
**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, 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 May 11, 2022, Biodesix, Inc. (the Company) issued a press release announcing the financial and operating results of the Company for the first quarter ended March 31, 2022. 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, 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: May 11, 2022

BIODESIX, INC.

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



Biodesix Announces First Quarter 2022 Results and Highlights

*First quarter 2022 core Lung Diagnostic revenue of \$4.6 million increased 17% over the comparable period in 2021;
Continued to strengthen financial position through an additional \$27.4 million in debt and equity funding during second quarter 2022;*

Conference Call and Webcast Today at 8:00 a.m. ET

BOULDER, CO, May 11, 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 first quarter ended March 31, 2022 and provided a corporate update.

“We are pleased by the progress we continue to make with our core lung diagnostic sales revenue, which grew 17% over the first quarter 2021 despite significant disruption from the COVID-19 Omicron variant during the first half of the quarter,” said Scott Hutton, CEO of Biodesix. “We recovered quickly from the Omicron wave, and March was an all-time high in core lung diagnostic test results delivered. We also added to our therapeutic guidance portfolio with a full commercial launch of the 72-hour blood based GeneStrat NGS test, introducing flexibility in addressing individual patient and physician needs when considering the most appropriate treatment options for cancer. In addition, we successfully executed several strategic fundraising efforts to further support our growth and recovery resulting in an additional \$27.4 million in debt and equity funding subsequent to quarter end, including a restructuring of our milestone payments to Integrated Diagnostics to provide further financial flexibility.”

First Quarter 2022 Financial Results

For the three-month period ended March 31, 2022, as compared to the same period of 2021 (where applicable):

- Total revenue of \$6.5 million, an expected decrease of 77%, driven primarily by an expected year-over-year decline in COVID-19 diagnostic testing due to lower rate of testing compared to the first quarter of 2021:
 - o Core lung diagnostic revenue of \$4.6 million, an increase of 17% driven primarily by growth in the Nodify lung nodule management tests;
 - o COVID-19 testing revenue of \$1.0 million, a decrease of 96% in line with expectations as the pandemic recedes and COVID testing trends continue to move to at-home testing;
 - o BioPharma Services revenue of \$0.9 million, a decrease of 45% driven by disruptions in clinical trials world-wide by the spike in the Omicron COVID-19 variant;
 - First quarter 2022 gross margin of \$3.3 million, or 51% as a percentage of revenue as compared to 37% 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 partially offset by costs related to the commercial launch of our GeneStrat NGS™ test in January;
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- Operating expenses (excluding direct costs and expenses) of \$17.8 million, an increase of 10% driven primarily by growth in sales and marketing to fund our growth in sales and recent GeneStrat NGS commercial launch;
 - *Includes non-cash stock compensation expense of \$1.3 million as compared to \$1.8 million in the prior year quarter;*
- Net loss of \$15.6 million, an increase of 124%;
- Cash and cash equivalents of \$16.4 million as of March 31;
 - *Included payment of \$4.625 million for scheduled milestone payment in January 2022 to Integrated Diagnostics (Indi);*
- Liquidity and capital improvements subsequent to March 31, 2022:
 - *Equity proceeds of \$11.7 million from a private placement;*
 - *Equity proceeds of approximately \$2.7 million through the at-the-market facility;*
 - *Completion of \$25.0 million debt facility of which \$15.0 million (approximately \$13.0 million, net, after deducting estimated debt issuance costs and original issue discounts) funded in May 2022 and remaining amount contingently available based on contract terms;*
 - *Repayment of \$3.0 million in outstanding principal balance on Term Loan;*
 - *Restructuring of Indi milestone payments reducing required payments by approximately \$7.5 million and \$7.2 million in 2022 and 2023, respectively.*

2022 Financial Outlook

The Company reaffirms our 2022 financial outlook and expects to generate between \$37.5 million and \$39.5 million in total revenue in 2022.

Conference call and webcast information

Management will host an investor conference call and webcast today, May 11, 2022 at 8:00 a.m. Eastern Time.

Investor dial-in (domestic):	833-665-0678
Investor dial-in (international):	929-517-0173
Conference ID:	7350548
Webcast:	https://edge.media-server.com/mmc/p/bqdzbx9a

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.

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 or subsequent quarterly reports on Form 10-Q during 2022, 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)

	March 31, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	\$ 16,427	\$ 32,712
Accounts receivable, net of allowance for doubtful accounts of \$100 and \$158	3,774	3,656
Other current assets	7,032	7,245
Total current assets	27,233	43,613
Non-current assets		
Property and equipment, net	4,028	4,179
Intangible assets, net	11,131	11,617
Operating lease right-of-use assets	2,219	—
Goodwill	15,031	15,031
Other long-term assets	2,009	1,657
Total non-current assets	34,418	32,484
Total assets	<u>\$ 61,651</u>	<u>\$ 76,097</u>
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 2,120	\$ 1,662
Accrued liabilities	6,173	7,665
Deferred revenue	2,499	1,850
Current portion of operating lease liabilities	1,110	—
Current portion of contingent consideration	17,821	17,764
Current portion of notes payable	51	19
Other current liabilities	37	—
Total current liabilities	29,811	28,960
Non-current liabilities		
Long-term notes payable, net of current portion	10,055	9,993
Long-term operating lease liabilities	1,177	—
Contingent consideration	12,212	16,028
Other long-term liabilities	615	1,389
Total non-current liabilities	24,059	27,410
Total liabilities	53,870	56,370
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized; 0 (2022 and 2021) shares issued and outstanding	—	—
Common stock, \$0.001 par value, 200,000,000 shares authorized; 31,889,317 (2022) and 30,789,649 (2021) shares issued and outstanding	32	31
Additional paid-in capital	325,308	321,669
Accumulated deficit	(317,559)	(301,973)
Total stockholders' equity	7,781	19,727
Total liabilities and stockholders' equity	<u>\$ 61,651</u>	<u>\$ 76,097</u>

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

	Three Months Ended	
	March 31,	
	2022	2021
Revenues		
COVID-19	\$ 984	\$ 23,232
Lung diagnostic	4,649	3,963
Diagnostic testing revenue	5,633	27,195
Biopharma services	915	1,671
Total revenues	6,548	28,866
Direct costs and expenses	3,235	18,218
Research and development	3,206	3,321
Sales, marketing, general and administrative	14,487	11,927
Change in fair value of contingent consideration	—	983
Impairment loss on intangible assets	81	—
Total operating expenses	21,009	34,449
Loss from operations	(14,461)	(5,583)
Other (expense) income:		
Interest expense	(1,137)	(651)
Loss on debt extinguishment	—	(728)
Other income, net	12	1
Total other expense	(1,125)	(1,378)
Net loss	<u>\$ (15,586)</u>	<u>\$ (6,961)</u>
Net loss per share, basic and diluted	\$ (0.50)	\$ (0.26)
Weighted-average shares outstanding, basic and diluted	31,070	26,604

