

**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**

November 7, 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 November 7, 2023, Biodesix, Inc. (the Company) issued a press release announcing the financial and operating results of the Company for the third quarter ended September 30, 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 November 7, 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: November 7, 2023

BIODESIX, INC.

By: /s/ Robin Harper Cowie

Name: Robin Harper Cowie

Title: Chief Financial Officer



Biodesix Announces Third Quarter 2023 Results and Highlights

Third quarter 2023 Lung Diagnostic test volume grew 60% over the comparable period in 2022 and 6% over second quarter of 2023;

Third quarter 2023 gross profit margin of 76% versus 67% for the third quarter 2022 and 73% for the second quarter of 2023;

Net loss, which includes certain non-cash items, of \$10.9 million improved by 20% over the comparable period in 2022 and 18% over the second quarter of 2023;

Adjusted EBITDA of (\$5.4 million) improved by 40% over both the third quarter of 2022 and the second quarter of 2023;

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

BOULDER, CO, November 7, 2023 – Biodesix, Inc. (Nasdaq: BDSX), a leading diagnostic solutions company with a focus in lung disease, today announced its financial and operating results for the third quarter ended September 30, 2023 and provided a corporate update.

“I am pleased to announce yet another impressive quarter of growth at Biodesix,” said Scott Hutton, President and Chief Executive Officer. “The team delivered over 10,400 Lung Diagnostics tests, growing 60% over the 6,500 tests delivered in the third quarter of 2022, the fifth straight quarter of at least 60% year-over-year growth, and 6% improvement over second quarter 2023. Our Biopharma Services business also had a strong quarter, growing 79% year-over-year and 181% over the second quarter. I am thrilled with Biodesix’s ability to consistently grow the business while maintaining a strong cost disciplined approach. Starting this quarter, we are now providing Adjusted EBITDA to provide additional insight into our progress toward profitability. Our third quarter Adjusted EBITDA was (\$5.4) million, a 40% improvement over both the third quarter of 2022 and the second quarter of 2023. In the fourth quarter we are continuing to improve our balance sheet with the final closing of our private placement announced in August and plan to draw down an additional \$10 million from the second tranche of our term loan with Perceptive Advisors. I am exceptionally pleased with our progress as we continue to increase test volumes, drive revenue growth, advance operational effectiveness, and improve Adjusted EBITDA as we strive to impact more patients with lung disease than ever before.”

Third Quarter 2023 Financial Results

For the three-month period ended September 30, 2023, as compared to the same period of 2022 (where applicable):

- Total revenue of \$13.5 million, an increase of 21%, including COVID testing revenue in third quarter 2022, driven primarily by strong year-over-year growth in lung diagnostics, and a 37% year-over-year increase excluding COVID testing revenues from the prior year comparison;
 - o Lung diagnostic revenue of \$12.3 million reflected a year-over-year increase of 34% driven primarily by the continued adoption of Nodify Lung® nodule risk assessment tests, and approximately 60% when excluding one-time cash revenue from tests performed in prior periods primarily from Medicare coverage of the Nodify CDT test;
 - o Biopharma Services and other revenue of \$1.2 million increased 79% year-over-year, a result of both delivering against our increasing book of business and new agreements;
-

- o *COVID-19 testing revenue decreased by 100% year-over-year, as the Company no longer provides COVID-19 diagnostic testing services;*
- Third quarter 2023 gross profit of \$10.3 million, or 76% gross margin compared to 67% gross margin in the comparable prior year period, 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 our lower-margin COVID-19 diagnostic testing;
- Operating expenses (excluding direct costs and expenses) of \$17.4 million, a decrease of approximately \$0.7 million, or 4% as compared to the third quarter 2022 (includes non-cash stock compensation expense of \$1.0 million as compared to \$1.2 million). This decrease 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 to enhance product awareness and drive adoption;
- Net loss of \$10.9 million, a decrease of approximately \$2.8 million, or 20%;
- Adjusted EBITDA was a loss of \$5.4 million, an improvement of \$3.6 million, or 40%;
- Cash and cash equivalents of \$19.8 million as of September 30, 2023, an increase of \$2.4 million from June 30, 2023;
 - o *The Company plans to draw down an additional \$10 million from the second tranche of its \$50 million term loan facility with Perceptive Advisors in the fourth quarter of 2023, subject to the terms and conditions of such facility;*
 - o *Cash balance includes \$15.3 million of the \$27.5 million private placement announced in August. The remaining \$12.2 million will be received in the fourth quarter of 2023.*

2023 Financial Outlook

Third quarter revenues were impacted by a change in the timing and assumptions regarding the anticipated collection of revenue from a backlog of previously unrecognized Medicare Advantage claims. Based on these new assumptions, the Company is adjusting its 2023 financial outlook to remove the backlog and is not making any change to core business expectations. The Company expects to generate \$50 to \$52 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).

Use of Non-GAAP Financial Measure

Biodesix's 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's 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 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 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](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 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 the COVID-19 pandemic and future pandemics 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'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.

Contacts:

Media:

Robbie Lunt

robbie.lunt@biodesix.com

1-(866)-432-5930

Investors:

Chris Brinzey

chris.brinzey@westwicke.com

(339) 970-2843

Biodesix, Inc.
Condensed Balance Sheets (unaudited)
(in thousands, except share data)

	September 30, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	\$ 19,841	\$ 43,088
Accounts receivable, net of allowance for doubtful accounts of \$57 and \$118	5,777	5,065
Other current assets	3,268	5,181
Total current assets	28,886	53,334
Non-current assets		
Property and equipment, net	25,395	5,848
Intangible assets, net	8,416	9,797
Operating lease right-of-use assets	2,093	2,973
Goodwill	15,031	15,031
Other long-term assets	6,965	5,923
Total non-current assets	57,900	39,572
Total assets	\$ 86,786	\$ 92,906
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities		
Accounts payable	\$ 2,904	\$ 1,685
Accrued liabilities	6,946	8,218
Deferred revenue	659	962
Current portion of operating lease liabilities	1,113	1,543
Current portion of contingent consideration	19,307	10,341
Current portion of notes payable	50	49
Other current liabilities	1,670	41
Total current liabilities	32,649	22,839
Non-current liabilities		
Long-term notes payable, net of current portion	24,950	25,004
Long-term operating lease liabilities	24,636	5,254
Contingent consideration	5,182	18,645
Other long-term liabilities	815	558
Total non-current liabilities	55,583	49,461
Total liabilities	88,232	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; 88,315,802 (2023) and 77,614,358 (2022) shares issued and outstanding	88	78
Additional paid-in capital	408,893	387,948
Accumulated deficit	(410,427)	(367,420)
Total stockholders' (deficit) equity	(1,446)	20,606
Total liabilities and stockholders' (deficit) equity	\$ 86,786	\$ 92,906

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues				
Lung diagnostic	\$ 12,301	\$ 9,157	\$ 32,382	\$ 21,058
COVID-19	—	1,286	13	5,224
Diagnostic testing revenue	12,301	10,443	32,395	26,282
Biopharma services and other revenue	1,190	664	2,024	2,323
Total revenues	13,491	11,107	34,419	28,605
Direct costs and expenses	3,229	3,633	9,636	10,848
Research and development	1,938	2,970	8,099	9,537
Sales, marketing, general and administrative	15,496	15,114	51,136	44,836
Impairment loss on intangible assets	—	—	20	81
Total operating expenses	20,663	21,717	68,891	65,302
Loss from operations	(7,172)	(10,610)	(34,472)	(36,697)
Other (expense) income:				
Interest expense	(2,386)	(3,039)	(7,207)	(5,522)
Loss on debt extinguishments, net	—	(52)	—	(3,004)
Change in fair value of warrant liability, net	(1,393)	—	(1,332)	—
Other income, net	2	2	4	114
Total other expense	(3,777)	(3,089)	(8,535)	(8,412)
Net loss	\$ (10,949)	\$ (13,699)	\$ (43,007)	\$ (45,109)
Net loss per share, basic and diluted	\$ (0.14)	\$ (0.34)	\$ (0.55)	\$ (1.22)
Weighted-average shares outstanding, basic and diluted	79,709	40,448	78,672	36,953

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

	Three Months Ended				
	September 30, 2023	June 30, 2023	March 31, 2023	December 31, 2022	September 30, 2022
Net loss	\$ (10,949)	\$ (13,356)	\$ (18,702)	\$ (20,337)	\$ (13,699)
Interest expense	2,386	2,430	2,391	2,550	3,039
Depreciation and amortization	782	784	785	898	893
Share-based compensation expense	954	1,057	2,281	2,077	1,170
Loss on debt extinguishments, net	—	—	—	3,977	52
COVID-19 Revenue	—	—	(13)	(16)	(1,286)
COVID-19 Direct costs and expenses	—	—	1	95	761
Change in fair value of warrant liability, net	1,393	—	(61)	(84)	—
Other income, net	(2)	(1)	(1)	5	(2)
Adjusted EBITDA	<u>\$ (5,436)</u>	<u>\$ (9,086)</u>	<u>\$ (13,319)</u>	<u>\$ (10,835)</u>	<u>\$ (9,072)</u>

