

Biodesix Announces First Quarter 2024 Results Driven by Growth in Lung Diagnostic Testing for Lung Nodule Management

May 8, 2024

First quarter 2024 Total Revenue of \$14.8 million, a year-over-year increase of 64%, and 7th consecutive quarter of >50% growth in Lung Diagnostic test volume;

First quarter 2024 gross profit margin of 79% versus 65% for the first quarter 2023 and 77% for the fourth quarter of 2023;

Raised \$55 million in gross proceeds from an oversubscribed and upsized underwritten public offering of common stock and concurrent private placement in April 2024;

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

LOUISVILLE, Colo.--(BUSINESS WIRE)--May 8, 2024-- Biodesix, Inc. (Nasdaq: BDSX), a leading diagnostic solutions company with a focus in lung disease, today announced its financial and operating results for the first quarter ended March 31, 2024, and provided a corporate update.

"I am very pleased to announce yet another quarter of greater than 50% revenue and volume growth and 14 percentage point improvement in gross margins," said Scott Hutton, CEO of Biodesix. "This is a year of execution with three main goals: growing top line revenue, implementing operational efficiencies while maintaining cost discipline, and making significant progress on our path to profitability. In the first quarter, we delivered approximately 11,900 Lung Diagnostic tests, an increase of 57% over the prior year comparable period and our seventh consecutive quarter of greater than 50% year-over-year volume growth. In addition, our Biopharmaceutical Services business grew 149% year-over-year, as we continue to deliver against our increasing book of contracted business and secure additional agreements with existing and new customers. We made operational improvements resulting in increased gross margins and combined with our disciplined expense management, we improved Net Loss by 27% and Adjusted EBITDA by 48% over the first quarter of 2023. Our team is off to a strong start, helping to impact more patients every quarter in the large and underserved lung nodule diagnostic testing market. Following the closing of the offering in April, we are well capitalized and positioned to execute on our plan of growing top line revenue and reaching profitability."

Key Business Highlights

- Lung Diagnostic testing revenue of \$13.8 million grew 60% from volumes of approximately 11,900, which grew 57% over the first quarter 2023.
- Record quarterly gross profit margin of 79% versus 65% for the first quarter 2023 and 77% for the fourth quarter of 2023.
- Announced new master collaborative research agreement with Memorial Sloan Kettering Cancer Center (MSKCC) under which the teams will collaborate on the development of diagnostic tests aimed at improving the treatment of cancer.
- At the American Association for Cancer Research (AACR) Annual Meeting in March 2024, investigators for the FLAURA2 study sponsored by AstraZeneca presented data in a plenary session demonstrating the use of blood-based ddPCR EGFR testing performed by Biodesix.
- Raised \$55.0 million in gross proceeds from an oversubscribed and upsized underwritten offering of common stock and concurrent private placement.

First Quarter 2024 Financial Results

For the three-month period ended March 31, 2024, as compared to the same period of 2023 (where applicable):

- Total revenue of \$14.8 million, an increase of 64%, driven by strong year-over-year growth in both Lung Diagnostics and Biopharmaceutical Services;
 - Lung Diagnostic revenue of \$13.8 million reflected a year-over-year increase of 60% driven primarily by the continued adoption of Nodify Lung[®] nodule risk assessment tests;
 - Biopharmaceutical Services and Other revenue of \$1.0 million increased 149% year-over-year, a result of both delivering against the Company's increasing book of contracted business and securing new agreements with both new and existing partners;
- First quarter 2024 gross profit of \$11.6 million, or 79% gross margin compared to 65% 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 increased process efficiencies in its Biopharmaceutical Services business:
- Operating expenses (excluding direct costs and expenses) of \$22.7 million, an increase of approximately \$0.4 million, or 2% as compared to the first quarter 2023 (includes non-cash stock compensation expense, depreciation and amortization, and asset impairment of \$4.1 million as compared to \$3.1 million). This increase is primarily attributable to an increase in depreciation expense related to the leasehold improvements in the Company's new Louisville, CO offices and laboratory,

increased sales and marketing costs to support lung diagnostic sales growth to enhance product awareness and drive adoption, partially offset by a decrease in research and development costs;

- Net loss of \$13.6 million, an improvement of approximately \$5.1 million, or 27%;
- Adjusted EBITDA was a loss of \$7.0 million, an improvement of \$6.4 million, or 48%;
- Cash and cash equivalents of \$11.5 million as of March 31, 2024, a decrease of \$14.8 million from December 31, 2023;
 - Cash and cash equivalents as of March 31, 2024 excludes \$55.0 million in gross proceeds raised from an underwritten offering of common stock and concurrent private placement completed on April 5, 2024. Net proceeds from the offering are expected to be used for commercial expansion of sales, research and development, and for general corporate purposes.
 - o Includes the scheduled milestone payment of \$3.4 million paid in January 2024 for the acquisition of Integrated Diagnostics in 2018. Payments include required milestone installments plus interest through the date of the payment. Subsequent to the end of the quarter the Company made the scheduled milestone payment of \$5.3 million on April 1 and prepaid the July 1, 2024 milestone payment of \$8.4 million which included interest through the date of payment. The Company has one payment of \$6.1 million remaining, which does not accrue interest.

2024 Financial Outlook

The Company reaffirms its 2024 financial outlook and expects to generate between \$65 million and \$68 million in total revenue in 2024.

Conference call and webcast information

Listeners can register for the webcast via this <u>link</u>. Analysts who wish to participate in the question and answer session should use this <u>link</u>. A replay of the webcast will be available via the Company's investor website approximately two hours after the call's conclusion. Participants are advised to join 15 minutes prior to the start time.

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

Use of Non-GAAP Financial Measure

Biodesix reported results are presented in accordance with generally accepted accounting principles in the United States (GAAP). Biodesix has provided in this press release financial information that has not been prepared in accordance with GAAP. Biodesix uses the non-GAAP financial measure, *Adjusted EBITDA*, internally in analyzing its financial results and believes that use of this non-GAAP financial measure is useful to investors as an additional tool to evaluate ongoing operating results and trends and in comparing Biodesix's financial results with other companies in its industry, many of which present similar non-GAAP financial measures. Non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable GAAP financial measures and should be read only in conjunction with Biodesix's financial statements prepared in accordance with GAAP. A reconciliation of Biodesix historical non-GAAP financial measure to the most directly comparable GAAP measure has been provided in the financial statement tables included in this press release, and investors are encouraged to review the reconciliation.

Adjusted EBITDA is a key performance measure that our management uses to assess our financial performance and is also used for internal planning and forecasting purposes. We believe that this non-GAAP financial measure is useful to investors and other interested parties in analyzing our financial performance because it provides a comparable overview of our operations across historical periods. In addition, we believe that providing Adjusted EBITDA, together with a reconciliation of Net loss to Adjusted EBITDA, helps investors make comparisons between our Company and other companies that may have different capital structures, different tax rates, and/or different forms of employee compensation.

Adjusted EBITDA is used by our management team as an additional measure of our performance for purposes of business decision-making, including managing expenditures. Period-to-period comparisons of Adjusted EBITDA help our management identify additional trends in our financial results that may not be shown solely by period-to-period comparisons of Net loss or Loss from operations. Our management recognizes that Adjusted EBITDA has inherent limitations because of the excluded items and may not be directly comparable to similarly titled metrics used by other companies.

We calculate Adjusted EBITDA as Net loss adjusted to exclude interest, income tax expense, if any, depreciation and amortization, share-based compensation expense, loss on debt extinguishments, net, COVID-19 revenue, COVID-19 direct costs and expenses, change in fair value of warrant liabilities, net, other income, net, and other non-recurring items. Non-recurring items are excluded as they are not representative of our underlying operating performance. We also exclude revenue and direct costs and expenses associated with COVID-19 because we believe that these revenues and expenses do not reflect expected future operating results as they do not represent our Lung Diagnostic and Biopharmaceutical Services business. Adjusted EBITDA should be viewed as a measure of operating performance that is a supplement to, and not a substitute for Loss from operations, Net loss, and other GAAP measures.

About Biodesix

Biodesix is a leading diagnostic solutions and services 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 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 collaborates 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 backlog and the timing and assumptions regarding collection of revenues on projections, availability of funds and future capital including under the term loan facility, expectations regarding revenue and margin growth and its impact on profitability, and the impact of a pandemic, epidemic, or outbreak, including the COVID-19 pandemic, on Biodesix and its operations and financial performance. 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 most recent annual report on Form 10-K, filed March 1, 2024 or subsequent quarterly reports on Form 10-Q during 2024, 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

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

	March 31, 2024		December 31, 2023	
Assets		· ·		
Current assets				
Cash and cash equivalents	\$	11,491	\$	26,284
Accounts receivable, net of allowance for doubtful accounts of \$161 and \$65		9,893		7,679
Other current assets		7,095		5,720
Total current assets		28,479		39,683
Non-current assets				
Property and equipment, net		28,575		27,867
Intangible assets, net		7,384		7,911
Operating lease right-of-use assets		1,557		1,745
Goodwill		15,031		15,031
Other long-term assets		6,175		6,859
Total non-current assets		58,722		59,413
Total assets	\$	87,201	\$	99,096
Liabilities and Stockholders' (Deficit) Equity	,			
Current liabilities				
Accounts payable	\$	3,213	\$	2,929
Accrued liabilities		7,898		7,710
Deferred revenue		313		324
Current portion of operating lease liabilities		272		252
Current portion of contingent consideration		19,195		21,857
Current portion of notes payable		45		51
Other current liabilities		294		293
Total current liabilities		31,230		33,416
Non-current liabilities				
Long-term notes payable, net of current portion		35,511		35,225
Long-term operating lease liabilities		25,347		25,163
Other long-term liabilities		615		712
Total non-current liabilities		61,473		61,100
Total liabilities		92,703		94,516
Commitments and contingencies				
Stockholders' equity				
Preferred stock, \$0.001 par value, 5,000,000 authorized; 0 (2024 and 2023) issued and outstanding		_		_
Common stock, \$0.001 par value, 200,000,000 authorized; 97,159,448 (2024) and 96,235,883 (2023) shares issued and outstanding		97		96
Additional paid-in capital		427,581		424,050
Accumulated deficit		(433,180)		(419,566 ₎
Total stockholders' (deficit) equity		(5,502)		4,580
Total liabilities and stockholders' equity	\$	87,201	\$	99,096

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

	Th	Three Months Ended March 31,			
		2024	2023		
Revenues				,	
Diagnostic Testing revenue	\$	13,796	\$	8,645	
Biopharmaceutical Services and other revenue		1,022		411	
Total revenues		14,818		9,056	
Direct costs and expenses		3,175		3,169	
Research and development		2,040		3,251	
Sales, marketing, general and administrative		20,556		18,989	
Impairment loss on intangible assets		68		20	
Total operating expenses		25,839		25,429	
Loss from operations		(11,021)		(16,373)	
Other (expense) income:					
Interest expense		(2,529)		(2,391)	
Change in fair value of warrant liability, net		_		61	
Other (expense) income, net		(64 ₎		1	
Total other expense		(2,593)		(2,329)	
Net loss	\$	(13,614)	\$	(18,702)	
Net loss per share, basic and diluted	\$	(0.14)	\$	(0.24)	
Weighted-average shares outstanding, basic and diluted		97,166		77,765	

Biodesix, Inc. Reconciliation of Net Loss to Adjusted EBITDA (unaudited) (in thousands)

		Three Months Ended March 31,			
Net loss		2023			
	\$	(13,614)	\$	(18,702)	
Interest expense		2,529		2,391	
Depreciation and amortization		1,420		785	
Share-based compensation expense		2,640		2,281	
COVID-19 Revenue		_		(13)	
COVID-19 Direct costs and expenses		_		1	
Change in fair value of warrant liability, net		_		(61)	
Other expense (income), net		64		(1)	
Adjusted EBITDA	\$	(6,961)	\$	(13,319)	

View source version on businesswire.com: https://www.businesswire.com/news/home/20240508256571/en/

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Source: Biodesix, Inc.