

**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 3, 2022

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 3, 2022, Biodesix, Inc. (the Company) issued a press release announcing the financial and operating results of the Company for the third quarter ended September 30, 2022. 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 3, 2022
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 3, 2022

BIODESIX, INC.

By: /s/ Robin Harper Cowie

Name: Robin Harper Cowie

Title: Chief Financial Officer



Biodesix Announces Third Quarter 2022 Results and Highlights

Third quarter 2022 core Lung Diagnostic revenue of \$9.2 million increased 102% over the comparable period in 2021;

U.S. Federal Supply Schedule Contract expands coverage to Veterans Health Administration and Military Health System Medical Centers for its entire Lung Diagnostic portfolio;

Conference Call and Webcast Today at 8:00 a.m. ET

BOULDER, CO, November 3, 2022 – 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 third quarter ended September 30, 2022 and provided a corporate update.

“Our core lung diagnostic testing momentum through the third quarter resulted in record test volume and revenue. Lung diagnostic revenue grew 102% over the third quarter of 2021 and 26% over the second quarter 2022,” said Scott Hutton, President and CEO. “In addition to a focus on sales growth, we have also accomplished several specific strategic reimbursement goals, including all five of our core lung diagnostic tests now being covered by Medicare and the addition of these tests to the Federal Fee Schedule contract for the U.S. Department of Veteran Affairs. These achievements have us well positioned for strong growth and continued high gross margin contributions as we look to the fourth quarter 2022 and beyond. We also remain committed to being a data-driven company through the expansion of our body of supportive clinical data and were proud to have recently participated in the American College of Chest Physicians (CHEST) annual meeting where we had several key presentations.”

Third Quarter 2022 Financial Results

For the three-month period ended September 30, 2022, as compared to the same period of 2021 (where applicable):

- Total revenue of \$11.1 million, an increase of 70%, driven primarily by strong year-over-year growth in core lung diagnostics:
 - o *Core lung diagnostic revenue of \$9.2 million, reflected a year-over-year increase of 102% driven primarily by the increased adoption of Nodify Lung nodule management tests (Nodify CDT & Nodify XL2 tests) and the recent GeneStrat NGS commercial launch;*
 - o *COVID-19 testing revenue of \$1.3 million reflected a year-over-year increase of 154% that was driven primarily by testing volume under a now expired contract with the State of Colorado;*
 - o *BioPharma Services revenue of \$0.7 million decreased 55% year-over-year. COVID-related delays in clinical study enrollment and sample shipping logistics have begun to recover but are still impacting timelines for existing and new agreements;*
 - Third quarter 2022 gross profit of \$7.5 million, or 67% gross margin as compared to 58% gross margin in the comparable prior year period primarily driven by the growth of sales in our higher-margin core lung diagnostics;
 - Operating expenses (excluding direct costs and expenses) of \$18.1 million, an increase of 7% driven primarily by growth in sales and marketing which support the record growth in core lung diagnostics sales as well as the recent GeneStrat NGS™ commercial launch;
 - o *Includes non-cash stock compensation expense of \$1.2 million as compared to \$1.4 million;*
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- Net loss of \$13.7 million, an increase of 19%, driven primarily by a gain on extinguishment of \$3.1 million in the third quarter 2021 related to the debt forgiveness under the Small Business Administration Loan forgiveness program and higher interest costs of \$1.5 million partially offset by a reduction in operating loss of \$2.5 million or 19%;
- Cash and cash equivalents of \$15.2 million as of September 30, 2022;
 - o *Raised net proceeds of \$1.8 million during the quarter through equity offerings;*
 - o *Includes payments during the quarter for principal repayment of \$2.0 million on the 2021 Term Loan and \$2.1 million for scheduled milestone payment to Indi.*

2022 Financial Outlook

The Company expects to be at the high end of its previously disclosed total revenue guidance for 2022 of \$37.5 million and \$39.5 million. Our guidance contemplates minimal COVID-19 and BioPharma Services revenue in the fourth quarter and continued growth within our core lung diagnostic testing.

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.

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 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® ddPCR™ test, the GeneStrat NGS™ test and the VeriStrat® test to support treatment decisions across all stages of lung cancer with results in an unprecedented average of 36-72 hours, expediting 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

the COVID-19 pandemic on Biodesix and its operations, it is 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 14, 2022 or subsequent quarterly reports on Form 10-Q during 2022, 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)

	<u>September 30, 2022</u>	<u>December 31, 2021</u>
Assets		
Current assets		
Cash and cash equivalents	\$ 15,175	\$ 32,712
Accounts receivable, net of allowance for doubtful accounts of \$50 and \$158	4,449	3,656
Other current assets	4,494	7,245
Total current assets	24,118	43,613
Non-current assets		
Property and equipment, net	4,259	4,179
Intangible assets, net	10,223	11,617
Operating lease right-of-use assets	3,475	—
Goodwill	15,031	15,031
Other long-term assets	6,092	1,657
Total non-current assets	39,080	32,484
Total assets	<u>\$ 63,198</u>	<u>\$ 76,097</u>
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities		
Accounts payable	\$ 2,100	\$ 1,662
Accrued liabilities	6,677	7,665
Deferred revenue	1,637	1,850
Current portion of operating lease liabilities	1,436	—
Current portion of contingent consideration	9,286	17,764
Current portion of notes payable	14,334	19
Other current liabilities	1,945	—
Total current liabilities	37,415	28,960
Non-current liabilities		
Long-term notes payable, net of current portion	4,880	9,993
Long-term operating lease liabilities	2,855	—
Contingent consideration	20,891	16,028
Other long-term liabilities	60	1,389
Total non-current liabilities	28,686	27,410
Total liabilities	66,101	56,370
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized; 0 (2022 and 2021) shares issued and outstanding	—	—
Common stock, \$0.001 par value, 200,000,000 shares authorized; 41,185,532 (2022) and 30,789,649 (2021) shares issued and outstanding	41	31
Additional paid-in capital	344,138	321,669
Accumulated deficit	(347,082)	(301,973)
Total stockholders' (deficit) equity	(2,903)	19,727
Total liabilities and stockholders' (deficit) equity	<u>\$ 63,198</u>	<u>\$ 76,097</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues				
COVID-19	\$ 1,286	\$ 506	\$ 5,224	\$ 29,802
Lung diagnostic	9,157	4,533	21,058	13,270
Diagnostic testing revenue	10,443	5,039	26,282	43,072
Biopharma services	664	1,492	2,323	4,210
Total revenues	11,107	6,531	28,605	47,282
Direct costs and expenses	3,633	2,722	10,848	28,025
Research and development	2,970	3,293	9,537	9,937
Sales, marketing, general and administrative	15,114	13,607	44,836	36,959
Change in fair value of contingent consideration	—	—	—	1,622
Impairment loss on intangible assets	—	—	81	—
Total operating expenses	21,717	19,622	65,302	76,543
Loss from operations	(10,610)	(13,091)	(36,697)	(29,261)
Other (expense) income:				
Interest expense	(3,039)	(1,546)	(5,522)	(3,012)
(Loss) gain on extinguishment of liabilities, net	(52)	3,123	(3,004)	2,395
Other income, net	2	—	114	1
Total other (expense) income	(3,089)	1,577	(8,412)	(616)
Net loss	\$ (13,699)	\$ (11,514)	\$ (45,109)	\$ (29,877)
Net loss per share, basic and diluted	\$ (0.34)	\$ (0.41)	\$ (1.22)	\$ (1.09)
Weighted-average shares outstanding, basic and diluted	40,448	28,051	36,953	27,467

