

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): March 5, 2020

Enzo Biochem, Inc.
(Exact Name of Registrant as Specified in Its Charter)

New York
(State or Other Jurisdiction of Incorporation)

001-09974
(Commission File Number)

13-2866202
(IRS Employer Identification No.)

527 Madison Avenue
New York, New York
(Address of Principal Executive Offices)

10022
(Zip Code)

(212) 583-0100
(Registrant's Telephone Number, Including Area Code)

(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 *fee* General Instruction A.2. below):

- 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	Name of Each Exchange on Which Registered
Common Stock, \$.01 par value	ENZ	The New York Stock Exchange

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-1 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 2.02 Results of Operations and Financial Condition

On March 5, 2020, Enzo Biochem, Inc. (the “Company”) issued a press release announcing its operating results for its second fiscal quarter ended January 31, 2020. A copy of the press release is furnished as Exhibit 99.1 attached hereto and is incorporated by reference in its entirety into this item 2.02 of this Current Report on Form 8-K.

Item 7.01. Regulation FD Disclosure.

The information provided in Item 2.02 of this Current Report on Form 8-K is incorporated herein by reference in its entirety.

The information discussed under Item 2.02 and Item 7.01 above, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or incorporated by reference in any filing by the Company under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

The information in this report (including the exhibits) is furnished pursuant to Item 2.02 and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits.**

99.1 [Press Release of Enzo Biochem, Inc., dated March 5, 2020](#)

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.

ENZO BIOCHEM, INC.

Date: March 5, 2020

By: /s/ David Bench
David Bench
Chief Financial Officer



news
release

Enzo Biochem, Inc.
527 Madison Avenue
New York, NY 10022

ENZO BIOCHEM REPORTS FISCAL SECOND QUARTER RESULTS

Approval of Proprietary GenFlex™ Platform Is Significant Milestone and Validates Ability to Leverage Leading Intellectual Property

Services Revenue and Margins Increase; Cost Cutting Initiatives Starting to Yield Results

NEW YORK, NY, March 5, 2020 -- Enzo Biochem, Inc. (NYSE:ENZ), an integrated diagnostics company focusing on delivering and applying advanced technology to produce affordable, reliable diagnostic products and services, today reported results for the fiscal second quarter ended January 31, 2020.

The Company reported both operational and financial progress against its stated objective to provide a cost-effective, comprehensive menu of molecular diagnostic products and services.

On February 11, 2020, Enzo announced it received New York State approval for its CT/NG/TV tests using liquid-based cytology sample collection on its proprietary GenFlex™ platform. GenFlex™ is a sample-to-result molecular diagnostic platform that includes sample collection, sample processing, amplification and detection (utilizing AMPIPROBE® technology). Compared favorably to all other proprietary platforms dominating the diagnostic testing market, Enzo's GenFlex™ platform offers 30-50% cost-savings over current closed systems. GenFlex™ addresses the \$450 million annualized global diagnostic market for the detection of *chlamydia trachomatis* (CT), *neisseria gonorrhoeae* (NG), and *trichomonas vaginalis* (TV) as well as the \$1.3 billion Women's Health market. Extensions of the GenFlex™ platform, which Enzo is currently developing, could eventually address the entire \$7 billion molecular diagnostic market.

The Company's laboratory services segment recognized top-line growth of 4% year-over-year to \$12.5 million in the second quarter. The lab segment experienced growing accession counts sequentially and year-over-year with more than 813,000 accessions in the last twelve months period. Days Sales Outstanding in the laboratory segment improved to 43 days in the second quarter, a 23 day improvement from 66 days in the previous year's period. Furthermore, gross margins expanded 1,000 basis points to 18.1% in the second quarter.

The products segment remained profitable despite continued investment in product development. The division's order value (average order size by dollar amount at which its products are sold) experienced its third straight quarter of sequential growth. This trend has continued into the first month of the third quarter. The product segment has experienced its fourth consecutive quarter of gross margins above 50% despite fluctuations in product mix and order timing. Overall, operating results from the two segments improved by \$1.7 million through the initiation of cost cutting and growth initiatives.

Enzo continues to make solid progress in its previously announced program to realize more than \$10 million in annualized cost savings. Benefits are already being realized, and full implementation is anticipated by the end of this year.

Highlights for the Quarter

- ***New Commercial Platform:*** Enzo received New York State Department of Health approval for its CT/NG/TV tests using liquid-based cytology sample collection on its proprietary GenFlex™ platform. GenFlex™ is a commercially available sample-to-result molecular diagnostic platform that includes sample collection, sample processing, amplification and detection. The GenFlex™ open system delivers high-throughput, high capacity, workflow efficiency and flexibility at a much greater level of affordability than existing systems. This is the latest successful development in Enzo's strategic plan to provide a cost-effective, comprehensive menu of molecular diagnostic products and services.
- ***Therapeutics Progress:*** Enzo continues to explore various avenues to unlock value in Enzo Therapeutics, a biopharmaceutical subsidiary of Enzo Biochem. Alternatives under consideration include a possible spin-off, sale, joint venture or licensing of its intellectual property. Also, underscoring Therapeutics' depth of opportunity, subsequent to the quarter end Enzo reported the publication of a Study Detailing a Promising Activity of Drug Candidate SK1-I in a Model of Lupus.
- ***Board / Management Additions:*** During the second quarter, Rebecca Fischer, CFO of Bellevue Hospital, was appointed as a new independent Director and David Bench was appointed as the Chief Financial Officer of Enzo. Subsequent to the quarter end, Fabian Blank and Peter Clemens IV were also added as directors.
- ***Patent Portfolio:*** The Company has built a substantial portfolio of intellectual property assets, comprised of 463 issued patents worldwide and over 75 pending patent applications, along with extensive enabling technologies and platforms. Enzo is currently evaluating its robust intellectual property portfolio and will continue to aggressively defend its patents.

Elazar Rabbani, PhD., Chairman and Chief Executive Officer, Commented:

"Enzo showed strong progress against many of our important growth initiatives during the second quarter. With the arduous proxy contest behind us, we welcome our new Directors to our

Board and look forward to working collaboratively to capitalize on our distinct and highly promising market position in the molecular diagnostics marketplace as well as our immunoassay, immunohistochemistry and cytology offerings. New York State approval of our proprietary GenFlex™ molecular diagnostics platform provides additional validation of our program as we focus on the next phase of commercialization of these products and services and we are preparing to engage with the FDA to secure the final stage of approval. This milestone achievement highlights our continued ability to deliver high performance, open, flexible, adaptable and cost-effective products, devices and services to a diagnostic industry that continues to be impacted by regulatory price cuts and sustained high product costs.

“Enzo’s strength in technology and product development is illustrated by GenFlex’s™ rapid development over the past four years as it offers important cost-savings over current closed systems. GenFlex™ particularly addresses the \$450 million annualized global CT/NG/TV diagnostic market as well as the \$1.3 billion Women’s Health market. Extensions of the GenFlex™ platform, currently under development, are aimed at addressing the entire \$7 billion molecular diagnostic market.

“At the same time, we are also making positive strides in our extensive cost reduction program at the labs while continuing to invest and grow the higher margin and growth segments of our business that will help assure our objective of building Enzo’s value.”

Second Quarter Operating Results

- Total second quarter revenue amounted to \$19.4 million, compared to \$19.3 million in the year ago period, up slightly year over year despite sharply lower industry-wide PAMA reimbursement rates.
 - Clinical Services revenue for the second quarter amounted to \$12.5 million compared to \$12.0 million in the previous year period, an increase of 4%. Volume increases in core and other non-genetic testing services contributed to the revenue gain. Total diagnostic testing volume measured by the number of accessions increased 7% in the period. However, the Protecting Access to Medicare Act (“PAMA”) continues to negatively impact reimbursements from Medicare and third-party payers. Gross profit margin at Clinical Services was 18% in the most recent quarter compared to 8% in the 2019 period. This margin expansion was attributable to reductions in outside reference testing expense and headcount efficiencies, partially offset by increased reagent costs resulting largely from higher accession volume.
 - Life Science revenue for the second quarter was \$6.9 million compared to \$7.3 million in the previous year’s second quarter. The decrease of 6% is primarily due to lower product sales volume in the U.S. market based on the timing of orders. The gross profit margin on products was 52% in the 2020 period and 50% in the 2019 period due to the mix of products sold.
 - Consolidated gross profit was \$5.8 million versus \$4.6 million in the previous year’s quarter. Gross margins for the quarter were 30% compared with 24% a year ago.
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- Research and development expenses were \$1.0 million in the 2020 period and \$0.8 million in the 2019 period, an increase of 28%. The increase is entirely attributed to the Clinical Services division for lab developed tests based on our proprietary GenFlex™ platform.
- Selling, general and administrative expenses declined to \$10.7 million during the 2020 period from \$11.5 million during the 2019 period, and as a percentage of revenue amounted to 55% versus 60% a year ago. The Clinical Services expense declined \$0.3 million, primarily due to the initial results of the aforementioned cost savings program. The Life Sciences Products expense decreased \$0.5 million primarily due to reductions in operating expenses and related costs.
- Legal and related expenses were approximately \$2.0 million during the 2020 period compared to \$1.1 million in the 2019 period, an increase of \$0.9 million. During the 2020 period, the Company incurred \$1.8 million for proxy costs relating to the February 2020 annual shareholders meeting.
- GAAP net loss was (\$7.7) million, or (\$0.16) per diluted share, an improvement of 9% compared with a year ago quarter net loss of (\$8.4) million, or (\$0.18) per diluted share. The non-GAAP net loss, adjusted primarily for proxy related costs, was (\$5.8) million, compared to (\$8.4 million) a year ago, an improvement of \$2.6 million. On a per share basis, the non-GAAP loss equaled (\$0.12), compared with (\$0.18) a year ago. Adjusted EBITDA loss in the quarter and a year ago approximated (\$5.3) million and (\$7.9) million reflecting a \$2.6 million improvement.

First Half Operating Results

Total revenue for the first half of fiscal year 2020 was \$39.6 million compared to \$40.6 million in the prior year, a decline of 2%. Gross profit totaled \$11.5 million, compared to \$11.7 million a year ago, with gross margins of 29% in each of the periods. Sales, General and Administrative Expenses decreased to \$21.8 million from \$22.5 million or 55% of revenue for both periods. Research & Development increased to \$2.1 million, or 36% in the period. Legal expenses amounted to \$3.8 million versus \$2.4 million in the prior year period. The GAAP net loss totaled \$15.3 million, or (\$0.32) per share compared to a net loss of \$14.4 million, or (\$0.30) per share in the previous period. Adjusted EBITDA was a loss of \$11.8 million compared to a loss of \$13.4 million a year ago.

At quarter-end, cash, cash equivalent and restricted cash totaled \$52 million, and working capital amounted to \$48 million. As of March 2, 2020, the company had 47.6 million shares outstanding.

Conference Call

The Company will conduct a conference call Friday, March 6, 2020 at 8:30 AM ET. The call can be accessed by dialing (888) 459-5609. International callers can dial (973) 321-1024. Please reference PIN number 4496317.

Interested parties may also listen over the Internet at: <https://tinyurl.com/rq732hc>

To listen to the live call, individuals should go to the website at least 15 minutes early to register, download and install any necessary audio software. Any pop up blocker installed on your PC should be disabled while accessing the webcast. A rebroadcast of the call will be available starting approximately two hours after the conference call ends, through March 20, 2020. The replay of the conference call can be accessed by dialing (855) 859-2056. International callers can dial (404) 537-3406 and, when prompted, use the same PIN number 4496317.

About Enzo Biochem, Inc.

Enzo Biochem is a pioneer in molecular diagnostics, leading the convergence of clinical laboratories, life sciences and intellectual property through the development of unique diagnostic platform technologies that provide numerous advantages over previous standards. A global company, Enzo Biochem utilizes cross-functional teams to develop and deploy products, systems and services that meet the ever-changing and rapidly growing needs of health care today and into the future. Underpinning Enzo Biochem's products and technologies is a broad and deep intellectual property portfolio, with 406 issued patents worldwide and over 75 pending patent applications, along with extensive enabling technologies and platforms.

Except for historical information, the matters discussed in this news release may be considered "forward-looking" statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements include declarations regarding the intent, belief or current expectations of the Company and its management, including those related to cash flow, gross margins, revenue, and expenses which are dependent on a number of factors outside of the control of the Company including, inter alia, the markets for the Company's products and services, costs of goods and services, other expenses, government regulations, litigation, and general business conditions. See Risk Factors in the Company's Form 10-K for the fiscal year ended July 31, 2019. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve a number of risks and uncertainties that could materially affect actual results. The Company disclaims any obligations to update any forward-looking statement as a result of developments occurring after the date of this press release.

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ENZO BIOCHEM, INC.
(in thousands, except per share data)

<u>Selected operations data:</u>	Three months ended January 31 (unaudited)		Six months ended January 31, (unaudited)	
	2020	2019	2020	2019
Total revenues	\$ 19,384	\$ 19,327	\$ 39,591	\$ 40,587
Gross profit	\$ 5,809	\$ 4,579	\$ 11,495	\$ 11,600
Gross profit %	30.0%	24%	29.0%	29%
Loss before income taxes	(7,687)	(8,408)	(15,335)	(14,389)
Net loss	\$ (7,687)	\$ (8,408)	\$ (15,335)	\$ (14,389)
Basic and diluted net income (loss) per share	(\$0.16)	(\$0.18)	(\$0.32)	(\$0.30)
Weighted average shares outstanding - basic and diluted	47,557	47,199	47,557	47,197
	1/31/2020 (unaudited)	7/31/2019 (unaudited)		
<u>Selected balance sheet data:</u>				
Cash and cash equivalents including restricted cash of \$750	\$ 52,252	\$ 60,896		
Working capital	\$ 47,900(a)	\$ 65,444		
Stockholders' equity	\$ 70,860	\$ 86,028		
Total assets	\$ 116,782	\$ 106,640		

(a) Includes impact of adoption of ASC 842 leases, the current portion of operating lease liabilities recorded is \$4,534

The following table presents a reconciliation of reported net loss and basic and diluted net loss per share to non-GAAP net loss and basic and diluted net loss per share for the three and six months ended January 31, 2020 and 2019:

ENZO BIOCHEM, INC.
Non-GAAP Reconciliation Table
(Unaudited, in thousands, except per share data)

	Three months ended January 31		Six months ended January 31,	
	2020	2019	2020	2019
Reported GAAP net loss	\$ (7,687)	\$ (8,408)	\$ (15,335)	\$ (14,389)
Adjusted for:				
Contested proxy expenses	1,847	—	2,493	—
Non-GAAP net loss	<u>\$ (5,840)</u>	<u>\$ (8,408)</u>	<u>\$ (12,842)</u>	<u>\$ (14,389)</u>
<i>Weighted Shares Outstanding</i>				
Basic and diluted	47,557	47,199	47,557	47,197
<i>Basic and diluted earnings per share</i>				
Basic and diluted net loss per share GAAP	(\$0.16)	(\$0.18)	(\$0.32)	(\$0.30)
Basic and diluted net loss per share non-GAAP	(\$0.12)	(\$0.18)	(\$0.27)	(\$0.30)

The following table presents a reconciliation of reported net loss for the three and six months ended January 31, 2020 and 2019, respectively to EBITDA and Adjusted EBITDA:

ENZO BIOCHEM, INC.
EBITDA & Adjusted EBITDA Reconciliation Table
(Unaudited, in thousands)

	Three months ended January 31		Six months ended January 31,	
	2020	2019	2020	2019
GAAP net loss	\$ (7,687)	\$ (8,408)	\$ (15,335)	\$ (14,389)
Plus (minus):				
Depreciation and amortization	709	768	1,434	1,534
Interest, net	(171)	(227)	(408)	(501)
EBITDA	<u>\$ (7,149)</u>	<u>\$ (7,867)</u>	<u>\$ (14,309)</u>	<u>\$ (13,356)</u>
Adjusted for:				
Contested proxy expenses	1,847	—	2,493	—
Adjusted EBITDA	<u>\$ (5,302)</u>	<u>\$ (7,867)</u>	<u>\$ (11,816)</u>	<u>\$ (13,356)</u>