

**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**

March 14, 2022

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 March 14, 2022, Biodesix, Inc. (the Company) issued a press release announcing the financial and operating results of the Company for the fourth quarter and year ended December 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 March 14, 2022
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: March 14, 2022

BIODESIX, INC.

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



Biodesix Announces Fourth Quarter and Year End 2021 Results and Highlights

Fourth Quarter and Fiscal Year 2021 Lung Diagnostic Revenue of \$5.4 Million and \$18.7 Million Increased 48% and 49% over the comparable 2020 periods, respectively

Full-Scale Launch of GeneStrat NGS™ Test in January 2022

Conference Call and Webcast Today at 8:30 a.m. ET

BOULDER, CO, March 14, 2022 – 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 fourth quarter and year ended December 31, 2021 (fiscal 2021) and provided a corporate update.

“Despite the ongoing challenges caused by the global pandemic, the fourth quarter and fiscal 2021 were very productive.” said Scott Hutton, CEO of Biodesix. “Most notably, we successfully executed on our revenue growth strategy by doubling our direct, dedicated sales force, which significantly contributed to our core lung diagnostic revenue growth of 48% and 49% for fourth quarter and fiscal 2021, respectively. We further executed on our third quarter 2021 commitment to a commercial launch of our GeneStrat NGS™ test in January 2022. From the clinical data standpoint, we presented new data during the fourth quarter of 2021 on our NodifyXL2® test from the prospective ORACLE study, and on our VeriStrat test from the prospective INSIGHT study. This new data truly underscores the value of both products in the real-world setting and adds to the body of evidence. We continue to be excited about the trajectory of the business, despite the challenges from the ongoing pandemic, which gives us confidence heading into 2022.”

Fourth Quarter and Full Year 2021 Financial Results

- Total revenue of \$7.2 million and \$54.5 million for the fourth quarter and fiscal 2021, respectively,
 - *Continued lung diagnostic year over year growth despite COVID-19 variant surges;*
 - Core lung diagnostic revenue of \$5.4 million and \$18.7 million for the fourth quarter and fiscal 2021, respectively, an increase of 48% and 49% over the respective prior year comparable periods;
 - *Nodify nodule management tests and sales force expansion continue to drive lung diagnostic growth;*
 - BioPharma Services revenue of \$1.4 million and \$5.6 million for the fourth quarter and fiscal 2021, respectively, a decrease of 29% and increase 20% over the respective prior year comparable periods;
 - COVID-19 testing revenue of \$0.4 million and \$30.2 million for the fourth quarter and fiscal 2021, respectively, a decrease of 98% and increase 7% over the respective comparable periods in 2020;
 - *Decline over the fourth quarter of 2020 commensurate with the shift away from lab-based testing and towards point-of-care and at-home rapid antigen testing during much of the back half of 2021;*
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- Fourth quarter 2021 gross margin of \$4.7 million or 65% as a percentage of revenue as compared to 46% in the comparable prior year period primarily driven by the mix shift of sales to higher-margin core lung diagnostics and away from lower-margin COVID-19 testing;
- Operating expenses (excluding direct costs and expenses) of \$16.4 million and \$64.9 million for the fourth quarter and fiscal 2021, an increase of 9% and 40% over the comparable prior year periods;
 - *Doubled the size of lung focused direct and dedicated sales force in 2021;*
 - *Includes non-cash stock compensation expense of \$1.3 million and \$4.9 million during fourth quarter and fiscal 2021, respectively;*
- Net loss of \$13.3 million and \$43.2 million for the fourth quarter and fiscal 2021, respectively, an increase of 193% and 38% over the respective comparable periods in 2020;
- Cash and cash equivalents of \$32.7 million, inclusive of a fourth quarter 2021 equity capital issuance of \$15.7 million in net proceeds and the prepayment of \$20 million of the 2021 Term Loan;
 - *Announced a Common Stock Purchase Agreement for up to \$50 million.*

2022 Financial Outlook

The Company anticipates generating between \$37.5 million to \$39.5 million in total revenue in 2022.

Conference call and webcast information

Management will host an investor conference call and webcast today, March 14, 2022 at 8:30 a.m. Eastern Time.

Investor dial-in (domestic):	833-665-0678
Investor dial-in (international):	929-517-0173
Conference ID:	7394339
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.

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

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 lung diseases. The blood based Nodify Lung® nodule risk assessment testing strategy, consisting of the Nodify XL2® and the Nodify CDT® tests, evaluates the risk of malignancy in incidental pulmonary nodules, enabling physicians to better triage patients to the most appropriate course of action. The blood based IQLung™ strategy for lung cancer patients integrates the GeneStrat ddPCR™ test, the GeneStrat NGS™ test and the VeriStrat® test to support treatment decisions across all stages of lung cancer with results in an unprecedented 36-72 hours, expediting time to treatment. Biodesix also leverages the proprietary and advanced Diagnostic Cortex® AI (Artificial Intelligence) platform, to collaborate with many of the world's leading biotechnology and pharmaceutical companies to solve complex diagnostic challenges in lung disease. 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. For more information about Biodesix, visit [biodesix.com](https://www.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. The Company’s ability to continue as a going concern could cause actual results to differ materially from those contemplated in this press release and additionally, other 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 14, 2022. 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)

	As of December 31,	
	2021	2020
Assets		
Current assets		
Cash and cash equivalents	\$ 32,712	\$ 62,126
Accounts receivable, net of allowance for doubtful accounts of \$158 and \$180	3,656	15,304
Other current assets	7,245	8,710
Total current assets	43,613	86,140
Non-current assets		
Property and equipment, net	4,179	3,178
Intangible assets, net	11,617	13,260
Goodwill	15,031	15,031
Other long-term assets	1,657	3,461
Total non-current assets	32,484	34,930
Total assets	\$ 76,097	\$ 121,070
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 1,662	\$ 8,964
Accrued liabilities	7,665	7,789
Deferred revenue	1,850	3,532
Current portion of contingent consideration	17,764	—
Current portion of notes payable	19	11,840
Total current liabilities	28,960	32,125
Non-current liabilities		
Long-term notes payable, net of current portion	9,993	15,926
Contingent consideration	16,028	29,932
Other long-term liabilities	1,389	1,921
Total non-current liabilities	27,410	47,779
Total liabilities	56,370	79,904
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$0.001 par value, 5,000,000 authorized; 0 (2021 and 2020) issued and outstanding	—	—
Common stock, \$0.001 par value, 200,000,000 authorized; 30,789,649 (2021) and 26,561,504 (2020) shares issued and outstanding	31	27
Additional paid-in capital	321,669	299,953
Accumulated deficit	(301,973)	(258,814)
Total stockholders' equity	19,727	41,166
Total liabilities and stockholders' equity	\$ 76,097	\$ 121,070

BIODESIX, INC.
Condensed Statements of Operations (Unaudited)
(in thousands, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Revenues				
COVID-19	\$ 425	\$ 21,434	\$ 30,227	\$ 28,340
Lung diagnostic	5,440	3,686	18,710	12,579
Diagnostic testing revenue	5,865	25,120	48,937	40,919
Biopharma services	1,359	1,908	5,569	4,638
Total revenues	7,224	27,028	54,506	45,557
Direct costs and expenses	2,493	14,652	30,518	21,998
Research and development	2,852	3,105	12,789	10,818
Sales, marketing, general and administrative	13,558	12,064	50,517	34,857
Change in fair value of contingent consideration	—	(138)	1,622	818
Total operating expenses	18,903	29,683	95,446	68,491
Loss from operations	(11,679)	(2,655)	(40,940)	(22,934)
Other (expense) income:				
Interest expense	(1,496)	(705)	(4,508)	(7,604)
Change in fair value of warrant liability	—	(1,220)	—	(1,252)
(Loss) gain on debt extinguishments, net	(97)	—	2,298	—
Other (expense) income, net	(10)	45	(9)	440
Total other expense	(1,603)	(1,880)	(2,219)	(8,416)
Net loss	\$ (13,282)	\$ (4,535)	\$ (43,159)	\$ (31,350)
Net loss per share, basic and diluted	\$ (0.49)	\$ (0.25)	\$ (1.58)	\$ (6.48)
Weighted-average shares outstanding, basic and diluted	27,063	18,431	27,365	4,838

