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 10, 2021

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)

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(Zip Code)

80301

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 \boxtimes

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 10, 2021, Biodesix, Inc. (the "Company") issued a press release announcing the financial and operating results of the Company for the second quarter ended June 30, 2021. 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
00.1	Press Deleges issued by Diedesin Inc. dated Assesset 10, 2021

- 99.1 <u>Press Release issued by Biodesix, Inc. dated August 10, 2021</u>
- 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 10, 2021

BIODESIX, INC.

By:/s/ Robin Harper CowieName:Robin Harper Cowie

Title: Chief Financial Officer



Biodesix Announces Second Quarter 2021 Results and Highlights

Second Quarter 2021 Revenue of \$11.9 Million Increased 180% and Lung Diagnostic Revenue of \$4.8 Million Increased 109% over Second Quarter 2020

Announcing Acceleration of the Launch of the 72-hour liquid NGS Test to Early First Quarter 2022

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

BOULDER, CO, August 10, 2021 – <u>Biodesix, Inc.</u> (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, 2021 and provided a corporate update.

"It was a productive quarter with 180% year over year growth in total revenue. Our first four blood-based tests which make up our core lung diagnostic testing, grew 109% year over year and 20% over the prior quarter," said Scott Hutton, CEO of Biodesix. "We expect growth in core lung diagnostic testing to continue through 2021 driven by the U.S.'s emergence from the pandemic, productivity from our growing salesforce, and our efforts to build on the body of evidence supporting the use of our tests. Beyond our currently marketed products, we also continue to develop our Diagnostic Cortex® Artificial Intelligence (AI) platform and expand our pipeline of products capable of providing broad lung diagnostics to address patients' needs over the course of their disease. The launch of our 72-hour liquid NGS test is now projected for the first quarter of 2022 and will supplement our 36-hour VeriStrat and GeneStrat tests. With this accelerated launch and multiple studies underway for our Risk of Recurrence (ROR) and Primary Immune Response (PIR) tests as well as our ALTITUDE, BEACON, INSIGHT, and ORACLE prospective studies actively enrolling or following patients, we look forward to a productive and exciting second half of the year."

Second Quarter 2021 Financial Results

For the three-month period ended June 30, 2021, as compared to the same period of 2020 (where applicable):

- Total revenue of \$11.9 million, an increase of 180%;
- Core lung diagnostic revenue of \$4.8 million, an increase of 109%;
 - Continued sequential recovery from initial rapid uptake of COVID-19 immunizations.
 - Growth driven primarily by Nodify XL2® and Nodify CDT®.
 - Nodify XL2 growth triggered the previously disclosed milestone resulting in a \$37 million obligation payable by us over six quarterly installments of approximately \$4.6 million beginning January 2022 and a final payment of approximately \$9.3 million in July 2023.
- COVID-19 testing revenue of \$6.1 million, an increase of 345%;
 - Sequential quarter over quarter decline commensurate with our prior commentary as US immunizations accelerated in second quarter.



• Services revenue of \$1.0 million, an increase of 76%;

- Clinical trial services showed improvement and we expect further recovery in clinical trial enrollments in second half of 2021.
- Gross profit of \$4.8 million, an increase of 103%, and gross margin percentage of 40% as compared to 56% representing a decline primarily attributable to the lower gross margin COVID-19 testing;
- Operating expenses (excluding direct costs and expenses) of \$15.4 million, which includes an investment in the planned expansion of our sales force, increased 93% over second quarter 2020;
 - On track to double size of lung focused direct and dedicated sales force in 2021.
 - Non-cash stock compensation expense of \$0.5 million as compared to \$0.1 million.
 - Non-cash expense for change in fair value of contingent consideration of \$0.6 million as compared to a gain of \$1.0 million.
- Net loss of \$11.4 million, an increase of 38% over second quarter of 2020; and
- Maintained fiscal discipline and strong liquidity with cash and cash equivalents of \$56.3 million as of June 30, 2021 and expect to qualify for PPP loan forgiveness of \$3.1 million later in 2021.

For a full list of Biodesix's press releases and webinars, please visit Biodesix.com.

Conference call and webcast information

Management will host an investor conference call and webcast today, August 10, 2021 at 4:30 p.m. Eastern Time.

Investor dial-in (domestic):	833-665-0678
Investor dial-in (international):	929-517-0173
Conference ID:	6519549
Webcast:	https://edge.media-server.com/mmc/p/2hp2grhc

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

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 seven non-invasive tests for patients with diseases of the lung. 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. The blood-based Biodesix Lung Reflex® strategy for lung cancer patients integrates the GeneStrat® and VeriStrat® tests to support treatment decisions with results in 36 hours, expediting time to treatment. 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. Biodesix also leverages the proprietary and advanced Diagnostic Cortex® AI 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. 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 16, 2021 or subsequent quarterly reports on Form 10-Q during 2021, 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 forwardlooking statements are qualified in their entirety by this cautionary statement.

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

	June 30, 2021		December 31, 2020	
Assets				
Current assets				
Cash and cash equivalents	\$	56,349	\$ 62,126	
Accounts receivable, net of allowance for doubtful accounts of \$168 and \$180		5,281	15,304	
Other current assets		6,820	8,710	
Total current assets		68,450	 86,140	
Non-current assets				
Property and equipment, net		3,378	3,178	
Intangible assets, net		12,400	13,260	
Other long-term assets		2,545	3,461	
Goodwill		15,031	15,031	
Total non-current assets		33,354	 34,930	
Total assets	\$	101,804	\$ 121,070	
Liabilities and Stockholders' Equity				
Current liabilities				
Accounts payable	\$	1,160	\$ 8,964	
Accrued liabilities		6,198	7,789	
Deferred revenue		2,182	3,532	
Current portion of contingent consideration		8,626	—	
Current portion of notes payable		3,106	 11,840	
Total current liabilities		21,272	32,125	
Non-current liabilities				
Long-term notes payable, net of current portion		29,955	15,926	
Contingent consideration		23,217	29,932	
Other long-term liabilities		1,587	1,921	
Total non-current liabilities		54,759	47,779	
Total liabilities		76,031	 79,904	
Commitments and contingencies				
Stockholders' equity				
Preferred stock, \$0.001 par value, 5,000,000 shares authorized;				
0 (2021 and 2020) shares issued and outstanding		—	—	
Common stock, \$0.001 par value, 200,000,000 shares authorized;				
26,948,879 (2021) and 26,561,504 (2020) shares issued and outstanding		27	27	
Additional paid-in capital		302,923	299,953	
Accumulated deficit		(277,177)	 (258,814)	
Total stockholders' equity		25,773	 41,166	
Total liabilities and stockholders' equity	\$	101,804	\$ 121,070	



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

	Three Months Ended June 30,				Six Months Ended June 30,			
	 2021		2020		2021		2020	
Revenues					_			
COVID-19	\$ 6,064	\$	1,363	\$	29,296	\$	1,363	
Lung diagnostic	4,774		2,280		8,737		5,883	
Diagnostic testing revenue	10,838		3,643		38,033		7,246	
Biopharma services	1,047		596		2,718		2,089	
Total revenues	11,885		4,239		40,751		9,335	
Direct costs and expenses	7,085		1,874		25,303		3,455	
Research and development	3,323		2,107		6,644		5,007	
Sales, marketing, general and administrative	11,425		6,834		23,352		14,914	
Change in fair value of contingent consideration	 639		(957)		1,622			
Total operating expenses	22,472		9,858		56,921		23,376	
Loss from operations	(10,587)		(5,619)		(16,170)		(14,041)	
Other income (expense):								
Interest expense	(815)		(2,784)		(1,466)		(4,241)	
Change in fair value of warrant liability	—		4		—		55	
Loss on debt extinguishment	_		_		(728)		_	
Other income, net	 		133		1		256	
Total other expense	(815)		(2,647)		(2,193)		(3,930)	
	 <u>.</u>							
Net loss	\$ (11,402)	\$	(8,266)	\$	(18,363)	\$	(17,971)	
Net loss per share, basic and diluted	\$ (0.41)	\$	(30.06)	\$	(0.68)	\$	(68.85)	
Weighted-average shares outstanding, basic and diluted	27,730		275		27,020		261	