
**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 1, 2024

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.)

919 West Dillon Rd
Louisville, Colorado
(Address of Principal Executive Office)

80027
(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 1, 2024, 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, 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 March 1, 2024
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 1, 2024

BIODESIX, INC.

By: /s/ Robin Harper Cowie

Name: Robin Harper Cowie

Title: Chief Financial Officer



Biodesix Announces Fourth Quarter and Fiscal Year 2023 Results and Business Highlights

Persistent, high double-digit growth in Lung Diagnostic test volume - growing 65% in FY2023 versus FY2022 - and the sixth consecutive quarter with greater than 50% year-over-year growth;

Ongoing improvement in gross profit margin with achievement of 77% in fourth quarter 2023, up 11 points over fourth quarter 2022;

2024 Total Revenue Guidance of \$65 million to \$68 million;

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

LOUISVILLE, CO, March 1, 2024 – Biodesix, Inc. (Nasdaq: BDSX), a leading diagnostic solutions and services company, today provided a corporate update and announced its financial and operating results for the fourth quarter and year ended December 31, 2023 (fiscal 2023).

“I am exceptionally proud of the Biodesix team and our record of accomplishments in 2023,” said Scott Hutton, CEO of Biodesix. “We were focused on three goals: driving increased revenue through adoption of our Lung Diagnostic tests and Biopharmaceutical Services, implementing operational efficiencies to improve gross margins, and maintaining a strict cost discipline. I am very pleased with our significant progress on each of these goals.”

Mr. Hutton continued, “The Biodesix team delivered 65% growth in Lung Diagnostic test volume for the full year 2023 and a sixth straight quarter of over 50% year-over-year growth, with the fourth quarter FY23 growing 54% over the fourth quarter of FY22. We made tremendous progress driving Lung Diagnostic test adoption in 2023, but we have just scratched the surface of a massive market opportunity addressing a critical unmet need to help improve the lives of patients with potentially cancerous lung nodules and lung cancer with our five blood-based tests. At the same time, our focus on growing Biodesix while maintaining a cost disciplined approach has resulted in a dramatic 77% gross profit margin and 55% improvement in Adjusted EBITDA in the fourth quarter FY23 compared to the fourth quarter FY22, and a clear path towards profitability. In 2024 we are committed to executing on those same three goals and we expect to deliver \$65 to \$68 million in total revenue.”

Fourth Quarter and Full Year 2023 Financial Results

- Total revenue of \$14.7 million and \$49.1 million for the fourth quarter and fiscal 2023, respectively, an increase of 52% and 49% over the respective prior year comparable periods excluding COVID testing revenues, and an increase of 53% and 28% over the respective prior year comparable periods including COVID testing revenues;
 - o *Lung Diagnostic revenue of \$12.8 million and \$45.1 million for the fourth quarter and fiscal 2023, respectively, an increase of 55% and 54% over the respective prior year comparable periods, primarily driven by the continued adoption of Nodify Lung® Nodule Risk Assessment tests;*
 - o *Biopharma Services and other revenue of \$1.9 million and \$3.9 million for the fourth quarter and fiscal 2023, respectively, an increase of 38% and 6% over the respective prior year comparable periods, a result of both delivering against our expanding book of business and securing new agreements; entering 2024 with increasing dollars under contract;*
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- Gross profit was \$11.3 million or 77% and \$36.1 million or 73% for the fourth quarter and fiscal 2023, respectively, as a percentage of revenue compared to 66% and 63% in the prior year comparable periods, primarily driven by growth in Lung Diagnostic testing and optimization of testing workflows that resulted in improvements in costs per test, the ongoing recovery of our Biopharma Services business, and the commercial discontinuation of lower-margin COVID-19 testing;
- Operating expenses (excluding direct costs and expenses) of \$18.2 million and \$77.4 million for the fourth quarter and fiscal 2023, a decrease of 10% and increase of 4% over the respective prior year comparable periods;
 - *Decrease in fourth quarter 2023 is primarily attributable to a decrease in research and development costs, partially offset by increased sales and marketing costs to support Lung Diagnostic sales growth, enhance product awareness and drive adoption, while the full year increase in operating expenses was driven by an increase in sales and marketing costs, partially offset by a reduction in research and development costs;*
 - *Includes non-cash stock compensation expense of \$1.1 million and \$5.4 million during fourth quarter and fiscal 2023, respectively, a decrease of 48% and 10% over the respective prior year comparable periods;*
- Net loss of \$9.1 million and \$52.1 million for the fourth quarter and fiscal 2023, respectively, an improvement of 55% and 20% over the respective prior year comparable periods;
 - *Fourth quarter and fiscal 2023 included a gain of \$0.1 million and loss of \$1.3 million, respectively, from the change in fair value of warrant liabilities associated with our term loan facility with Perceptive Advisors (Perceptive);*
 - *Fourth quarter and fiscal 2022 included loss on debt extinguishment and modification of \$4.0 million and \$7.0 million, respectively;*
- Adjusted EBITDA was a loss of \$4.9 million and \$32.7 million for the fourth quarter and fiscal 2023, respectively, an improvement of 55% and 24% over the respective prior year comparable periods;
- Cash and cash equivalents of \$26.3 million as of December 31, 2023;
 - *The Company successfully drew down the second tranche of \$10 million from its \$50 million term loan facility with Perceptive in the fourth quarter of 2023;*
 - *Cash balance includes the remaining \$12.2 million of the \$27.5 million private placement announced in August 2023.*

2024 Financial Outlook

- The Company anticipates generating between \$65 million to \$68 million in total revenue in 2024, representing an approximate 32% to 39% year-over-year growth rate.

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 press releases and webinars, please visit the Investors Page on biodesix.com.

Use of Non-GAAP Financial Measure

Biodesix reported results are presented in accordance with generally accepted accounting principles in the United States (GAAP). Biodesix has provided in this press release financial information that has not been prepared in accordance with GAAP. Biodesix uses the non-GAAP financial measure, *Adjusted EBITDA*, internally in analyzing its financial results and believes that use of this non-GAAP financial measure is useful to investors as an additional tool to evaluate ongoing operating results and trends and in comparing Biodesix's financial results with other companies in its industry, many of which present similar non-GAAP financial measures. Non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable GAAP financial measures and should be read only in conjunction with Biodesix's financial statements prepared in accordance with GAAP. A reconciliation of Biodesix historical non-GAAP financial measure to the most directly comparable GAAP measure has been provided in the financial statement tables included in this press release, and investors are encouraged to review the reconciliation.

Adjusted EBITDA is a key performance measure that our management uses to assess our financial performance and is also used for internal planning and forecasting purposes. We believe that this non-GAAP financial measure is useful to investors and other interested parties in analyzing our financial performance because it provides a comparable overview of our operations across historical periods. In addition, we believe that providing Adjusted EBITDA, together with a reconciliation of Net loss to Adjusted EBITDA, helps investors make comparisons between our Company and other companies that may have different capital structures, different tax rates, and/or different forms of employee compensation.

Adjusted EBITDA is used by our management team as an additional measure of our performance for purposes of business decision-making, including managing expenditures. Period-to-period comparisons of Adjusted EBITDA help our management identify additional trends in our financial results that may not be shown solely by period-to-period comparisons of Net loss or Loss from operations. Our management recognizes that Adjusted EBITDA has inherent limitations because of the excluded items and may not be directly comparable to similarly titled metrics used by other companies.

We calculate Adjusted EBITDA as Net loss adjusted to exclude interest, income tax expense, if any, depreciation and amortization, share-based compensation expense, loss on debt extinguishments, net, COVID-19 revenue, COVID-19 direct costs and expenses, change in fair value of warrant liabilities, net, other income, net, and other non-recurring items. Non-recurring items are excluded as they are not representative of our underlying operating performance. We also exclude revenue and direct costs and expenses associated with COVID-19 because we believe that these revenues and expenses do not reflect expected future operating results as they do not represent our Lung Diagnostic and Biopharma Services business. Adjusted EBITDA should be viewed as a measure of operating performance that is a supplement to, and not a substitute for Loss from operations, Net loss, and other GAAP measures.

About Biodesix

Biodesix is a leading diagnostic solutions and services 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 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® 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 the 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.

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 backlog and the timing and assumptions regarding collection of revenues on projections, availability of funds and future capital including under the term loan facility, expectations regarding revenue and margin growth and its impact on profitability, and the impact of a pandemic, epidemic, or outbreak, including the COVID-19 pandemic, on Biodesix and its operations and financial performance. 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 most recent annual report on Form 10-K, filed March 1, 2024. 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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Bioesix, Inc.
Condensed Balance Sheets (unaudited)
(in thousands, except share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	\$ 26,284	\$ 43,088
Accounts receivable, net of allowance for doubtful accounts of \$65 and \$118	7,679	5,065
Other current assets	5,720	5,181
Total current assets	39,683	53,334
Non-current assets		
Property and equipment, net	27,867	5,848
Intangible assets, net	7,911	9,797
Operating lease right-of-use assets	1,745	2,973
Goodwill	15,031	15,031
Other long-term assets	6,859	5,923
Total non-current assets	59,413	39,572
Total assets	\$ 99,096	\$ 92,906
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 2,929	\$ 1,685
Accrued liabilities	7,710	8,218
Deferred revenue	324	962
Current portion of operating lease liabilities	252	1,543
Current portion of contingent consideration	21,857	10,341
Current portion of notes payable	51	49
Other current liabilities	293	41
Total current liabilities	33,416	22,839
Non-current liabilities		
Long-term notes payable, net of current portion	35,225	25,004
Long-term operating lease liabilities	25,163	5,254
Contingent consideration	—	18,645
Other long-term liabilities	712	558
Total non-current liabilities	61,100	49,461
Total liabilities	94,516	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; 96,235,883 (2023) and 77,614,358 (2022) shares issued and outstanding	96	78
Additional paid-in capital	424,050	387,948
Accumulated deficit	(419,566)	(367,420)
Total stockholders' equity	4,580	20,606
Total liabilities and stockholders' equity	\$ 99,096	\$ 92,906

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Revenues				
Lung Diagnostic	\$ 12,753	\$ 8,241	\$ 45,135	\$ 29,298
COVID-19	44	16	57	5,240
Diagnostic Testing revenue	12,797	8,257	45,192	34,538
Biopharma Services and other revenue	1,871	1,351	3,895	3,674
Total revenues	14,668	9,608	49,087	38,212
Direct costs and expenses	3,374	3,306	13,010	14,154
Research and development	1,889	3,565	9,988	13,102
Sales, marketing, general and administrative	16,251	16,626	67,387	61,462
Impairment loss on intangible assets	24	—	44	81
Total operating expenses	21,538	23,497	90,429	88,799
Loss from operations	(6,870)	(13,889)	(41,342)	(50,587)
Other (expense) income:				
Interest expense	(2,329)	(2,550)	(9,536)	(8,072)
Loss on debt extinguishments, net	—	(3,977)	—	(6,981)
Change in fair value of warrant liability, net	58	84	(1,274)	84
Other income, net	2	(5)	6	109
Total other expense	(2,269)	(6,448)	(10,804)	(14,860)
Net loss	\$ (9,139)	\$ (20,337)	\$ (52,146)	\$ (65,447)
Net loss per share, basic and diluted	\$ (0.10)	\$ (0.35)	\$ (0.64)	\$ (1.55)
Weighted-average shares outstanding, basic and diluted	92,325	57,805	82,113	42,103

Biodesix, Inc.
Reconciliation of Net Loss to Adjusted EBITDA (unaudited)
(in thousands)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Net loss	\$ (9,139)	\$ (20,337)	\$ (52,146)	\$ (65,447)
Interest expense	2,329	2,550	9,536	8,072
Depreciation and amortization	977	898	3,328	3,597
Share-based compensation expense	1,081	2,077	5,373	5,961
Loss on debt extinguishments, net	—	3,977	—	6,981
COVID-19 Revenue	(44)	(16)	(57)	(5,240)
COVID-19 Direct costs and expenses	—	95	1	3,109
Change in fair value of warrant liability, net	(58)	(84)	1,274	(84)
Other income, net	(2)	5	(6)	(109)
Adjusted EBITDA	\$ (4,856)	\$ (10,835)	\$ (32,697)	\$ (43,160)

