and
- Cash and cash equivalents of \$47.9 million.

For a full list of Biodesix’s press releases and webinars, please visit [Biodesix.com](https://www.biodesix.com).

Conference call and webcast information

Management will host an investor conference call and webcast today, November 15, 2021 at 9:00 a.m. Eastern Time.

Investor dial-in (domestic):	833-665-0678
Investor dial-in (international):	929-517-0173
Conference ID:	9692532
Webcast:	https://edge.media-server.com/mmc/p/n9jcchdt

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 eight non-invasive tests for patients with diseases of the lung. Biodesix launched the SARS-CoV-2 ddPCR™ test, the Platelia SARS-CoV-2 Total Ab, and the cPass™ SARS-CoV-2 Neutralization Antibody test (cPass™ Neutralization Test Kit, GenScript, Inc.) 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®, GeneStrat NGS™, 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 leverages the proprietary and advanced Diagnostic Cortex® AI platform, to collaborate 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 or subsequent quarterly reports on Form 10-Q during 2021, if applicable. 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.

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

	September 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	\$ 47,913	\$ 62,126
Accounts receivable, net of allowance for doubtful accounts of \$168 and \$180	2,784	15,304
Other current assets	5,748	8,710
Total current assets	56,445	86,140
Non-current assets		
Property and equipment, net	4,432	3,178
Intangible assets, net	11,992	13,260
Other long-term assets	2,097	3,461
Goodwill	15,031	15,031
Total non-current assets	33,552	34,930
Total assets	\$ 89,997	\$ 121,070
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 1,600	\$ 8,964
Accrued liabilities	6,279	7,789
Deferred revenue	1,760	3,532
Current portion of contingent consideration	13,128	—
Current portion of notes payable	20	11,840
Total current liabilities	22,787	32,125
Non-current liabilities		
Long-term notes payable, net of current portion	29,975	15,926
Contingent consideration	19,722	29,932
Other long-term liabilities	1,480	1,921
Total non-current liabilities	51,177	47,779
Total liabilities	73,964	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; 27,020,070 (2021) and 26,561,504 (2020) shares issued and outstanding	27	27
Additional paid-in capital	304,697	299,953
Accumulated deficit	(288,691)	(258,814)
Total stockholders' equity	16,033	41,166
Total liabilities and stockholders' equity	\$ 89,997	\$ 121,070



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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues				
COVID-19	\$ 506	\$ 5,543	\$ 29,802	\$ 6,906
Lung diagnostic	4,533	3,009	13,270	8,892
Diagnostic testing revenue	5,039	8,552	43,072	15,798
Biopharma services	1,492	641	4,210	2,730
Total revenues	6,531	9,193	47,282	18,528
Direct costs and expenses	2,722	3,891	28,025	7,346
Research and development	3,293	2,706	9,937	7,713
Sales, marketing, general and administrative	13,607	7,879	36,959	22,793
Change in fair value of contingent consideration	—	957	1,622	957
Total operating expenses	19,622	15,433	76,543	38,809
Loss from operations	(13,091)	(6,240)	(29,261)	(20,281)
Other income (expense):				
Interest expense	(1,546)	(2,658)	(3,012)	(6,899)
Change in fair value of warrant liability	—	(24)	—	31
Gain on debt extinguishment, net	3,123	—	2,395	—
Other income, net	—	77	1	332
Total other expense	1,577	(2,605)	(616)	(6,536)
Net loss	\$ (11,514)	\$ (8,845)	\$ (29,877)	\$ (26,817)
Net loss per share, basic and diluted	\$ (0.41)	\$ (31.93)	\$ (1.09)	\$ (99.69)
Weighted-average shares outstanding, basic and diluted	28,051	277	27,467	269