
**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**

Date of Report (Date of earliest event reported): April 30, 2021

T2 BIOSYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-36571
(Commission
File Number)

20-4827488
(IRS Employer
Identification Number)

101 Hartwell Avenue, Lexington, Massachusetts 02421
(Address of principal executive offices, including Zip Code)

(781) 761-4646
(Registrant's telephone number, including area code)

N/A
(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 communications 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 communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications 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 \$0.001 per share | TTOO | The Nasdaq Stock Market LLC (Nasdaq Global Market) |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 1.01. Entry into a Material Definitive Agreement.

On May 6, 2021, T2 Biosystems, Inc., a Delaware corporation (the “Company”), announced the modification of Option One (the “Modification”), under its existing cost sharing contract (the “BARDA Contract”) with the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services (“BARDA”). Pursuant to the Modification, dated April 30, 2021, the Company and BARDA have agreed to accelerate product development by modifying the contract to advance future deliverables into the currently funded Option 1 of the BARDA Contract for T2NxT, T2Biothreat, T2Resistance and T2AMR. The Modification does not change the overall total potential value of the BARDA Contract.

The foregoing summary is qualified in its entirety by reference to the Modification, a copy of which will be attached as an exhibit to the Company’s Quarterly Report on Form 10-Q for the period ending March 31, 2021.

Item 2.02 Results of Operations and Financial Condition

On May 6, 2021, T2 Biosystems, Inc. (the “Company”) issued a press release announcing preliminary estimated financial results for its fiscal quarter ending March 31, 2021. A copy of the Company’s press release is furnished with this report as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 2.02 and Exhibit 99.1 of this Current Report on Form 8-K is being furnished and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. Furthermore, such information, including Exhibit 99.1 attached hereto, shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly stated by specific reference in such a filing.

Item 8.01 Other Events.

On May 6, 2021, the Company reported the following unaudited first quarter 2021 financial results:

- Total revenue of \$7.0 million, an increase of 173% compared to the prior year period.
- Product revenue of \$4.7 million, an increase of 345% compared to the prior year period.
- Research and contribution revenue for the first quarter of 2021 was \$2.3 million, an increase of 54% compared to the prior year period.
- Operating expenses for the first quarter of 2021 were \$10.9 million, a decrease of \$0.6 million compared to the prior year period
- Cash, equivalents, marketable securities and restricted cash were \$43.9 million as of March 31, 2021.
- Increased U.S. sepsis test utilization by 85% compared to the prior year period
- Sold 4 T2Dx® Instruments during the first quarter, including 1 in the U.S. and 3 internationally
- Confirmed the T2SARS-CoV-2™ Panel is capable of detecting the India B.1.617 variant of the SARS-CoV-2 virus based on sequence alignments and *in silico* analysis.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 99.1 | Press Release issued May 6, 2021 |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 6, 2021

T2 BIOSYSTEMS, INC.

By: /s/ John Sprague
John Sprague
Chief Financial Officer



T2 Biosystems Announces First Quarter 2021 Financial Results

LEXINGTON, Mass., May 6, 2020 (GLOBE NEWSWIRE)—T2 Biosystems, Inc. (NASDAQ:TTOO), a leader in the rapid detection of sepsis-causing pathogens, today announced financial results for the three months ended March 31, 2021.

Recent Highlights

- Achieved first quarter 2021 revenue of \$7.0 million, including product revenue of \$4.7 million, representing growth of 173% and 345%, respectively, compared to the prior year period
- Increased U.S. sepsis test utilization by 85% compared to the prior year period, resulting in a first quarter annualized test run rate of approximately \$111,000 per legacy sepsis instrument
- Sold 4 T2Dx® Instruments during the first quarter, including 1 in the U.S. and 3 internationally
- Expanded U.S. salesforce to 9 Regional Account Managers
- Announced newly published independent study concluding the use of T2 sepsis panels provides faster time to detection, faster time to targeted therapy, and shortened length-of-stay
- Confirmed the T2SARS-CoV-2™ Panel is capable of detecting the India B.1.617 variant of the SARS-CoV-2 virus based on sequence alignments and *in silico* analysis
- Modified terms of existing BARDA contract to add T2Resistance® Panel and accelerate development of comprehensive sepsis panel, next generation instrument, and biothreat panel

“Entering 2021, we set three corporate priorities: accelerating our sales, improving our operations, and advancing our pipeline. We are very pleased with our progress during the first quarter, which included 173% total revenue growth, 345% product revenue growth and 85% sepsis test revenue growth,” stated John Sperzel, President and CEO of T2 Biosystems. “We have rebuilt a clinically focused U.S. sales team to drive greater adoption of our novel sepsis products and we are strengthening our medical and clinical affairs teams to support our customers. We remain excited about our product pipeline, including the T2Resistance Panel, and our opportunity to lead the change in the standard of care for the management of patients suspected of sepsis.”

First Quarter 2021 Financial Results

Total revenue for the first quarter of 2021 was \$7.0 million, an increase of 173% compared to the prior year period. Product revenue for the first quarter of 2021 was \$4.7 million, an increase of 345% compared to the prior year period, driven by increased test panel and instrument sales. Research and contribution revenue for the first quarter of 2021 was \$2.3 million, an increase of 54% compared to the prior year period, driven by increased BARDA contract activity.

Operating expenses for the first quarter of 2021 were \$10.9 million, a decrease of \$0.6 million compared to the prior year period, driven by increased BARDA contract research and development activity offset by lower selling, general and administrative headcount.

Net loss for the first quarter of 2021 was \$(10.7) million, \$(0.07) per share, compared to a net loss of \$(14.9) million, \$(0.22) per share, in the prior year period.

Cash, equivalents, marketable securities and restricted cash were \$43.9 million as of March 31, 2021.

2021 Financial Outlook

The Company continues to expect revenue for the full year 2021 to be between \$24.0 million and \$26.0 million, including product revenue between \$16.0 million and \$18.0 million and research and contribution revenue of \$8.0 million. The Company continues to expect to close at least 30 T2Dx Instrument contracts in 2021.

Webcast and Conference Call Information

T2's management team will host a conference call today, May 6, 2021, beginning at 4:30pm ET. Investors interested in listening to the call may do so by dialing 1-800-496-4125 for domestic callers or 1-856-344-9209 for International callers. A live and recorded webcast of the call will be available on the "Investors" section of the Company's website at www.t2biosystems.com.

About T2 Biosystems

T2 Biosystems, a leader in the rapid detection of sepsis-causing pathogens, is dedicated to improving patient care and reducing the cost of care by helping clinicians effectively treat patients faster than ever before. T2 Biosystems' products include the T2Dx[®] Instrument, T2Candida[®] Panel, the T2Bacteria[®] Panel, the T2Resistance[®] Panel, and the T2SARS-CoV-2[™] Panel and are powered by the proprietary T2 Magnetic Resonance (T2MR[®]) technology. T2 Biosystems has an active pipeline of future products, including the T2Cauris[™] Panel, and T2Lyme[™] Panel, as well as additional products for the detection of bacterial and fungal pathogens and associated antimicrobial resistance markers, and biothreat pathogens.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding our revenue results and cash balance, financial outlook, anticipated strategic priorities, product demand, commitments or opportunities, and growth expectations or targets, , as well as statements that include the words "expect," "intend," "plan", "believe", "project", "forecast", "estimate," "may," "should," "anticipate," and similar statements of a future or forward looking nature.. These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, (i) any inability to (a) realize anticipated benefits from commitments, contracts or products; (b) successfully execute strategic priorities; (c) bring products to market; (d) expand product usage or adoption; (e) obtain customer testimonials; (f) accurately predict growth assumptions; (g) realize anticipated revenues; (h) incur expected levels of operating expenses; or (i) increase the number of high-risk patients at customer facilities; (ii) failure of early data to predict eventual outcomes; (iii) failure to make or obtain anticipated FDA filings or clearances within expected time frames or at all; or (iv) the factors discussed under Item 1A. "Risk Factors" in the company's Annual Report on Form 10-K for the year ended December 31, 2020, filed with the U.S. Securities and Exchange Commission, or SEC, on March 31, 2021, and other filings the company makes with the SEC from time to time. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While the company may elect to update such forward-looking statements at some point

in the future, unless required by law, it disclaims any obligation to do so, even if subsequent events cause its views to change. Thus, no one should assume that the Company's silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. These forward-looking statements should not be relied upon as representing the company's views as of any date subsequent to the date of this press release.

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T2 BIOSYSTEMS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)
(Unaudited)

| | March 31, 2021 | December 31, 2020 |
|---|-------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 10,691 | \$ 16,793 |
| Marketable securities | 22,617 | 25,396 |
| Accounts receivable | 4,034 | 5,099 |
| Inventories | 4,525 | 3,636 |
| Prepaid expenses and other current assets | 2,720 | 2,660 |
| Total current assets | 44,587 | 53,584 |
| Property and equipment, net | 4,202 | 3,771 |
| Operating lease right-of-use assets | 10,606 | 11,034 |
| Restricted cash | 551 | 551 |
| Marketable securities | 10,002 | 10,002 |
| Other assets | 104 | 136 |
| Total assets | \$ 70,052 | \$ 79,078 |
| Liabilities and stockholders' (deficit) equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 3,907 | \$ 2,058 |
| Accrued expenses and other current liabilities | 6,094 | 7,512 |
| Deferred revenue | 400 | 230 |
| Total current liabilities | 10,401 | 9,800 |
| Notes payable | 45,855 | 45,235 |
| Operating lease liabilities, net of current portion | 10,255 | 10,533 |
| Deferred revenue, net of current portion | 281 | 424 |
| Derivative liability | 181 | 1,010 |
| Other liabilities | 3,645 | 3,350 |
| Commitments and contingencies | | |
| Stockholders' (deficit) equity: | | |
| Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2021 and December 31, 2020 | — | — |
| Common stock, \$0.001 par value; 200,000,000 shares authorized; 148,491,673 and 148,078,974 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively | 148 | 148 |
| Additional paid-in capital | 432,905 | 431,544 |
| Accumulated other comprehensive income | 16 | 9 |
| Accumulated deficit | (433,635) | (422,975) |
| Total stockholders' (deficit) equity | (566) | 8,726 |
| Total liabilities and stockholders' (deficit) equity | \$ 70,052 | \$ 79,078 |

T2 BIOSYSTEMS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)
(Unaudited)

| | Three Months Ended | |
|---|---------------------------|---------------------------|
| | March 31, | |
| | 2021 | 2020 |
| Revenue: | | |
| Product revenue | \$ 4,650 | \$ 1,045 |
| Contribution revenue | 2,306 | 1,500 |
| Total revenue | 6,956 | 2,545 |
| Costs and expenses: | | |
| Cost of product revenue | 5,790 | 4,671 |
| Research and development | 4,665 | 4,780 |
| Selling, general and administrative | 6,203 | 6,655 |
| Total costs and expenses | 16,658 | 16,106 |
| Loss from operations | (9,702) | (13,561) |
| Other income (expense): | | |
| Interest income | 6 | — |
| Interest expense | (1,013) | (1,417) |
| Other income, net | 49 | 29 |
| Total other expense | (958) | (1,388) |
| Net loss | <u>\$ (10,660)</u> | <u>\$ (14,949)</u> |
| Net loss per share — basic and diluted | <u>\$ (0.07)</u> | <u>\$ (0.22)</u> |
| Weighted-average number of common shares used in computing net loss per share — basic and diluted | <u>148,231,412</u> | <u>68,637,322</u> |
| Other comprehensive loss: | | |
| Net loss | \$ (10,660) | \$ (14,949) |
| Change in net unrealized gain on marketable securities, net of taxes: | | |
| Net unrealized gain on marketable securities arising during the period | 9 | — |
| Less: net realized gain on marketable securities included in net loss | (2) | — |
| Net unrealized gain on marketable securities | 7 | — |
| Comprehensive loss | <u>\$ (10,653)</u> | <u>\$ (14,949)</u> |