

**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

August 7, 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 August 7, 2024, Biodesix, Inc. (the Company) issued a press release announcing the financial and operating results of the Company for the second quarter ended June 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 August 7, 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: August 7, 2024

BIODESIX, INC.

By: /s/ Robin Harper Cowie

Name: Robin Harper Cowie

Title: Chief Financial Officer



Biodesix Announces Second Quarter 2024 Results and Highlights

Q2 2024 revenue grew 51% over Q2 2023 to \$17.9 million;

Q2 2024 gross profit margin of 78.4%, a 5.7% improvement from Q2 2023;

Raises full-year 2024 revenue guidance to \$70-72 million from \$65-68 million;

Q2 24 Net loss, including certain non-cash items, and Adjusted EBITDA improved by 19% and 38% over Q2 2023;

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

LOUISVILLE, CO, August 7, 2024 – Biodesix, Inc. (Nasdaq: BDSX), a leading diagnostic solutions company, today announced its financial and operating results for the second quarter ended June 30, 2024.

“The second quarter marks sustained excellence in our execution, resulting in outstanding revenue growth coupled with consistently strong gross margins, and continued improvement on our path to profitability,” said Scott Hutton, CEO of Biodesix. “The team’s performance led to 51% growth in revenue and as a result we are raising our 2024 total revenue guidance to \$70-\$72 million, up from previously provided guidance of \$65-\$68 million. In combination with our revenue growth, our cost-disciplined approach resulted in improvements of 19% in Net Loss and 38% in Adjusted EBITDA, demonstrating progress on our path to profitability.”

“It is important to note that our industry-leading commercial engine is continuing to drive market adoption of our five on-market lung diagnostic tests. These tests are transforming the diagnosis and treatment of patients with lung cancer. We have an incredible team of professionals dedicated and driven to making a difference in patients’ lives. I continue to be thankful for the team and our intentional focus on workplace culture so that we attract and retain the best talent.”

Second Quarter Ended June 30, 2024 Business Highlights

- Named to Inc. Magazine’s 2024 Best Workplaces list. The ranking is based on a comprehensive, data-driven measurement process through anonymous employee surveys to identify which American companies have excelled in creating high-engagement workplaces and excellent company cultures.
- Grew Lung Diagnostic test volume to 13,900, a 42% improvement over the second quarter of 2023 and 17% over the first quarter of 2024.
- Quarterly gross profit margin of 78.4% versus 72.7% for the second quarter of 2023 and 78.6% for the first quarter of 2024.
- Presented compelling new data¹ at the American Thoracic Society (ATS) Conference, May 2024, that highlighted the Nodify XL2 test and its ability to identify benign nodules in patients with emphysema, demonstrating further test utility in patients with common comorbidities.

- Peer-reviewed data was published in June in the Annals of Oncology² that highlight the role of Biodesix diagnostic services in monitoring efficacy of new therapeutic regimens.

Second Quarter Ended June 30, 2024 Financial Highlights

- Total revenue of \$17.9 million, an increase of 51% over the second quarter 2023. This results in now eight consecutive quarters of over 40% revenue growth and is driven by strong year-over-year growth in both lines of business:
 - **Lung Diagnostic** revenue of \$16.5 million reflected a year-over-year increase of 44% driven primarily by the continued adoption of Nodify Lung® nodule risk assessment tests;
 - **Biopharmaceutical Services** of \$1.4 million increased 228% year-over-year; a result of both delivering against the Company's book of contracted business and securing new agreements;
 - Second quarter 2024 gross profit of \$14.0 million, or 78.4% gross margin compared to 72.7% 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, and increased process efficiencies in the Company's Biopharmaceutical Services business;
 - Operating expenses (excluding direct costs and expenses) of \$22.3 million, an increase of approximately \$2.7 million, or 14% as compared to the second quarter 2023 (includes \$2.7 million of non-cash stock compensation expense, depreciation and amortization, and asset impairment as compared to \$1.9 million). This increase is primarily attributable to an increase in sales and marketing costs to support lung diagnostic sales growth to enhance product awareness and drive adoption, an increase in depreciation expense related to the leasehold improvements in the Company's new Louisville, Colorado offices and laboratory, partially offset by a decrease in research and development and general and administrative costs;
 - Net loss of \$10.8 million, an improvement of approximately \$2.5 million, or 19% as compared to the same period of 2023. Net loss included \$0.6 million of one-time cash and non-cash Other Expenses, net primarily related to our probability of not utilizing the Lincoln Park Capital Equity Line of Credit prior to expiration and costs associated with debt-extinguishment;
 - Adjusted EBITDA was a loss of \$5.6 million, an improvement of \$3.5 million, or 38% over the second quarter of 2023 and fifth straight quarter of year-over-year improvement in Adjusted EBITDA;
 - Cash and cash equivalents of \$42.2 million as of June 30, 2024, an increase of \$30.7 million from March 31, 2024;
 - *Cash and cash equivalents as of June 30, 2024, includes \$55.0 million in gross proceeds raised from an oversubscribed and upsized offering of common stock and concurrent private placement completed on April 5, 2024.*
 - *Includes the second quarter scheduled milestone payment of \$5.3 million and pre-payment of the third quarter \$8.4 million scheduled milestone payment paid in April 2024 for the acquisition of Integrated Diagnostics in 2018. The pre-payment of the third quarter milestone resulted in cash savings from interest that was eliminated by the pre-payment. The Company has one final payment of \$6.1 million remaining, which does not accrue interest and is expected to be paid at the end of the third quarter 2024.*
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2024 Financial Outlook

The Company is increasing its 2024 revenue forecast and now expects to generate between \$70 million and \$72 million in total revenue in 2024, versus prior guidance of \$65 million and \$68 million in total revenue in 2024.

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](https://www.biodesix.com).

The Biodesix logo, 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.

Footnotes:

1. Performance comparison of blood-based integrated classifier for lung nodule risk stratification in patients with versus without emphysema. American Thoracic Society, May 2024. Dr. Romera, University of Nevada, Las Vegas.
2. "Amivantamab plus lazertinib versus osimertinib in first-line EGFR-mutant advanced non-small-cell lung cancer with biomarkers of high-risk disease: a secondary analysis from MARIPOSA," *Annals of Oncology*, June 2024.

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)

	June 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	\$ 42,219	\$ 26,284
Accounts receivable, net of allowance for credit losses of \$238 and \$65	10,128	7,679
Other current assets	5,232	5,720
Total current assets	57,579	39,683
Non-current assets		
Property and equipment, net	28,019	27,867
Intangible assets, net	6,884	7,911
Operating lease right-of-use assets	1,767	1,745
Goodwill	15,031	15,031
Other long-term assets	6,561	6,859
Total non-current assets	58,262	59,413
Total assets	\$ 115,841	\$ 99,096
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 2,220	\$ 2,929
Accrued liabilities	8,324	7,710
Deferred revenue	447	324
Current portion of operating lease liabilities	300	252
Current portion of contingent consideration	5,838	21,857
Current portion of notes payable	37	51
Other current liabilities	386	293
Total current liabilities	17,552	33,416
Non-current liabilities		
Long-term notes payable, net of current portion	35,807	35,225
Long-term operating lease liabilities	25,478	25,163
Other long-term liabilities	744	712
Total non-current liabilities	62,029	61,100
Total liabilities	79,581	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; 145,149,630 (2024) and 96,235,883 (2023) shares issued and outstanding	145	96
Additional paid-in capital	480,103	424,050
Accumulated deficit	(443,988)	(419,566)
Total stockholders' equity	36,260	4,580
Total liabilities and stockholders' equity	\$ 115,841	\$ 99,096

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenues				
Diagnostic Testing revenue	\$ 16,539	\$ 11,449	\$ 30,335	\$ 20,094
Biopharmaceutical Services and other revenue	1,386	423	2,408	834
Total revenues	17,925	11,872	32,743	20,928
Direct costs and expenses	3,877	3,238	7,052	6,407
Research and development	2,558	2,910	4,598	6,161
Sales, marketing, general and administrative	19,660	16,651	40,216	35,640
Impairment loss on intangible assets	67	—	135	20
Total operating expenses	26,162	22,799	52,001	48,228
Loss from operations	(8,237)	(10,927)	(19,258)	(27,300)
Other (expense) income:				
Interest expense	(1,936)	(2,430)	(4,465)	(4,821)
Loss on extinguishment of liabilities	(248)	—	(248)	—
Change in fair value of warrant liability, net	—	—	—	61
Other (expense) income, net	(387)	1	(451)	2
Total other expense	(2,571)	(2,429)	(5,164)	(4,758)
Net loss	\$ (10,808)	\$ (13,356)	\$ (24,422)	\$ (32,058)
Net loss per share, basic and diluted	\$ (0.08)	\$ (0.17)	\$ (0.22)	\$ (0.41)
Weighted-average shares outstanding, basic and diluted	127,168	78,506	112,167	78,138

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Net loss	\$ (10,808)	\$ (13,356)	\$ (24,422)	\$ (32,058)
Interest expense	1,936	2,430	4,465	4,821
Depreciation and amortization	1,412	784	2,832	1,569
Share-based compensation expense	1,218	1,057	3,858	3,338
Loss on extinguishment of liabilities	248	—	248	—
COVID-19 Revenue	—	—	—	(13)
COVID-19 Direct costs and expenses	—	—	—	1
Change in fair value of warrant liability, net	—	—	—	(61)
Other expense (income), net	387	(1)	451	(2)
Adjusted EBITDA	<u>\$ (5,607)</u>	<u>\$ (9,086)</u>	<u>\$ (12,568)</u>	<u>\$ (22,405)</u>

