

**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 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 November 1, 2024, Biodesix, Inc. (the Company) issued a press release announcing the financial and operating results of the Company for the third quarter ended September 30, 2024. 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 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: November 1, 2024

BIODESIX, INC.

By: /s/ Robin Harper Cowie

Name: Robin Harper Cowie

Title: Chief Financial Officer



Biodesix Announces Third Quarter 2024 Results and Highlights

Q3 2024 revenue grew 35% over Q3 2023 to \$18.2 million;

Q3 2024 gross profit margin of 77.0%, up from 76.1% in Q3 2023;

Q3 2024 Net loss improved by 6% compared to Q3 2023;

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

LOUISVILLE, CO, November 1, 2024 – Biodesix, Inc. (Nasdaq: BDSX), a leading diagnostic solutions company, today announced its financial and operating results for the third quarter ended September 30, 2024.

“The Biodesix team is pleased to report another solid quarter focused on executing and delivering on our three main goals - driving revenue growth through the adoption of our lung diagnostic tests and biopharma services, continued implementation of operational efficiencies, and maintaining a cost-disciplined approach as we drive our business to profitability,” said Scott Hutton, CEO of Biodesix.

“We reported 40% year-over-year growth in lung diagnostics revenue, a growing book of biopharma services contracts, sustained gross margins in the high 70% range, and improved Net Loss on our path to profitability. In addition, at the annual meeting of the American College of Chest Physicians (CHEST), we presented new clinical data on our Nodify XL2® and Nodify CDT® tests, and announced a new clinical study (CLARIFY) to expand our data in diverse patient populations tested in a real-world clinical setting. Building on this momentum, we are reiterating our prior guidance of \$70-\$72 million for 2024 and we look forward to achieving Adjusted EBITDA profitability in the second half of 2025. At Biodesix, our tests play a vital role in treating the deadliest of all cancers. Our committed and driven team embraces the opportunity, and the responsibility, to transform the standard of care to improve outcomes for patients.”

Third Quarter Ended September 30, 2024 Business Highlights

- Grew Lung Diagnostic test volume to 13,900, a 34% improvement over the third quarter of 2023.
 - Quarterly gross profit margin of 77.0% versus 76.1% for the third quarter of 2023.
 - Presented compelling new data at the CHEST Annual Meeting and announced the launch of a new clinical study, CLARIFY.
 - o New data was presented detailing the experience of healthcare providers using the Nodify Lung® Nodule Risk Assessment Tests (Nodify XL2 and Nodify CDT tests) in over 35,000 patients tested in a real-world clinical setting. Results shared were consistent with prior studies, highlighting the high proportion of results that up- or down-classify patients into actionable risk categories with clear, guideline-recommended, diagnostic plans.
 - o The new study, CLARIFY, is designed to confirm performance of the Nodify CDT and Nodify XL2 tests in diverse patient subgroups through a retrospective chart review of up to 4,000 patients that were tested in a real-world clinical setting. The study’s intent is to expand the extensive evidence characterizing the validation and utility of Nodify Lung testing.
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Third Quarter Ended September 30, 2024 Financial Highlights

- Total revenue of \$18.2 million, an increase of 35% over the third quarter 2023:
 - **Lung Diagnostic** revenue of \$17.2 million reflected a year-over-year increase of 40% driven by the continued adoption of Nodify XL2 and Nodify CDT nodule risk assessment tests and strong reimbursement. However, test volumes were impacted at the end of the third quarter by disruption to patients, healthcare providers, and Biodesix teammates in the southeast due to Hurricane Helene;
 - **Biopharmaceutical Services** revenue of \$1.0 million decreased 17% year-over-year, driven by the timing of receipt of samples and shift of the completion of certain projects from the end of the third quarter into the beginning of the fourth;
- Third quarter 2024 gross profit of \$14.0 million, or 77.0% gross margin compared to 76.1% gross margin in the comparable prior year period. Our steady margin performance is primarily driven by volume growth in Lung Diagnostic testing that continues to drive down the per test costs;
- Operating expenses (excluding direct costs and expenses) of \$22.6 million, an increase of 29% as compared to the third quarter 2023, which includes \$3.0 million of non-cash stock compensation expense and depreciation and amortization as compared to \$1.7 million in third quarter of 2023. This increase is primarily attributable to an increase in sales and marketing costs to support both business lines' sales growth to enhance product awareness and drive adoption, and an increase in depreciation expense related to the leasehold improvements in the Company's Louisville, CO offices and laboratory which opened in January 2024;
- Net loss of \$10.3 million, an improvement of 6% as compared to the same period of 2023;
- Adjusted EBITDA was a loss of \$5.6 million, a slight increase over the loss of \$5.4 million in the third quarter of 2023 and consistent with the second quarter of 2024;
- Cash and cash equivalents of \$31.4 million as of September 30, 2024, a decrease from \$42.2 million from June 30, 2024;
 - *Cash and cash equivalents as of September 30, 2024 includes the final milestone payment of \$6.1 million for the acquisition of Integrated Diagnostics in 2018.*

2024 - 2025 Financial Outlook

The Company is reiterating the 2024 revenue forecast of between \$70 million and \$72 million.

Conference call and webcast information

Listeners can register for the webcast via this link. Analysts who wish 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 relations page on the website approximately two hours after the call's conclusion. Participants are advised to join 15 minutes prior to the start time.

For a full list of Biodesix press releases and webinars, please visit [biodesix.com](https://www.biodesix.com).

About Biodesix

Biodesix is a leading diagnostic solutions company with five Medicare-covered tests available for patients with lung diseases. The blood-based Nodify Lung® Nodule Risk Assessment, 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™ test portfolio 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 and expedite personalized treatment. In addition, Biodesix collaborates with the world's leading biopharmaceutical companies to provide biomarker discovery, diagnostic test development, and clinical trial support services. For more information about Biodesix, visit biodesix.com.

Trademarks: Biodesix, Nodify Lung, Nodify XL2, Nodify CDT, IQLung, GeneStrat, GeneStrat NGS, and VeriStrat are trademarks or registered trademarks of Biodesix, Inc. The ddPCR technology is a trademark of Bio-Rad Laboratories, Inc.

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 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 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 Biopharmaceutical 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.

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 or subsequent quarterly reports on Form 10-Q during 2024, 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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Bioesix, Inc.
Condensed Balance Sheets (unaudited)
(in thousands, except share data)

	September 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	\$ 31,406	\$ 26,284
Accounts receivable, net of allowance for credit losses of \$246 and \$65	8,036	7,679
Other current assets	4,575	5,720
Total current assets	44,017	39,683
Non-current assets		
Property and equipment, net	28,683	27,867
Intangible assets, net	6,438	7,911
Operating lease right-of-use assets	1,918	1,745
Goodwill	15,031	15,031
Other long-term assets	6,656	6,859
Total non-current assets	58,726	59,413
Total assets	\$ 102,743	\$ 99,096
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 2,537	\$ 2,929
Accrued liabilities	8,553	7,710
Deferred revenue	676	324
Current portion of operating lease liabilities	624	252
Current portion of contingent consideration	—	21,857
Current portion of notes payable	29	51
Other current liabilities	544	293
Total current liabilities	12,963	33,416
Non-current liabilities		
Long-term notes payable, net of current portion	36,112	35,225
Long-term operating lease liabilities	25,191	25,163
Other long-term liabilities	620	712
Total non-current liabilities	61,923	61,100
Total liabilities	74,886	94,516
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$0.001 par value, 5,000,000 authorized; 0 (2024 and 2023) issued and outstanding	—	—
Common stock, \$0.001 par value, 200,000,000 authorized; 145,465,941 (2024) and 96,235,883 (2023) shares issued and outstanding	145	96
Additional paid-in capital	481,958	424,050
Accumulated deficit	(454,246)	(419,566)
Total stockholders' equity	27,857	4,580
Total liabilities and stockholders' equity	\$ 102,743	\$ 99,096

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues				
Diagnostic Testing revenue	\$ 17,168	\$ 12,301	\$ 47,503	\$ 32,395
Biopharmaceutical Services and other revenue	983	1,190	3,391	2,024
Total revenues	18,151	13,491	50,894	34,419
Direct costs and expenses				
Research and development	4,179	3,229	11,231	9,636
Sales, marketing, general and administrative	2,547	1,938	7,145	8,099
Impairment loss on intangible assets	20,016	15,496	60,232	51,136
	—	—	135	20
Total operating expenses	26,742	20,663	78,743	68,891
Loss from operations	(8,591)	(7,172)	(27,849)	(34,472)
Other (expense) income:				
Interest expense	(2,041)	(2,386)	(6,506)	(7,207)
Loss on extinguishment of liabilities	—	—	(248)	—
Change in fair value of warrant liability, net	—	(1,393)	—	(1,332)
Other (expense) income, net	374	2	(77)	4
Total other expense	(1,667)	(3,777)	(6,831)	(8,535)
Net loss	\$ (10,258)	\$ (10,949)	\$ (34,680)	\$ (43,007)
Net loss per share, basic and diluted	\$ (0.07)	\$ (0.14)	\$ (0.28)	\$ (0.55)
Weighted-average shares outstanding, basic and diluted	146,296	79,709	123,634	78,672

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net loss	\$ (10,258)	\$ (10,949)	\$ (34,680)	\$ (43,007)
Interest expense	2,041	2,386	6,506	7,207
Depreciation and amortization	1,492	782	4,324	2,351
Share-based compensation expense	1,515	954	5,373	4,292
Loss on extinguishment of liabilities	—	—	248	—
COVID-19 Revenue	—	—	—	(13)
COVID-19 Direct costs and expenses	—	—	—	1
Change in fair value of warrant liability, net	—	1,393	—	1,332
Other expense (income), net	(374)	(2)	77	(4)
Adjusted EBITDA	\$ (5,584)	\$ (5,436)	\$ (18,152)	\$ (27,841)

