# 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 4, 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)

following provisions:

**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

☐ 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					
ndicate by check mark whether the registrant is an emerging gr Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §2-		le 405 of the Securities Act of 1933 (17 CFR §230.405) or					
		le 405 of the Securities Act of 1933 (17 CFR §230.405) or					
Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §2-	40.12b-2). registrant has elected not to use t	he extended transition period for complying with any new					

#### Item 2.02. Results of Operations and Financial Condition.

On August 4, 2022, Biodesix, Inc. (the Company) issued a press release announcing the financial and operating results of the Company for the second quarter ended June 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 August 4, 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: August 4, 2022 BIODESIX, INC.

By: /s/ Robin Harper Cowie

Name: Robin Harper Cowie
Title: Chief Financial Officer



# **Biodesix Announces Second Quarter 2022 Results and Highlights**

Second quarter 2022 core Lung Diagnostic revenue of \$7.3 million increased 52% over the comparable period in 2021;

Received Medicare coverage for the Nodify CDT® Lung Nodule Test;

Announced strategic arrangements during the quarter (Royal Philips, Memorial Sloan Kettering Cancer Center and Bio-Rad);

Reaffirm 2022 revenue outlook of between \$37.5 million and \$39.5 million;

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

**BOULDER, CO, August 4, 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 second quarter ended June 30, 2022 and provided a corporate update.

"We are thrilled to announce strong growth from our core lung diagnostic testing, with an increase in revenue of 52% over the second quarter of 2021 and 56% over the first quarter of 2022," said Scott Hutton, CEO of Biodesix. "With the recent Medicare coverage of the Nodify CDT® test, all five of our core lung diagnostic tests are now covered, which will help drive adoption of the test and improve margins over the long term.

In addition, we announced two exciting corporate arrangements. The first, announced with Royal Phillips, integrates our Nodify Lung® tests into its Lung Cancer Orchestrator patient management system to help facilitate digital ordering of the tests following detection of a lung nodule with the ultimate goal of improving patient care and outcomes. The second, announced with Memorial Sloan Kettering Cancer Center and Bio-Rad Laboratories, allows us to leverage the capabilities of these leading organizations to potentially bring new transformative diagnostics to market, including our initial intention to co-develop a molecular minimal residual disease (MRD) test for solid tumors.

Overall, our progress and positive trends in our core lung diagnostics tests in the first half of the year solidifies our confidence in reaffirming our 2022 revenue guidance."

#### **Second Quarter 2022 Financial Results**

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

- Total revenue of \$11.0 million, a decrease of 8%, driven primarily by an anticipated year-over-year decline in COVID-19 diagnostic testing revenue, offset by strong year-over-year growth in core lung diagnostics:
  - o Core lung diagnostic revenue of \$7.3 million, reflected a year-over-year increase of 52% that was driven primarily by the increased adoption of Nodify Lung nodule management tests (Nodify CDT & Nodify XL2 tests);
  - o COVID-19 testing revenue of \$3.0 million reflected a year-over-year decrease of 51% that was driven by the shift to at-home rapid antigen testing;
  - o BioPharma Services revenue of \$0.7 million decreased 29% 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;

- Second quarter 2022 gross margin of \$7.0 million, or 64% as a percentage of revenue as compared to 40% in the comparable prior year period primarily driven by the shift of sales to higher-margin core lung diagnostics and away from lower-margin COVID-19 testing;
- Operating expenses (excluding direct costs and expenses) of \$18.6 million, an increase of 21% driven primarily by growth in sales and marketing to drive our growth in core lung diagnostics sales as well as the recent GeneStrat NGS™ commercial launch:
  - o Includes non-cash stock compensation expense of \$1.4 million as compared to \$0.5 million;
- Net loss of \$15.8 million, an increase of 39%, driven primarily by the loss on extinguishment charge resulting from the restructuring of the contingent consideration agreement with Integrated Diagnostics (Indi);
- Cash and cash equivalents of \$28.7 million, inclusive of \$5.1 million in restricted cash, as of June 30;
  - o Raised net proceeds of \$27.3 million during the quarter through debt and equity offerings;
  - o Includes principal payment of \$3.0 million on the 2021 Term Loan and \$2.0 million for scheduled milestone payment in April 2022 to Indi.

#### 2022 Financial Outlook

The Company reaffirms its 2022 financial outlook and expects to generate between \$37.5 million and \$39.5 million in total revenue in 2022.

#### Conference call and webcast information

Management will host an investor conference call and webcast today, August 4, 2022 at 8:00 a.m. Eastern Time.

Investor dial-in (domestic): 800-715-9871 Investor dial-in (international): 646-307-1963 Conference ID: 8620846

Webcast: https://edge.media-server.com/mmc/p/rf64jw58

An archived replay of the webcast will be available on the Company's website for a period of 90 days.

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 is the first company to offer eight non-invasive 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 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. Biodesix launched the SARS-CoV-2 ddPCR™ test, the Platelia SARS-CoV-2 Total Ab, and the cPass™ SARS-CoV-2 Neutralization Antibody test (cPass™ Neutralization Test Kit, GenScript, Inc,) in response to the global pandemic and virus that impacts the lung and causes COVID-19. 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 forwardlooking statements. All forward-looking statements are qualified in their entirety by this cautionary statement.

#### **Contacts:**

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#### **Investors:**

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

	Jui	June 30, 2022		December 31, 2021		
Assets						
Current assets						
Cash and cash equivalents	\$	23,586	\$	32,712		
Accounts receivable, net of allowance for doubtful accounts of \$52 and \$158		5,452		3,656		
Other current assets		6,019		7,245		
Total current assets		35,057		43,613		
Non-current assets						
Restricted cash		5,000		_		
Property and equipment, net		3,950		4,179		
Intangible assets, net		10,688		11,617		
Operating lease right-of-use assets		3,952		_		
Goodwill		15,031		15,031		
Other long-term assets		1,551		1,657		
Total non-current assets		40,172		32,484		
Total assets	\$	75,229	\$	76,097		
Liabilities and Stockholders' Equity						
Current liabilities						
Accounts payable	\$	1,791	\$	1.662		
Accrued liabilities	Ψ	6,667	Ψ	7,665		
Deferred revenue		2,230		1,850		
Current portion of operating lease liabilities		1,315				
Current portion of contingent consideration		8,151		17,764		
Current portion of notes payable		11,771		19		
Other current liabilities		1,149		_		
Total current liabilities		33,074	-	28,960		
Non-current liabilities		55,07		20,500		
Long-term notes payable, net of current portion		8,596		9,993		
Long-term operating lease liabilities		2,902				
Contingent consideration		22,916		16,028		
Other long-term liabilities		70		1,389		
Total non-current liabilities		34,484		27,410		
Total liabilities		67,558		56,370		
Commitments and contingencies		07,550		30,370		
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;		<u> </u>				
39,978,844 (2022) and 30,789,649 (2021) shares issued and outstanding		40		31		
Additional paid-in capital		341,014		321,669		
Accumulated deficit		(333,383)		(301,973)		
Total stockholders' equity		7,671		19,727		
Total liabilities and stockholders' equity	\$	75,229	\$	76,097		

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

	Three Months Ended June 30,			Six Months Ended June 30,			
		2022		2021	2022		2021
Revenues							
COVID-19	\$	2,954	\$	6,064	\$ 3,938	\$	29,296
Lung diagnostic		7,252		4,774	 11,901		8,737
Diagnostic testing revenue		10,206		10,838	15,839		38,033
Biopharma services		744		1,047	 1,659		2,718
Total revenues		10,950		11,885	17,498		40,751
Direct costs and expenses		3,980		7,085	7,215		25,303
Research and development		3,361		3,323	6,567		6,644
Sales, marketing, general and administrative		15,235		11,425	29,722		23,352
Change in fair value of contingent consideration				639	_		1,622
Impairment loss on intangible assets					 81		_
Total operating expenses		22,576		22,472	 43,585		56,921
Loss from operations		(11,626)		(10,587)	(26,087)		(16,170)
Other (expense) income:							
Interest expense		(1,346)		(815)	(2,483)		(1,466)
Loss on extinguishment of liabilities		(2,952)		_	(2,952)		(728)
Other income, net		100		<u> </u>	 112		1
Total other expense		(4,198)		(815)	(5,323)		(2,193)
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Net loss	\$	(15,824)	\$	(11,402)	\$ (31,410)	\$	(18,363)
Net loss per share, basic and diluted	\$	(0.40)	\$	(0.41)	\$ (0.89)	\$	(0.68)
Weighted-average shares outstanding, basic and diluted		39,239		27,730	35,177		27,020