

**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**

October 11, 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 October 11, 2022, Biodesix, Inc. (the “Company”) issued a press release announcing certain preliminary and unaudited financial 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 included in this Current Report on Form 8-K (including Exhibit 99.1 hereto) that is furnished pursuant to this Item 2.02 shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Exchange Act or Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

No.	Exhibit
99.1	Press Release issued by Biodesix, Inc. dated October 11, 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: October 11, 2022

BIODESIX, INC.

By: /s/ Robin Harper Cowie

Name: Robin Harper Cowie

Title: Chief Financial Officer



Biodesix Announces Preliminary Revenue for Third Quarter 2022

Third quarter 2022 core lung diagnostic testing revenues growth up 96% to 103% compared to third quarter 2021

Boulder, CO, October 11, 2022- Biodesix, Inc. (NASDAQ: BDSX), a leading data-driven diagnostic solutions company with a focus in lung disease, today announced that the Company expects to report third quarter 2022 total revenue to be in the range of \$10.6 million to \$11.2 million, representing growth of 62% to 71% over the third quarter 2021. The strength in the third quarter 2022 total revenue reflects continued growth in the Company's core lung diagnostic testing. The financial results included in this release pertaining to the third quarter 2022 are preliminary, subject to completion of internal procedures and review.

Third Quarter 2022 Financial Highlights

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

- Total quarterly revenue estimated to be in the range of \$10.6 million to \$11.2 million, an increase of \$4.1 million to \$4.7 million, or 62% to 71%;
- Total quarterly lung diagnostic testing revenue estimated to be in the range of \$8.9 million to \$9.2 million, an increase of \$4.4 million to \$4.7 million, or 96% to 103%;
- Total quarterly COVID diagnostic testing revenue estimated to be in the range of \$1.1 million to \$1.3 million, an increase of \$0.6 million to \$0.8 million, or 117% to 157%;
- Total quarterly biopharma services revenue estimated to be in the range of \$0.6 million to \$0.7 million, a decrease of \$0.8 million to \$0.9 million, or 53% to 60%;
- Cash and cash equivalents of \$15.2 million as of September 30, 2022.

"We had another strong quarter that builds upon recent momentum and again was highlighted by record revenue and volume growth from our core lung diagnostic testing business," stated Scott Hutton, Chief Executive Officer. "Our lung diagnostic portfolio consists of five Medicare-covered tests to help physicians quickly and confidently decipher the risk of malignancy of a lung nodule and then help guide treatment decisions if a patient has been diagnosed with lung cancer. While we are pleased with our COVID testing results for the quarter, we do not expect any significant continued revenue generation from this testing given the previously disclosed expiration of our contract with the State of Colorado. We continue to be pleased with the interest and ongoing discussions around our BioPharma services although the revenue represents the continued delay in clinical study enrollment and sample shipping logistics impacting timelines for existing and new agreements. At Biodesix we have worked hard to build one of the most comprehensive suites of precision diagnostic tests to support clinical decision-making across the lung cancer continuum and are very pleased with the increased adoption of our tests by physicians to help improve patient care."

The Company expects to be at the high end of the range of its previously disclosed total revenue guidance for 2022 of \$37.5 million and \$39.5 million. We expect the fourth quarter 2022 to maintain continued growth in our core lung diagnostic business while COVID revenue is expected to decline to an immaterial amount based on current trends in COVID testing.

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® targeted 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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