

**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, 2023

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, 2023, Biodesix, Inc. (the Company) issued a press release announcing the financial and operating results of the Company for the first quarter ended March 31, 2023. 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, 2023
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, 2023

BIODESIX, INC.

By: /s/ Robin Harper Cowie

Name: Robin Harper Cowie

Title: Chief Financial Officer



Biodesix Announces First Quarter 2023 Results and Highlights

First quarter 2023 Core Lung Diagnostic revenue of \$8.6 million increased 86% over the comparable period in 2022;

Record number of Core Lung Diagnostic tests delivered in Company history;

Conference Call and Webcast Today at 4:30 p.m. ET

BOULDER, CO, May 11, 2023 – 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 first quarter ended March 31, 2023 and provided a corporate update.

“Throughout the quarter we continued to make excellent progress and I am pleased with the start to the year. Looking at our financial performance, we reported total revenue of \$9.1 million for the first quarter 2023, which represents growth of 38% compared to the first quarter of 2022, while core lung diagnostic revenue of \$8.6 million grew by 86% over the comparable period,” said Scott Hutton, President and Chief Executive Officer. “Importantly, the momentum seen in the first quarter and the continued growth in our core lung diagnostic testing business clearly indicates the clinical need and growing acceptance of our on-market tests.”

First Quarter 2023 Financial Results

For the three-month period ended March 31, 2023, as compared to the same period of 2022 (where applicable):

- Total revenue of \$9.1 million, an increase of 38%, driven primarily by strong year-over-year growth in core lung diagnostics:
 - o *Core lung diagnostic revenue of \$8.6 million reflected a year-over-year increase of 86% driven primarily by the continued adoption of Nodify Lung® nodule management tests;*
 - o *BioPharma Services revenue of \$0.4 million decreased 55% year-over-year. Timelines for existing and new agreements continue to be impacted by delayed enrollment in clinical trials; entered the second quarter of 2023 with continued strong dollars under contract;*
 - o *COVID-19 testing revenue decreased by 99% year-over-year, and consistent with our revenue guidance. In connection with the expected expiration of the Public Health Emergency declaration, the Company will no longer provide COVID-19 diagnostic testing services commercially;*
 - First quarter 2023 gross profit of \$5.9 million, or 65% gross margin as compared to 51% gross margin 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 \$22.3 million, an increase of approximately \$4.5 million, or 25% as compared to the first quarter 2022 (includes non-cash stock compensation expense of \$2.3 million as compared to \$1.3 million);
 - o *Approximately \$3.0 million of the increase was attributable to increased sales and marketing costs to support core lung diagnostic sales growth including growth in the sales force, increased travel-related costs, and marketing programs to enhance product awareness;*
 - o *Approximately \$1.6 million was associated with increased general and administrative expenses primarily associated with non-cash stock compensation costs;*
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- Net loss of \$18.7 million and basic and diluted net loss per share of \$0.24;
- Cash and cash equivalents of \$25.3 million as of March 31, 2023;
 - *Scheduled milestone payment of \$2.2 million paid in January 2023 to Integrated Diagnostics.*

2023 Financial Outlook

The Company reaffirms our 2023 financial outlook and expects to generate between \$52 million and \$55 million in total revenue in 2023.

Conference call and webcast information

Listeners can register for the webcast via this link. Analysts wishing to participate in the question-and-answer session should use this link. A replay of the webcast will be available via the Company's investor website approximately two hours after the call's conclusion. Those who plan on participating are advised to join 15 minutes prior to the start time.

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 offers five Medicare-covered 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 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[®] targeted ddPCR[™] test, the GeneStrat NGS[™] test and the VeriStrat[®] test to support treatment decisions across all stages of lung cancer with results in an average of two to three business days, 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. 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, its 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 6, 2023 or subsequent quarterly reports on Form 10-Q during 2023, 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, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	\$ 25,275	\$ 43,088
Accounts receivable, net of allowance for doubtful accounts of \$200 and \$118	4,901	5,065
Other current assets	4,608	5,181
Total current assets	34,784	53,334
Non-current assets		
Property and equipment, net	13,097	5,848
Intangible assets, net	9,311	9,797
Operating lease right-of-use assets	2,194	2,973
Goodwill	15,031	15,031
Other long-term assets	6,376	5,923
Total non-current assets	46,009	39,572
Total assets	\$ 80,793	\$ 92,906
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 1,563	\$ 1,685
Accrued liabilities	5,740	8,218
Deferred revenue	1,133	962
Current portion of operating lease liabilities	1,762	1,543
Current portion of contingent consideration	11,706	10,341
Current portion of notes payable	50	49
Other current liabilities	144	41
Total current liabilities	22,098	22,839
Non-current liabilities		
Long-term notes payable, net of current portion	25,084	25,004
Long-term operating lease liabilities	12,039	5,254
Contingent consideration	16,374	18,645
Other long-term liabilities	648	558
Total non-current liabilities	54,145	49,461
Total liabilities	76,243	72,300
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$0.001 par value, 5,000,000 authorized; 0 (2023 and 2022) issued and outstanding	—	—
Common stock, \$0.001 par value, 200,000,000 authorized; 77,979,376 (2023) and 77,614,358 (2022) shares issued and outstanding	78	78
Additional paid-in capital	390,594	387,948
Accumulated deficit	(386,122)	(367,420)
Total stockholders' equity	4,550	20,606
Total liabilities and stockholders' equity	\$ 80,793	\$ 92,906

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

	Three Months Ended March 31,	
	2023	2022
Revenues		
COVID-19	\$ 13	\$ 984
Lung diagnostic	8,632	4,649
Diagnostic testing revenue	8,645	5,633
Biopharma services	411	915
Total revenues	9,056	6,548
Direct costs and expenses	3,169	3,235
Research and development	3,251	3,206
Sales, marketing, general and administrative	18,989	14,487
Impairment loss on intangible assets	20	81
Total operating expenses	25,429	21,009
Loss from operations	(16,373)	(14,461)
Other (expense) income:		
Interest expense	(2,391)	(1,137)
Change in fair value of warrant liability	61	—
Other income, net	1	12
Total other expense	(2,329)	(1,125)
Net loss	\$ (18,702)	\$ (15,586)
Net loss per share, basic and diluted	\$ (0.24)	\$ (0.50)
Weighted-average shares outstanding, basic and diluted	77,765	31,070

