

Egalet Corp
Form 8-K
September 28, 2018

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): **September 28, 2018**

Egalet Corporation

(Exact name of Registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation or Organization)

001-36295
(Commission
File Number)

46-3575334
(I.R.S. Employer
Identification No.)

600 Lee Road, Suite 100

Wayne, Pennsylvania 19087

(610) 833-4200

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Edgar Filing: Egalet Corp - Form 8-K

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 communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17CFR 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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company **X**

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. **X**

Material Impairments.

To the extent required by Item 2.06 of Form 8-K, the information contained in Item 8.01 of this Current Report on Form 8-K is incorporated herein by reference.

Other Events.

On September 28, 2018, Egalet Corporation (the Company) notified the U.S. Food and Drug Administration that, for business reasons, the Company is discontinuing the manufacture and promotion of Arymo® ER (morphine sulfate) extended-release tablets (ARYMO ER) effective September 28, 2018 (the Discontinuation). As part of its notice, the Company requested that the Orange Book staff move ARYMO ER to the Discontinued Drug Products List of the Approved Drug Products and Therapeutic Equivalence Evaluations (Orange Book) publication, and that the User Fee staff note the discontinued status of the product.

The Company tests its intangible and long-lived assets for impairment annually or more frequently if events or circumstances indicate that there may be impairment. The Discontinuation may result in indications of potential impairment of certain assets related to ARYMO ER. Consequently, in connection with the preparation and review of the Company's financial statements for the third quarter of fiscal 2018, the Company intends to perform an interim evaluation of its intangible and long-lived assets for possible impairment, although the Company is not certain whether it will complete the testing procedures in time to incorporate the related results into its financial statements for such quarter. The analysis may result in the Company incurring a charge to impair its intangible or long-lived assets.

Safe Harbor Statement

This Current Report on Form 8-K contains forward-looking statements that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the words *may*, *might*, *will*, *could*, *would*, *should*, *expect*, *intend*, *plan*, *anticipate*, *believe*, *project*, *potential*, *continue*, *seek to* and *ongoing*, or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although the Company believes that it has a reasonable basis for each such forward-looking statement, the Company cautions you that these statements are based on a combination of facts and factors currently known by the Company and its expectations of the future, about which it cannot be certain, including, but not limited to, risks related to: the Company's ongoing discussions regarding a potential restructuring of its obligations and other strategic alternatives and its ability to consummate any such transaction and/or address its long-term capital structure needs. You should refer to the *Risk Factors* section of the Company's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q as filed with the SEC, which are incorporated herein by reference, for a discussion of additional important factors that may cause the Company's actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these risks and uncertainties, readers are cautioned not to place undue reliance on any forward-looking statements included herein or that may be made elsewhere from time to time by, or on behalf of, the Company. Furthermore, such forward-looking statements speak only as of the date of this report. The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

SIGNATURE

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.

Dated: September 28, 2018

Egalet Corporation

By:	/s/ Stan Musial	
Name:		Stan Musial
Title:		Chief Financial Officer