

**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 6, 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 March 6, 2023, 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, 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 March 6, 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: March 6, 2023

BIODESIX, INC.

By: /s/ Robin Harper Cowie

Name: Robin Harper Cowie

Title: Chief Financial Officer



Biodesix Announces Fourth Quarter and Fiscal Year End 2022 Results and Highlights

Fourth Quarter and Fiscal Year 2022 Core Lung Diagnostic Revenue of \$8.2 Million and \$29.3 Million Increased 51% and 57% over the comparable 2021 periods, respectively

2023 Total Revenue Guidance Expected to be Between \$52 Million and \$55 Million - Mid-point of the range represents growth in excess of 60% over 2022 revenues excluding revenues from COVID-19 testing

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

BOULDER, CO, March 6, 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 fourth quarter and year ended December 31, 2022 (fiscal 2022) and provided a corporate update.

“It has been a productive year for Biodesix, and I am extremely proud of our team’s performance. 2022 saw a significant increase in adoption of our core lung diagnostics business, growing test volume by 54% and revenue 57% year over year. In addition, we continued to produce compelling clinical utility data, expand reimbursement coverage including Medicare coverage of our Nodify CDT® test and new private coverage policies for our Nodify XL2® test.” said Scott Hutton, CEO of Biodesix. “Our strong performance and positive momentum gives us continued confidence for 2023.”

Fourth Quarter and Full Year 2022 Financial Results

- Total revenue of \$9.6 million and \$38.2 million for the fourth quarter and fiscal 2022, respectively, an increase of 33% and decrease of 30% over the respective prior year comparable periods;
 - o *Continued growth in core lung diagnostic sales, offset by the expected year-over-year decline in COVID-19 revenue due to the decrease in testing across the year.*
 - Core lung diagnostic revenue of \$8.2 million and \$29.3 million for the fourth quarter and fiscal 2022, respectively, an increase of 51% and 57% over the respective prior year comparable periods;
 - o *Strong year-over-year performance in core lung diagnostics primarily driven by the increased adoption of Nodify Lung® nodule management tests and, the highest total tests delivered in Company history.*
 - COVID-19 testing revenue declined to an immaterial amount for the fourth quarter and \$5.2 million for fiscal 2022, a decrease of 96% and 83% over the respective prior year comparable periods;
 - o *Commensurate with prior guidance resulting from the increase in COVID-19 vaccination rates across the U.S. and the adoption and availability of at-home testing, including the expiration of our most significant testing contracts.*
 - Biopharma Services revenue of \$1.4 million and \$3.7 million for the fourth quarter and fiscal 2022, respectively, a decrease of 1% and 34% over the respective prior year comparable periods;
 - o *Clinical trial enrollment and shipping logistics continue to recover but are still impacting timelines for existing and new agreements;*
 - o *Entering 2023 with highest dollars under contract in Company history, including both prospective and retrospective studies.*
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- Gross margin was \$6.3 million or 66% and \$24.1 million or 63% for the fourth quarter and fiscal 2022, respectively, as a percentage of revenue compared to 65% and 44% in the comparable prior year periods, 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 \$20.2 million and \$74.6 million for the fourth quarter and fiscal 2022, an increase of 23% and 15% over the respective prior year comparable periods;
 - o *Increase in operating expenses is primarily from increased sales and marketing expense from the hiring of new sales reps, increased travel-related costs as access to physicians returned to pre-pandemic levels, and increases in other non-employee related costs all resulting from year-over-year growth in core lung diagnostic revenue;*
 - o *Includes non-cash stock compensation expense of \$2.1 million and \$6.0 million during fourth quarter and fiscal 2022, respectively.*
- Net loss of \$20.3 million and \$65.4 million for the fourth quarter and fiscal 2022, respectively, an increase of 53% and 52% over the respective prior year comparable periods;
 - o *Includes loss on debt extinguishment and modification of \$4.0 million and \$7.0 million in the fourth quarter and fiscal 2022, respectively;*
 - o *Fiscal 2021 included gain on debt extinguishment and modification of \$2.3 million.*
- Cash and cash equivalents of \$43.1 million as of December 31, 2022;
 - o *Raised \$65.7 million of net proceeds during the quarter through debt and equity offerings and utilized \$23.9 million to extinguish outstanding debt.*

2023 Financial Outlook

- The Company anticipates generating between \$52 million to \$55 million in total revenue in 2023;
 - o *Guidance represents anticipated 36-44% growth over 2022 total revenue from Lung Diagnostic testing, Biopharmaceutical Services and COVID-19 testing;*
 - o *Excluding 2022 COVID-19 testing revenue, Guidance represents anticipated 58-67% growth.*

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. 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,	
	2022	2021
Assets		
Current assets		
Cash and cash equivalents	\$ 43,088	\$ 32,712
Accounts receivable, net of allowance for doubtful accounts of \$118 and \$158	5,065	3,656
Other current assets	5,181	7,245
Total current assets	53,334	43,613
Non-current assets		
Property and equipment, net	5,848	4,179
Intangible assets, net	9,797	11,617
Operating lease right-of-use assets	2,973	—
Goodwill	15,031	15,031
Other long-term assets	5,923	1,657
Total non-current assets	39,572	32,484
Total assets	\$ 92,906	\$ 76,097
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 1,685	\$ 1,662
Accrued liabilities	8,218	7,665
Deferred revenue	962	1,850
Current portion of operating lease liabilities	1,543	—
Current portion of contingent consideration	10,341	17,764
Current portion of notes payable	49	19
Other current liabilities	41	—
Total current liabilities	22,839	28,960
Non-current liabilities		
Long-term notes payable, net of current portion	25,004	9,993
Long-term operating lease liabilities	5,254	—
Contingent consideration	18,645	16,028
Other long-term liabilities	558	1,389
Total non-current liabilities	49,461	27,410
Total liabilities	72,300	56,370
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$0.001 par value, 5,000,000 authorized; 0 (2022 and 2021) issued and outstanding	—	—
Common stock, \$0.001 par value, 200,000,000 authorized; 77,614,358 (2022) and 30,789,649 (2021) shares issued and outstanding	78	31
Additional paid-in capital	387,948	321,669
Accumulated deficit	(367,420)	(301,973)
Total stockholders' equity	20,606	19,727
Total liabilities and stockholders' equity	\$ 92,906	\$ 76,097

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Revenues				
COVID-19	\$ 16	\$ 425	\$ 5,240	\$ 30,227
Lung diagnostic	8,241	5,439	29,298	18,710
Diagnostic testing revenue	8,257	5,864	34,538	48,937
Biopharma services	1,351	1,359	3,674	5,569
Total revenues	9,608	7,223	38,212	54,506
Direct costs and expenses	3,306	2,493	14,154	30,518
Research and development	3,565	2,852	13,102	12,789
Sales, marketing, general and administrative	16,626	13,558	61,462	50,517
Change in fair value of contingent consideration	—	—	—	1,622
Impairment loss on intangible assets	—	—	81	—
Total operating expenses	23,497	18,903	88,799	95,446
Loss from operations	(13,889)	(11,680)	(50,587)	(40,940)
Other (expense) income:				
Interest expense	(2,550)	(1,496)	(8,072)	(4,508)
(Loss) gain on debt extinguishments, net	(3,977)	(97)	(6,981)	2,298
Change in fair value of warrant liability	84	—	84	—
Other (expense) income, net	(5)	(10)	109	(9)
Total other expense	(6,448)	(1,603)	(14,860)	(2,219)
Net loss	\$ (20,337)	\$ (13,283)	\$ (65,447)	\$ (43,159)
Net loss per share, basic and diluted	\$ (0.35)	\$ (0.49)	\$ (1.55)	\$ (1.58)
Weighted-average shares outstanding, basic and diluted	57,805	27,063	42,103	27,365

