

**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): May 2, 2019

EMERGENT BIOSOLUTIONS INC.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation)

001-33137
(Commission File Number)

14-1902018
(IRS Employer
Identification No.)

**400 Professional Drive, Suite 400,
Gaithersburg, Maryland 20879**
(Address of principal executive offices, including zip code)

(240) 631-3200
(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 (see 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))

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.

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	EBS	New York Stock Exchange

Item 2.02 Results of Operations and Financial Condition.

On May 2, 2019, Emergent BioSolutions Inc. announced financial and operating results for the period ended March 31, 2019. The full text of the press release issued in connection with the announcement is attached as Exhibit 99 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99	Press release issued by the company on May 2, 2019.

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.

EMERGENT BIOSOLUTIONS INC.

Dated: May 2, 2019

By: /s/ RICHARD S. LINDAHL
Name: Richard S. Lindahl
Title: Executive Vice President, Chief Financial
Officer and Treasurer

News Release

EMERGENT BIOSOLUTIONS REPORTS FIRST QUARTER 2019 FINANCIAL RESULTS

- Reaffirms full year 2019 financial forecast and operational goals
- Provides Q2 2019 revenue forecast of \$200M-\$220M

GAITHERSBURG, Md., May 2, 2019—Emergent BioSolutions Inc. (NYSE: EBS) reported financial results for the three months ended March 31, 2019.

FINANCIAL HIGHLIGHTS

(in millions)	Q1 2019 (unaudited)	Q1 2018 (unaudited)
Total Revenues	\$190.6	\$117.8
Pre-tax Loss	\$(37.8)	\$(9.4)
Net Loss	\$(26.0)	\$(4.9)
Adjusted Net Loss (1)	\$(6.8)	\$(1.6)
EBITDA (1)	\$(1.6)	\$3.1
Adjusted EBITDA (1)	\$7.4	\$3.3

Q1 2019 AND RECENT BUSINESS ACCOMPLISHMENTS

Procurement Contract

- Signed a contract with the U.S. Department of State valued at up to \$100 million over 10 years to establish a long-term, reliable supply chain of medical countermeasures for chemical threats, including the supply of RSDL® (Reactive Skin Decontamination Lotion Kit) and Trobigard® atropine sulfate/obidoxime chloride auto-injector.

Product Development

- Initiated a Phase III trial to evaluate the lot consistency, immunogenicity and safety of AV7909 (anthrax vaccine adsorbed with CPG 7909 adjuvant), with funding from the U.S. Biomedical Advanced Research and Development Authority (BARDA) pursuant to a development and procurement contract signed in September 2016; the Company also initiated manufacturing of AV7909 in Q1 2019.
- Provided interim analysis of the Phase II clinical study evaluating the safety and immunogenicity of the Company's chikungunya virus virus-like-particle vaccine candidate, CHIKV-VLP, showing with a single dose administered up to 98% of study participants produced neutralizing antibodies against the chikungunya virus by day 7, with persistent effect out to the six-month visit, including in the single-dose regimen.

2019 FINANCIAL PERFORMANCE

Revenues

Total Revenues

For Q1 2019, total revenues were \$190.6 million, an increase of 62% over 2018. Total revenues reflect a significant increase in product sales due to the contribution of recently acquired products.

Product Sales

For Q1 2019, product sales were \$153.0 million, an increase of \$77.2 million or 102% as compared to 2018. The increase primarily reflects sales of NARCAN® (naloxone HCl) Nasal Spray, which was acquired in October 2018, and ACAM2000® (Smallpox (Vaccinia) Vaccine, Live).

(in millions) (unaudited)	Three Months Ended March 31,		
	2019	2018	% Change
Product Sales			
NARCAN Nasal Spray	\$65.5	\$0.0	NA
ACAM2000	\$45.6	\$21.8	109%
BioThrax	\$11.7	\$20.2	(42)%
Other	\$30.2	\$33.8	(11)%
Total Product Sales	\$153.0	\$75.8	102%

Contract Manufacturing

For Q1 2019, revenue from the Company's contract manufacturing operations was \$15.9 million, a decrease of \$10.2 million or 39% as compared to 2018. The decrease primarily reflects contracted service work in Q1 2018 that did not recur in Q1 2019.

Contracts and Grants

For Q1 2019, revenue from the Company's development-based contracts and grants was \$21.7 million, an increase of \$5.8 million or 36% as compared to 2018. The increase primarily reflects increased R&D activities related to certain ongoing funded development programs, most notably AV7909.

Operating Expenses

Cost of Product Sales and Contract Manufacturing

For Q1 2019, cost of product sales and contract manufacturing was \$91.8 million, an increase of \$37.5 million or 69% as compared to 2018. The increase primarily reflects the impact of an increase in product sales due to the contribution of recently acquired products NARCAN Nasal Spray, Vivotif® (Typhoid Vaccine Live Oral Ty21a), and Vaxchora® (Cholera Vaccine, Live, Oral), which were all acquired in October 2018, as well as the contribution of increased ACAM2000 sales.

Research and Development (Gross and Net)

For Q1 2019, gross R&D expenses were \$46.1 million, an increase of \$17.0 million or 58% as compared to 2018. The increase primarily reflects costs associated with incremental development programs from the recent acquisitions of PaxVax and Adapt Pharma in October 2018, as well as timing of manufacturing development activities related to the AV7909 program.

For Q1 2019, net R&D expense, which reflects investments made in development programs that are not currently funded in whole or in part by third-party partners and is calculated as gross research and development expenses minus contracts and grants revenue, was \$24.4 million, an increase of \$11.2 million or 85% as compared to 2018. The increase primarily reflects investments in the development of the CHIKV-VLP vaccine, FLU-IGIV hyperimmune and various programs related to opioid overdose response, which are part of the development portfolio resulting from the Adapt Pharma acquisition in October 2018. The Q1 2019 net R&D expense was 14% of net revenue (total revenue less contracts & grants) compared to 13% of net revenue in Q1 2018.

(in millions) (unaudited)	Three Months Ended March 31,		
	2019	2018	% Change
Research and Development Expenses	\$46.1	\$29.1	58%
Adjustments:			
Less Contracts and Grants Revenue	\$21.7	\$15.9	36%
Net Research and Development Expenses	\$24.4	\$13.2	84.8%
Adjusted Revenue (Total Revenue less Contracts and Grants Revenue)	\$168.9	\$101.9	66%
Net R&D as % of Adjusted Revenue (Net R&D Margin)	14.4%	13.0%	NA

Selling, General and Administrative

For Q1 2019, selling, general and administrative expenses were \$65.4 million, an increase of \$25.4 million or 64% as compared to 2018. The increase primarily reflects the addition of the operations associated with the October 2018 acquisitions of both PaxVax and Adapt Pharma.

Amortization of Intangible Assets

For Q1 2019, amortization of intangible assets was \$14.5 million versus \$3.9 million as compared to 2018. The increase entirely reflects higher non-cash intangible asset amortization costs associated with the PaxVax and Adapt Pharma acquisitions, which both closed in October 2018.

Income Taxes

For Q1 2019, the benefit from income taxes in the amount of \$11.8 million includes the impact of non-deductible acquisition transaction costs and other permanent items. The effective tax rate for Q1 2019 is not meaningful given the lack of any pre-tax income for the quarter.

Net Income (Loss) & Adjusted Net Income (Loss)

For Q1 2019, the Company recorded a net loss of \$26.0 million, or \$0.51 per diluted share, versus a net loss of \$4.9 million, or \$0.10 per diluted share, in 2018.

For Q1 2019, the Company recorded an adjusted net loss of \$6.8 million, or \$0.13 per diluted share, versus an adjusted net loss of \$1.6 million, or \$0.03 per diluted share, in 2018.

EBITDA & Adjusted EBITDA

For Q1 2019, the Company recorded EBITDA of \$(1.6) million versus \$3.1 million in 2018.

For Q1 2019, the Company recorded adjusted EBITDA of \$7.4 million versus \$3.3 million in 2018. (1)

2019 FINANCIAL FORECAST (Reaffirmed)

For full year 2019, the company reaffirms its expectation of the following forecasted financial metrics:

(in millions)	FULL YEAR 2019 (As of 5/2/2019)
Total Revenues	\$1,060 -- \$1,140
Net Income (1)	\$80 -- \$110
Adjusted Net Income (1)	\$150 -- \$180
EBITDA (1)	\$255 -- \$285
Adjusted EBITDA (1)	\$280 -- \$310

The Company's financial forecast for 2019 includes the anticipated impact of full year product sales, continued contract manufacturing and contracts & grants revenue as well as continued investment in discretionary funding development projects. The outlook for 2019 does not include estimates for potential new corporate development or other M&A transactions.

Q2 2019 REVENUE FORECAST

For Q2 2019, the Company forecast for total revenues is \$200 million to \$220 million.

FOOTNOTES

(1) See "Reconciliation of Net Income (Loss) to Adjusted Net Income (Loss), EBITDA and Adjusted EBITDA" for a definition of terms and a reconciliation table.

CONFERENCE CALL AND WEBCAST INFORMATION

Company management will host a conference call at 5:00 pm (Eastern Time) today, May 2, 2019, to discuss these financial results. This conference call can be accessed live by telephone or through Emergent's website:

Live Teleconference Information:

Dial in: [US] (855) 766-6521; [International] (262) 912-6157

Conference ID: 8099738

Live Webcast Information:

Visit <https://edge.media-server.com/m6/p/5bkqm2hj> for the live webcast feed.

A replay of the call can be accessed at www.emergentbiosolutions.com under "Investors."

ABOUT EMERGENT BIOSOLUTIONS INC.

Emergent BioSolutions Inc. is a global life sciences company seeking to protect and enhance life by focusing on providing specialty products for civilian and military populations that address accidental, deliberate, and naturally occurring public health threats. We aspire to be a Fortune 500 company recognized for protecting and enhancing life, driving innovation, and living our values. Additional information about the company may be found at www.emergentbiosolutions.com. Find us on LinkedIn and follow us on Twitter @emergentbiosolu and Instagram @life_at_emergent.

SAFE HARBOR STATEMENT

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including, without limitation, our financial guidance, statements regarding product sales, continued contract manufacturing and contracts & grants revenue as well as continued investment in discretionary funding development projects and any other statements containing the words “will,” “believes,” “expects,” “anticipates,” “intends” “plans,” “targets,” “forecasts,” “estimates” and similar expressions in conjunction with, among other things, discussions of the Company's outlook, financial performance or financial condition, financial and operation goals, strategic goals, growth strategy, product sales, government development or procurement contracts or awards, government appropriations, manufacturing capabilities, and Emergency Use Authorization (EUA) and the timing of other regulatory approvals or expenditures are forward-looking statements. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Investors are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date of this press release, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause the Company's actual results to differ materially from those indicated by such forward-looking statements, including the availability of funding and the exercise of options under our BioThrax and AV7909 contracts; appropriations for the procurement of our products; our ability to secure EUA designation and licensure of AV7909 from the FDA within the anticipated timeframe, if at all; availability of funding for our U.S. government grants and contracts; our ability to successfully integrate and develop the operations, products or product candidates, programs, and personnel of any entities, businesses or products that we acquire, including our acquisitions of PaxVax and Adapt; our ability to complete expected deliveries of BioThrax, and raxibacumab; our ability to establish a multi-year follow-on contract for ACAM2000; our ability to advance the technology transfer of raxibacumab to the Company's Bayview facility; our ability to identify and acquire or in-license products or product candidates that satisfy our selection criteria; our ability and the ability of our collaborators to defend underlying patents from infringement by generic naloxone entrants; whether anticipated synergies and benefits from an acquisition or in-license will be realized within expected time periods, if at all; our ability to utilize our manufacturing facilities and expand our capabilities; our ability and the ability of our contractors and suppliers to maintain compliance with Current Good Manufacturing Practices and other regulatory obligations; the results of regulatory inspections; the success of our ongoing and planned development programs; the timing and results of clinical trials; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; and our commercialization, marketing and manufacturing capabilities and strategy. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this cautionary statement as well as the risk factors identified in our periodic reports filed with the Securities and Exchange Commission when evaluating our forward-looking statements.

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Emergent BioSolutions Inc.
Consolidated Balance Sheets
(in millions, except per share data)

	March 31, 2019	December 31, 2018
ASSETS	(Unaudited)	
Current assets:		
Cash and cash equivalents	\$ 137.2	\$ 112.2
Restricted cash	0.2	0.2
Accounts receivable, net	121.5	262.5
Inventories	211.0	205.8
Prepaid expenses and other current assets	58.6	40.1
Total current assets	528.5	620.8
Property, plant and equipment, net	513.4	510.2
Intangible assets, net	757.1	761.6
In-process research and development	41.0	50.0
Goodwill	267.7	259.7
Other assets	46.0	27.1
Total assets	\$ 2,153.7	\$ 2,229.4
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 78.6	\$ 80.7
Accrued expenses	49.6	30.7
Contingent consideration, current portion	62.7	5.6
Accrued compensation	36.9	58.2
Long-term indebtedness, current portion	10.1	10.1
Other current liabilities	10.5	15.1
Total current liabilities	248.4	200.4
Contingent consideration	10.0	54.4
Long-term indebtedness	732.4	784.5
Deferred tax liability	66.4	67.5
Deferred revenue, net of current portion	64.7	62.5
Other liabilities	44.1	49.2
Total liabilities	1,166.0	1,218.5
Stockholders' equity:		
Preferred stock, \$0.001 par value; 15.0 shares authorized, no shares issued or outstanding at both 2019 and 2018	--	--
Common stock, \$0.001 par value; 200.0 shares authorized, 52.6 shares issued and 51.4 shares outstanding at 2019; 52.4 shares issued and 51.2 shares outstanding at 2018	0.1	0.1
Treasury stock, at cost, 1.2 common shares at both 2019 and 2018	(39.6)	(39.6)
Additional paid-in capital	690.2	688.6
Accumulated other comprehensive loss	(4.5)	(5.5)
Retained earnings	341.5	367.3
Total stockholders' equity	987.7	1,010.9
Total liabilities and stockholders' equity	\$ 2,153.7	\$ 2,229.4

Emergent BioSolutions Inc.
Consolidated Statements of Operations
(in millions, except per share data)

	Three months ended March 31,	
	2019	2018
	(Unaudited)	
Revenues:		
Product sales, net	\$ 153.0	\$ 75.8
Contract manufacturing, net	15.9	26.1
Contracts and grants	21.7	15.9
Total revenues	190.6	117.8
Operating expenses:		
Cost of product sales and contract manufacturing	91.8	54.3
Research and development	46.1	29.1
Selling, general and administrative	65.4	40.0
Amortization of intangible assets	14.5	3.9
Total operating expenses	217.8	127.3
Loss from operations	(27.2)	(9.5)
Other income (expense):		
Interest expense	(9.6)	(0.2)
Other income (expense), net	(1.0)	0.3
Total other income (expense), net	(10.6)	0.1
Loss before benefit from income taxes	(37.8)	(9.4)
Benefit from income taxes	(11.8)	(4.5)
Net loss	\$ (26.0)	\$ (4.9)
Net loss per share - basic	\$ (0.51)	\$ (0.10)
Net loss per share - diluted	\$ (0.51)	\$ (0.10)
Weighted-average number of shares - basic	51.2	49.6
Weighted-average number of shares - diluted	51.2	49.6

RECONCILIATION OF NET INCOME (LOSS) TO ADJUSTED NET INCOME (LOSS), EBITDA AND ADJUSTED EBITDA

This press release contains three financial measures (**Adjusted Net Income (Loss)**, **EBITDA (Earnings Before Interest, Taxes, Depreciation and Amortization)**, and **Adjusted EBITDA**) that are considered “non-GAAP” financial measures under applicable Securities and Exchange Commission rules and regulations. These non-GAAP financial measures should be considered supplemental to and not a substitute for financial information prepared in accordance with generally accepted accounting principles. The Company’s definition of these non-GAAP measures may differ from similarly titled measures used by others. Adjusted Net Income (Loss) adjusts for specified items that can be highly variable or difficult to predict, or reflect the non-cash impact of charges resulting from purchase accounting (which are all tax effected utilizing the statutory tax rate for the US). EBITDA reflects net income excluding the impact of depreciation, amortization, interest expense and provision for income taxes. Adjusted EBITDA also excludes specified items that can be highly variable and the non-cash impact of certain purchase accounting adjustments (which are all tax effected utilizing the statutory tax rate for the US). The Company views these non-GAAP financial measures as a means to facilitate management’s financial and operational decision-making, including evaluation of the Company’s historical operating results and comparison to competitors’ operating results. These non-GAAP financial measures reflect an additional way of viewing aspects of the Company’s operations that, when viewed with GAAP results and the reconciliations to the corresponding GAAP financial measure, may provide a more complete understanding of factors and trends affecting the Company’s business.

The determination of the amounts that are excluded from these non-GAAP financial measures are a matter of management judgment and depend upon, among other factors, the nature of the underlying expense or income amounts. Because non-GAAP financial measures exclude the effect of items that will increase or decrease the Company’s reported results of operations, management strongly encourages investors to review the Company’s consolidated financial statements and publicly filed reports in their entirety.

Reconciliation of Net Income (Loss) to Adjusted Net Income (Loss) (Unaudited)

(in millions, except per share value)	Three Months Ended March 31, 2019		
	2019	2018	Source
Net Loss	(\$26.0)	(\$4.9)	
Adjustments:			
+ Acquisition-related costs (transaction & integration)	4.0	0.2	SG&A
+ Non-cash amortization charges	15.3	4.0	COGS, SG&A, Other Income
+ Impact of purchase accounting on inventory step-up	5.0	—	COGS
Tax effect	(5.1)	(0.9)	
Total Adjustments:	19.2	3.3	
Adjusted Net Loss	(\$6.8)	(\$1.6)	
Adjusted Net Loss Per Diluted Share	(\$0.13)	(\$0.03)	

(in millions)	Full Year Forecast	
	2019F	Source
Net Income	\$80 - \$110	
Adjustments:		
+ Acquisition-related costs (transaction & integration)	14	SG&A
+ Non-cash amortization charges	64	COGS, SG&A, Other Income
+ Exit and disposal costs	4	SG&A
+ Impact of purchase accounting on inventory step-up	7	COGS
Tax effect	(19)	
Total Adjustments:	70	
Adjusted Net Income	\$150 - \$180	

Reconciliation of Net Income (Loss) to EBITDA and Adjusted EBITDA (Unaudited)

(in millions, except per share value)	Three Months Ended March 31, 2019	
	2019	2018
Net Loss	(\$26.0)	(\$4.9)
Adjustments:		
+ Depreciation & amortization	26.6	12.3
+ Benefit from income taxes	(11.8)	(4.5)
+ Total interest expense	9.6	0.2
Total Adjustments	24.4	8.0
EBITDA	(\$1.6)	\$3.1
Additional Adjustments:		
+ Acquisition-related costs (transaction & integration)	4.0	0.2
+ Impact of purchase accounting on inventory step-up	5.0	—
Total Additional Adjustments	9.0	0.2
Adjusted EBITDA	\$7.4	\$3.3

(in millions)	Full Year Forecast
	2019F
Net Income	\$80 - \$110
Adjustments:	
+ Depreciation & amortization	106
+ Provision for income taxes	30
+ Total interest expense	39
Total Adjustments	175
EBITDA	\$255 - \$285
Additional Adjustments:	
+ Acquisition-related costs (transaction & integration)	14
+ Exit and disposal costs	4
+ Impact of purchase accounting on inventory step-up	7
Total Additional Adjustments	25
Adjusted EBITDA	\$280 - \$310