

**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, 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 August 7, 2023, Biodesix, Inc. (the Company) issued a press release announcing the financial and operating results of the Company for the second quarter ended June 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 August 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: August 7, 2023

BIODESIX, INC.

By: /s/ Robin Harper Cowie

Name: Robin Harper Cowie

Title: Chief Financial Officer



Biodesix Announces Second Quarter 2023 Results and Highlights

Second quarter 2023 Core Lung Diagnostic revenue of \$11.4 million increased 58% over the comparable period in 2022 and 33% over the first quarter of 2023;

Second quarter 2023 gross profit margin of 73% versus 64% for the second quarter 2022 and 65% for the first quarter 2023;

Revenue continues to track to 2023 full year guidance of \$52-55 million;

Approximately \$27.5 million in common shares sold under a private placement from the Company's largest investors, Board of Directors members, and Executive Leadership team;

Multiple publications and data presentations on the clinical utility and health economic benefits of Core Lung Diagnostics tests;

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

BOULDER, CO, August 7, 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 second quarter ended June 30, 2023 and provided a corporate update

“I am very pleased to announce another record-setting quarter from our core lung diagnostics,” said Scott Hutton, President and Chief Executive Officer. “In addition to continued sales growth, we had a number of important publications this past quarter that highlighted the benefits to patient care of our lung diagnostic tests in a real-world, clinical setting.

We are also happy to announce the successful completion of a private placement that included some of our largest shareholders and management. All board members, all Section 16 officers, and additional members of the Biodesix leadership team participated in the round raising \$27.5 million in equity funding to further support our growth. We also maintained strong cost discipline, with sustainable and improving gross margins to 73% from 65%, and reducing our Operating Expense excluding direct costs and expenses by \$2.7 million, all versus first quarter 2023. We continue to focus on projects and initiatives that drive near term-revenue growth, while reducing expenses and cash burn. Overall, the progress and positive trends in our core lung diagnostics tests in the first half of the year solidifies our confidence in reaffirming our 2023 revenue guidance and making progress on our path to profitability.”

Business Highlights

Biodesix continues to publish new data supporting the value and utility of their lung diagnostics portfolio. The Company was pleased to announce the following accomplishments:

- Published the achievement of the primary endpoint of the prospective ORACLE clinical utility study, demonstrating that use of the Nodify XL2 test resulted in a 74% decrease in unnecessary invasive procedures on patients with benign lung nodules compared to the control group;
 - Researchers from Beth Israel Deaconess, Tulane University, and Einstein Medical Center published an independent, multi-center study demonstrating that use of the Nodify XL2 test resulted in a 73% reduction in the number of invasive procedures compared to the control arm;
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- Presented new health economics data on the Nodify XL2®, Nodify CDT®, and VeriStrat® tests at the American Society of Clinical Oncology (ASCO) and the International Society for Pharmaceutical and Outcomes Research (ISPOR). These data indicate savings to the US healthcare system with use of the tests;
- Completed enrollment of 5,000 patients with non-small cell lung cancer (NSCLC) in the large multi-center observational registry study INSIGHT. The study was designed to further validate the utility of the VeriStrat test;
- Announced that CMS has designated the Nodify CDT Test as an Advanced Diagnostic Laboratory Test (ADLT) effective June 30, 2023. ADLT status is reserved for innovative tests with Medicare coverage that provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests.

Second Quarter 2023 Financial Results

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

- Total revenue of \$11.9 million, an increase of 8% including COVID testing revenue in second quarter 2022, driven primarily by strong year-over-year growth in core lung diagnostics, and a 48% year-over-year increase excluding COVID testing revenues from the prior year comparison.
 - o *Core lung diagnostic revenue of \$11.4 million reflected a year-over-year increase of 58% driven primarily by the continued adoption of Nodify Lung® nodule management tests;*
 - o *BioPharma Services revenue of \$0.4 million decreased 43% year-over-year. Timelines for existing and new agreements continue to be impacted by delayed enrollment in clinical trials; entered the third quarter of 2023 with continued strong dollars under contract;*
 - o *COVID-19 testing revenue decreased by 100% year-over-year, the Company no longer provides COVID-19 diagnostic testing services commercially;*
 - Second quarter 2023 gross profit of \$8.6 million, or 73% gross margin as compared to 64% 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 the commercial discontinuation of our lower-margin COVID-19 diagnostic testing;
 - Operating expenses (excluding direct costs and expenses) of \$19.6 million, an increase of approximately \$1.0 million, or 5% as compared to the second quarter 2022 (includes non-cash stock compensation expense of \$1.1 million as compared to \$1.4 million). This increase is primarily attributable to increased sales and marketing costs to support core lung diagnostic sales growth including increased travel-related costs and marketing programs to enhance product awareness as we actively participate in an increasing number of peer-to-peer physician educational events;
 - Net loss of \$13.4 million, a decrease of approximately \$2.5 million, or 16%;
 - Cash and cash equivalents of \$17.4 million as of June 30, 2023, a decrease of \$7.9 million from March 31, 2023. This represented an improvement of approximately 56% in cash utilization versus the cash utilized in the first quarter 2023;
 - o *Scheduled milestone payment of \$2.3 million paid in April 2023 to Integrated Diagnostics;*
 - o *Subsequent to quarter end, raised \$27.5 million in gross equity proceeds from a private placement to be used for commercial expansion of sales, research and development, and for general corporate purposes.*
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2023 Financial Outlook

The Company reaffirms our 2023 financial outlook and expects to generate between \$52 million and \$55 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).

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 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 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 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.

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

	June 30, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	\$ 17,409	\$ 43,088
Accounts receivable, net of allowance for doubtful accounts of \$150 and \$118	4,119	5,065
Other current assets	3,717	5,181
Total current assets	25,245	53,334
Non-current assets		
Property and equipment, net	18,996	5,848
Intangible assets, net	8,871	9,797
Operating lease right-of-use assets	2,492	2,973
Goodwill	15,031	15,031
Other long-term assets	6,988	5,923
Total non-current assets	52,378	39,572
Total assets	\$ 77,623	\$ 92,906
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities		
Accounts payable	\$ 3,501	\$ 1,685
Accrued liabilities	6,981	8,218
Deferred revenue	1,069	962
Current portion of operating lease liabilities	1,504	1,543
Current portion of contingent consideration	14,561	10,341
Current portion of notes payable	50	49
Other current liabilities	285	41
Total current liabilities	27,951	22,839
Non-current liabilities		
Long-term notes payable, net of current portion	24,658	25,004
Long-term operating lease liabilities	18,808	5,254
Contingent consideration	12,303	18,645
Other long-term liabilities	896	558
Total non-current liabilities	56,665	49,461
Total liabilities	84,616	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; 78,610,663 (2023) and 77,614,358 (2022) shares issued and outstanding	79	78
Additional paid-in capital	392,406	387,948
Accumulated deficit	(399,478)	(367,420)
Total stockholders' (deficit) equity	(6,993)	20,606
Total liabilities and stockholders' (deficit) equity	\$ 77,623	\$ 92,906

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Revenues				
Lung diagnostic	\$ 11,449	\$ 7,252	\$ 20,081	\$ 11,901
COVID-19	—	2,954	13	3,938
Diagnostic testing revenue	11,449	10,206	20,094	15,839
Biopharma services	423	744	834	1,659
Total revenues	11,872	10,950	20,928	17,498
Direct costs and expenses	3,238	3,980	6,407	7,215
Research and development	2,910	3,361	6,161	6,567
Sales, marketing, general and administrative	16,651	15,235	35,640	29,722
Impairment loss on intangible assets	—	—	20	81
Total operating expenses	22,799	22,576	48,228	43,585
Loss from operations	(10,927)	(11,626)	(27,300)	(26,087)
Other (expense) income:				
Interest expense	(2,430)	(1,346)	(4,821)	(2,483)
Loss on debt extinguishments, net	—	(2,952)	—	(2,952)
Change in fair value of warrant liability	—	—	61	—
Other income, net	1	100	2	112
Total other expense	(2,429)	(4,198)	(4,758)	(5,323)
Net loss	\$ (13,356)	\$ (15,824)	\$ (32,058)	\$ (31,410)
Net loss per share, basic and diluted	\$ (0.17)	\$ (0.40)	\$ (0.41)	\$ (0.89)
Weighted-average shares outstanding, basic and diluted	78,506	39,239	78,138	35,177

