**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, DC 20549**



**FORM 8-K**



**CURRENT REPORT**

**Pursuant to Section 13 or 15(d)**

**of the Securities Exchange Act of 1934**

**Date of report (Date of earliest event reported): December 10, 2020**



**Biodesix, Inc.**

**(Exact Name of Registrant as Specified in Charter)**



|  |  |  |
| --- | --- | --- |
| **Delaware** | **001-39659** | **20-3986492** |
| **(State or other jurisdiction** | **(Commission** | **(I.R.S. Employer** |
| **of incorporation)** | **File Number)** | **Identification No.)** |
| **2970 Wilderness Place, Suite 100** |  |  |
| **Boulder, Colorado** |  | **80301** |
| **(Address of Principal Executive Office)** |  | **(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** | **Name of each exchange** |  |
| **Symbol(s)** | **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 December 10, 2020, Biodesix, Inc. (the “Company”) issued a press release announcing its financial results for the fiscal quarter ended September 30, 2020. A copy of the press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

Exhibit 99.1 is furnished pursuant to Item 2.02 of this Form 8-K and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, or incorporated by reference in any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as shall be expressly set forth by specific reference in such filing.

**Item 9.01.** **Financial Statements and Exhibits.**

*(d) Exhibits:*

**No.** **Exhibit**

99.1 [Press Release issued by Biodesix, Inc. dated December 10, 2020](#page4)

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: December 10, 2020 | BIODESIX, INC. |
|  | By: | /s/ Robin Harper Cowie |
|  | Name: | Robin Harper Cowie |
|  | Title: | Chief Financial Officer |

**Exhibit 99.1**



**Biodesix Announces Third Quarter 2020 Results and Provides Corporate Update**

*Generates record quarterly revenue of $9.2 million*

*Raises net proceeds of $63 million through initial public offering*

*Adds to the significant and growing body of evidence demonstrating the clinical value of its portfolio of blood based diagnostic tests for lung disease*

**Boulder, CO, December 10, 2020** - Biodesix, Inc. a leading data-driven diagnostic solutions company with a focus in lung disease, today announcedfinancial and operating results for the third quarter ended September 30, 2020 and provided a corporate update.

**Third Quarter 2020 and Recent Highlights**

* Generated record quarterly revenue of $9.2 million for the third quarter ended September 30, 2020.
* Completed initial public offering (IPO) that raised net proceeds of approximately $63 million after deducting offering costs, underwriting discounts and commissions.
* Announced a strategic partnership with the Big Ten Conference whereby Biodesix is conducting ddPCR™ COVID-19 validation testing and managing the onsite testing of rapid antigen SARS-CoV-2 testing for all student-athletes and staff personnel involved in close contact sports competition.
* Published an extended analysis of data from the company’s Nodify XL2® lung nodule test in the American College of Chest Physicians (CHEST) Journal. The data demonstrate that all nodules in the study group that were established as benign after one year remained benign after two years, the guideline-recommended surveillance period to radiologically confirm a benign diagnosis.
* Presented data from three studies at the American College of Chest Physicians (CHEST 2020) Annual Meeting highlighting the clinical value of the company’s Nodify XL2® and Nodify CDT™ lung nodule risk assessment tests.

“We recently achieved a very significant milestone with our IPO and transition to a public company,” stated Scott Hutton, Chief Executive Officer of Biodesix. “With the proceeds from the offering, we plan to continue to market our suite of commercially available diagnostic tests, including our Biodesix Lung Reflex® and Nodify Lung™ testing strategies, in addition to our COVID-19 testing, while also investing in the discovery, development, and validation of innovative new tests leveraging our proprietary AI-driven discovery platform.

“We continue to monitor the COVID-19 pandemic carefully in light of the recent surge in case counts around the country, and we are pleased to be able to play an important part in the fight against this dangerous virus through our WorkSafe testing program. To this point, our lung disease-focused core business continues to perform well even while healthcare facilities devote time and resources to combat COVID-19 and travel restrictions affect our commercial efforts. We believe this is a testament to the valuable clinical information that our tests provide along critical points of the lung disease care continuum,” concluded Mr. Hutton.



**Financial Results**

**Revenue.** Revenue for the three months ended September 30, 2020 was $9.2 million, as compared to $3.9 million for the comparable period in 2019, anincrease of 133%. This increase was due to $5.5 million of revenue from our two COVID-19 diagnostic tests, partially offset by a modest decline in our non-COVID-19 diagnostic test volumes of $0.7 million as health care practitioners, including pulmonologists, were increasingly diverted to pandemic-related care. In addition, company sales efforts continued to be impacted by travel and other COVID-19 pandemic related restrictions. Revenue for the nine months ended September 30, 2020 was $18.5 million, as compared to $16.3 million for the comparable period in 2019, an increase of 14%.

**Direct costs and expenses.** Direct costs and expenses for the three months ended September 30, 2020 were $3.9 million, as compared to $1.5 millionfor the comparable period of 2019, an increase of 159%. Direct costs and expenses for the nine months ended September 30, 2020 were $7.3 million compared to $4.2 million for the nine months ended September 30, 2019, an increase of 73%. The increase in costs were primarily driven by the release of the company’s Nodify CDT™ test and its COVID-19 testing program in 2020.

**Research and development.** Research and development expenses for the three months ended September 30, 2020 were $2.7 million, as compared to$2.4 million for the comparable period in 2019, an increase of 15%. Research and development expenses for the nine months ended September 30, 2020 were $7.7 million, as compared to $8.0 million for the comparable period in 2019, a decrease of 3%.

**Sales, marketing, general and administrative.** Sales, marketing, general and administrative expenses for the three months ended September 30, 2020were $7.9 million, as compared to $8.2 million for the comparable period in 2019, a decrease of 4%. Sales, marketing, general and administrative expenses for the nine months ended September 30, 2020 were $22.8 million, as compared to $24.1 million for the comparable period in 2019, a decrease of 5%. The decrease was driven by reductions in travel and related expenses as the COVID-19 pandemic reduced or eliminated the travel and related expenses.

**Operating loss.** Operating loss for the three months ended September 30, 2020 was $6.2 million, as compared to an operating loss of $9.0 million forthe comparable period in 2019, a decrease of 31%. Operating loss for the nine months ended September 30, 2020 was $20.3 million, as compared to an operating loss of $23.2 million for the comparable period in 2019, a decrease of 13%. The decrease was due in part to higher revenue in the third quarter of 2020 as compared to the third quarter of 2019.

**Net loss.** Net loss for the three months ended September 30, 2020 was $8.9 million, as compared to $9.6 million for the comparable period in 2019, adecrease of 8%. Net loss for the nine months ended September 30, 2020 was $26.8 million, as compared to $24.2 million for the comparable period in 2019, an increase of 11%.



**Cash and cash equivalents.** As of September 30, 2020, the company held cash and cash equivalents of $6.3 million, as compared to $5.3 million as ofDecember 31, 2019. Subsequent to the end of the third quarter, the company completed a successful initial public offering that raised net proceeds of approximately $63 million. As a result of the completion of the initial public offering, the company estimates that it has sufficient cash resources to meet its cash obligations through at least the next 12 months.

**About Biodesix**

Biodesix is a leading diagnostic 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 six non-invasive tests for patients with diseases of the lung. Biodesix launched the SARS-CoV-2 ddPCR™ test and the Platelia SARS-CoV-2 Total Ab 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 72 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 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 the COVID-19 pandemic on Biodesix and its operations, its 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 public filings with the Securities and Exchange Commission, including Biodesix’s final prospectus filed on October 29, 2020 under Rule 424(b)(4) in connection with the company’s initial public offering. 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.**

**Consolidated Balance Sheet (unaudited)**

**(in thousands, except per share data)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | September 30, | December 31, |  |
|  |  |  | 2020 |  |  | 2019 |  |  |
| **Assets** |  |  |  |  |  |  |  |  |
| Current assets |  |  |  |  |  |  |  |  |
| Cash and cash equivalents | $ | 6,348 | $ | 5,286 |  |
| Accounts receivable |  |  | 5,396 |  | 5,292 |  |
| Other current assets |  |  | 6,405 |  | 2,122 |  |
| Total current assets |  |  | 18,149 |  |  | 12,700 |  |  |
| Non-current assets |  |  |  |  |  |  |  |  |
| Property and equipment, net |  |  | 3,005 |  | 2,120 |  |
| Intangible assets, net |  |  | 13,667 |  | 15,092 |  |
| Deposits |  |  | 95 |  | 90 |  |
| Goodwill |  |  | 11,631 |  | 11,631 |  |
| Total non-current assets |  |  | 28,398 |  |  | 28,933 |  |  |
| Total assets | $ | 46,547 | $ | 41,633 |  |
| **Liabilities and Stockholders’ Deficit** |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| Current liabilities |  |  |  |  |  |  |  |  |
| Accounts payable | $ | 3,485 | $ | 1,717 |  |
| Accrued liabilities |  |  | 6,953 |  | 4,180 |  |
| Deferred revenue |  |  | 5,673 |  | 1,283 |  |
| Convertible notes payable |  |  | 26,600 |  | 12,159 |  |
| Current portion of note payable |  |  | 7,202 |  | — |  |
| Put option liability |  |  | 6,650 |  | 3,261 |  |
| Total current liabilities |  |  | 56,563 |  |  | 22,600 |  |  |
| Non-current liabilities |  |  |  |  |  |  |  |  |
| Warrant liability |  |  | 403 |  | 329 |  |
| Other liabilities |  |  | 392 |  | 358 |  |
| Long-term notes payable |  |  | 17,236 |  | 23,812 |  |
| Paycheck protection program note payable |  |  | 3,099 |  | — |  |
| Contingent consideration |  |  | 30,071 |  |  | 29,114 |  |
|  |  |  |  |  |  |  |  |  |
| Total non-current liabilities |  |  | 51,201 |  |  | 53,613 |  |
| Total liabilities |  |  | 107,764 |  |  | 76,213 |  |  |
| Commitments and contingencies |  |  |  |  |  |  |  |  |
| Convertible Preferred stock |  |  |  |  |  |  |  |  |
| Convertible preferred stock, $0.001 par value, 185,432,719 (2020) and 174,237,067 (2019) authorized; |  |  |  |  |  |  |  |  |
| 118,766,273 (2020 and 2019) issued and outstanding; liquidation preference of $202,582 (2020 and 2019) |  |  | 193,959 |  | 193,959 |  |
| Stockholders’ deficit |  |  |  |  |  |  |  |  |
| Common stock, $0.001 par value, 220,000,000 (2020) and 190,000,000 (2019) authorized; 289,508 (2020) and |  |  |  |  |  |  |  |  |
| 254,918 (2019) issued and outstanding |  |  | 2 |  | 1 |  |
| Additional paid-in capital |  |  | 2,503 |  | 2,324 |  |
| Accumulated deficit |  |  | (257,681) |  | (230,864) |  |
| Total stockholders’ deficit |  |  | (255,176) |  |  | (228,539) |  |  |
| Total liabilities, convertible preferred stock, and stockholders’ deficit | $ | 46,547 | $ | 41,633 |  |
|  |  |  |  |  |  |  |  |  |



**Biodesix, Inc.**

**Condensed Statements of Operations (unaudited)**

**(in thousands, except share data)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Three Months Ended |  | Nine Months Ended |
|  |  | September 30, |  | September 30, |
|  |  | 2020 |  |  | 2019 |  |  | 2020 |  | 2019 |  |
| Revenues | $ | 9,193 |  | $ | 3,942 |  | $ | 18,528 |  |  | $ 16,281 |  |
| Operating expenses |  |  |  |  |  |  |  |  |  |  |  |  |
| Direct costs and expenses |  | 3,891 |  | 1,503 |  | 7,346 | 4,244 |
| Research and development |  | 2,706 |  | 2,359 |  | 7,713 | 7,966 |
| Sales, marketing, general and administrative |  | 7,879 |  | 8,212 |  | 22,793 | 24,080 |
| Accretion of contingent consideration |  | 957 |  | 896 |  | 2,901 | 2,525 |
| Change in fair value of contingent consideration |  | — |  | — |  | (1,944) | 663 |
| Total operating expenses |  | 15,433 |  |  | 12,970 |  |  | 38,809 |  |  | 39,478 |  |
| Loss from operations |  | (6,240) |  | (9,028) |  | (20,281) | (23,197) |
| Interest expense |  | (2,658) |  |  | (706) |  |  | (6,899) |  |  | (2,005) |  |
| Other income, net |  | 53 |  | 133 |  | 363 | 1,001 |
| Net loss | $ | (8,845 | ) | $ | (9,601 | ) | $ | (26,817 | ) | $(24,201 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Net loss per share, basic and diluted | $ | (31.93) | $ | (39.35) | $ | (99.69) | $(103.87) |
| Weighted-average shares outstanding, basic and diluted |  | 277 |  | 244 |  | 269 | 233 |