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): February 28, 2019

Akorn, Inc.
(Exact Name of Registrant as Specified in Charter)

Louisiana	**001-32360**	**72-0717400**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

1925 W. Field Court, Suite 300, Lake Forest, Illinois 60045
(Address of Principal Executive Offices) (Zip Code)

(847) 279-6100
(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:

[ ] 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 (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 February 28, 2019, Akorn, Inc. (the "Company") issued a press release announcing financial results as of and for the quarter and year to date period ended December 31, 2018. A copy of the press release is furnished as Exhibit 99.1 to this report.

The information in this Item 2.02, including Exhibit 99.1 attached hereto, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed to be 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 a filing.

Item 7.01. Regulation FD Disclosure.

The U.S. Food and Drug Administration (FDA) issued the Company a Form 483 dated February 13, 2019, related to an inspection of the Company's Amityville, New York manufacturing facility in January and February of 2019. A redacted copy of the Form 483 is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information in this Item 7.01, including exhibit 99.2 attached hereto, shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall it be deemed to be 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 a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Press release dated February 28, 2018 entitled "Akorn Provides Fourth Quarter and Full Year 2018 Results."
99.2	FDA Form 483 dated February 13, 2019 (redacted).

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.

Akorn, Inc.

Date: February 28, 2019

By: /s/ Duane A. Portwood
Duane A. Portwood
Chief Financial Officer

EXHIBIT 99.1

Akorn Provides Fourth Quarter and Full Year 2018 Results

LAKE FOREST, Ill., Feb. 28, 2019 (GLOBE NEWSWIRE) -- Akorn, Inc. (Nasdaq: AKRX), a leading specialty generic pharmaceutical company, today announced its financial results for the year ended 2018.

Fourth Quarter 2018 and Recent Business Highlights

- Net revenue was $153 million, a decline of $33 million, or 17.6%, compared to the fourth quarter of 2017, predominantly due to the effect of competition on key products and shortfalls in supply
- Net loss was $215 million compared to a net loss of $65 million in the fourth quarter of 2017. Adjusted EBITDA was $(20) million compared to $28 million in the fourth quarter of 2017
- Continued progress on completion of FDA action items related to the inspections of our facilities in Decatur and Somerset
- Appointed Douglas Boothe as President and Chief Executive Officer, bringing significant generic and specialty pharmaceutical leadership experience
- Announced new additions to Board of Directors and Executive Management team adding significant expertise to the Company's leadership
- Focused on moving forward and rebuilding shareholder value as an independent company following the terminated Fresenius Kabi AG merger agreement
- Engaged financial, operational, and legal advisors to help develop and execute long-term growth plan
- Healthy cash position of $225 million as of December 31, 2018

Douglas Boothe, Akorn's President and Chief Executive Officer, commented, "I am excited to join Akorn at such a critical time for the Company. Our recent financial results reflect the many challenges that have impacted our business of late, including increased competition for many of our generic and promoted products, supply issues, and regulatory and legal challenges. Despite these significant headwinds, we have strong fundamentals to build upon, including a diverse product portfolio, a solid pipeline, niche manufacturing capabilities and, most importantly, a dedicated and extremely talented workforce."

"During my first two months with Akorn, we have made structural and organizational changes to emphasize compliance, transparency, and accountability. Additionally, we have decided to explore strategic alternatives to exit our India facility. I believe these initial changes provide the foundational elements that will strengthen our business and enhance trust with our many stakeholders," stated Boothe. "I look forward to providing updates in the coming months on our go-forward strategy and plan to rebuild value for all of our stakeholders."

Summary Financial Results for the Quarter Ended December 31, 2018:

Akorn reported revenues of $153.4 million for the three month period ended December 31, 2018, representing a decrease of $32.7 million, or 17.6%, as compared to net revenue of $186.1 million for the three month period ended December 31, 2017. The decrease in net revenue in the period was primarily due to $32.6 million decline in organic revenue. The $32.6 million decline in organic revenue was due to approximately $39.9 million, or 21.4% in volume declines partially offset by an increase of $7.3 million, or 3.9% in price. The organic revenue decline was principally due to the effect of competition on Ephedrine Sulfate Injection, Nembutal Injection and Clobetasol Cream, and shortfalls in supply due to slower than expected resumption in manufacturing at our Decatur and Somerset manufacturing facilities after their extended planned shutdowns.

Gross profit for the quarter ended December 31, 2018 was $25.2 million, or 16.4% of net revenue, compared to $82.9 million, or 44.6% of net revenue, in the corresponding prior year quarter. The decline in the gross profit percentage was principally due to: unfavorable variances related to decreased production at our Decatur and Somerset manufacturing facilities, increased operating costs associated with FDA compliance related improvement activities, as well as unfavorable product mix.

Net loss for the fourth quarter 2018 was $215.0 million, or $(1.71) per diluted share, compared to net loss of $65.2 million, or $(0.52) per diluted share, in the same quarter of 2017. Including a net adjustment of $179.2 million to net income for non-GAAP items, adjusted diluted earnings per share for the fourth quarter 2018 were $(0.29), compared to $0.14 in the same quarter 2017, after a net adjustment of $82.4 million to net income for non-GAAP items.

Earnings before interest, taxes, depreciation and amortization (EBITDA) was $(174.1) million for the fourth quarter 2018, compared to $(98.4) million for the fourth quarter 2017. Adjusted EBITDA, which is another non-GAAP measure used by management to evaluate the operations of the Akorn business, was $(19.9) million for the fourth quarter 2018, compared to $28.3 million for the fourth quarter 2017. See "Non-GAAP Financial Measures" below.

Summary Financial Results for the Year Ended December 31, 2018:

Net revenue was $694.0 million for the twelve month period ended December 31, 2018, representing a decrease of $147.0 million, or 17.5%, as compared to net revenue of $841.0 million for the twelve month period ended December 31, 2017. The decline was principally due to the effect of competition on Ephedrine Sulfate Injection, Nembutal, Lidocaine Ointment and Clobetasol Cream. In addition, the Company experienced lower net revenue as a result of extended planned shutdowns at our Decatur and Somerset manufacturing facilities during the year.

Gross profit for the twelve month period ended December 31, 2018 was $246.0 million, or 35.4% of revenue, compared to $432.2 million, or 51.4% of revenue, for the twelve month period ended December 31, 2017. The decline in the gross profit percentage was principally due to unfavorable product mix, unfavorable variances due to decreased production at our Decatur and Somerset manufacturing facilities, as well as increased operating costs associated with FDA compliance related improvement activities.

Net loss for 2018 was $401.9 million, or $(3.21) per diluted share, compared to net loss of $24.6 million, or $(0.20) per diluted share, for 2017. Including a net adjustment of $378.2 million to net income for non-GAAP items, adjusted diluted earnings per share for 2018 were $(0.19), compared to $0.93 for 2017, after a net adjustment of $141.0 million to net income for non-GAAP items.

EBITDA was $(309.5) million for 2018, compared to $64.0 million for 2017. Adjusted EBITDA was $49.3 million for 2018, compared to $245.5 million for 2017. See "Non-GAAP Financial Measures" below.

Conference Call and Webcast Details:

As previously announced, Akorn's management will hold a conference call with interested investors and analysts at 10:00 a.m. EST on February 28, 2019 to discuss these results and updates in more detail. The dial-in number to access the call is (844) 249-9382 in the U.S. and Canada and (270) 823-1530 for international callers. The conference ID is 4099919. To access the live webcast, please go to Akorn's Investor Relations web site at http://investors.akorn.com.

A webcast replay of the conference call will be available shortly following the conclusion of the call and will be available for 90 days following the call. To access the webcast replay, please go to Akorn's Investor Relations web site at http://investors.akorn.com.

About Akorn:

Akorn, Inc. is a specialty generic pharmaceutical company engaged in the development, manufacture and marketing of multisource and branded pharmaceuticals. Akorn has manufacturing facilities located in Decatur, Illinois; Somerset, New Jersey; Amityville, New York; Hettlingen, Switzerland and Paonta Sahib, India that manufacture ophthalmic, injectable and specialty sterile and non-sterile pharmaceuticals. Additional information is available on Akorn's website at www.akorn.com.

Non-GAAP Financial Measures:

To supplement Akorn's financial results presented in accordance with U.S. generally accepted accounting principles ("GAAP"), the Company uses certain non-GAAP (also referred to as "adjusted" or "non-GAAP adjusted") financial measures in this press release and the accompanying tables, including (1) EBITDA, (2) adjusted EBITDA, (3) adjusted net income, (4) adjusted diluted earnings per share, (5) net debt, and (6) net debt to adjusted EBITDA ratio. These non-GAAP measures adjust for certain specified items that are described in this release. The Company believes that each of these non-GAAP financial measures is helpful in understanding its past financial performance and potential future results. The non-GAAP financial measures are not meant to be considered in isolation or as a substitute for or superior to comparable GAAP measures.

Akorn's management uses EBITDA, adjusted EBITDA, adjusted net income and adjusted diluted earnings per share in managing and analyzing its business and financial condition. Akorn's management believes that the presentation of these and other non-GAAP financial measures provide investors greater transparency into Akorn's ongoing results of operations allowing investors to better compare the Company's results from period to period.

Investors should note that these non-GAAP financial measures used to present financial guidance are not prepared under any comprehensive set of accounting rules or principles and do not reflect all of the amounts associated with the Company's results of operations as determined in accordance with GAAP. Investors should also note that these non-GAAP financial measures have no standardized meaning prescribed by GAAP and, therefore, have limits in their usefulness to investors. In addition, from time-to-time in the future there may be other items that the Company may exclude for purposes of its non-GAAP financial measures; likewise, the Company may in the future cease to exclude items that it has historically excluded for purposes of its non-GAAP financial measures. Because of the non-standardized definitions, the non-GAAP financial measures as used by Akorn in this press release and the accompanying tables may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by the Company's competitors and other companies.

Set forth below is the definition of each non-GAAP financial measure as used by the Company in this press release and a full reconciliation of each non-GAAP financial measure to the most directly comparable GAAP financial measures.

EBITDA, as defined by the Company, represents net income before net interest expense, income tax expense, depreciation and amortization.

Adjusted EBITDA, as defined by the Company, is calculated as follows:

Net (loss) income, (minus) plus:

- Interest income (expense), net
- Provision for income taxes
- Depreciation and amortization
- Non-cash expenses, such as impairment of long-lived assets, share-based compensation expense, and amortization of deferred financing costs
- Other adjustments, such as legal settlements, restatement expenses and various merger and acquisition-related expenses, fixed asset impairment, executive termination payments, data integrity investigations & assessment, and Fresenius transaction & litigation

Adjusted EBITDA is deemed by the Company to be a useful performance indicator because it includes an add back of non-cash or non-recurring operating expenses that have no impact on continuing cash flows as well as other items that are not expected to recur and therefore are not reflective of continuing operating performance.

Adjusted net (loss) income, as defined by the Company, is calculated as follows:

Net (loss) income, (minus) plus:

- Intangible asset amortization and impairment
- Non-cash expenses, such as, share-based compensation expense, and amortization of financing costs
- Other adjustments, such as legal settlements, restatement expenses and various merger and acquisition-related expenses, fixed asset impairment, executive termination payments, data integrity investigations & assessment, and Fresenius transaction & litigation
- Less an estimated tax provision, net of the benefit from utilizing net operating loss carry-forwards effected for the adjustments noted above

Adjusted diluted earnings per share, as defined by the Company, is equal to adjusted net income divided by the actual or anticipated diluted share count for the applicable period. The Company believes that adjusted net income and adjusted diluted earnings per share are meaningful financial indicators, to both Company management and investors, in that they exclude non-cash income and expense items that have no impact on current or future cash flows, as well as other income and expense items that are not expected to recur and therefore are not reflective of continuing operating performance.

The shortcomings of non-GAAP financial measures as guidance or performance measures are that they provide a view of the Company's results of operations without including all events during a period. For example, Adjusted EBITDA does not take into account the impact of capital expenditures on either the liquidity or the financial performance of the Company and likewise omits share-based compensation expenses, which

may vary over time and may represent a material portion of overall compensation expense. Adjusted net income does not take into account non-cash expenses that reflect the amortization of past expenditures, or include share-based compensation, which is an important and material element of the Company's compensation package for its directors, officers and other key employees. Due to the inherent limitations of non-GAAP financial measures, investors should consider non-GAAP measures only as a supplement to, not as a substitute for or as a superior measure to, measures of financial performance prepared in accordance with GAAP. Investors and other readers are encouraged to review the related GAAP financial measures and the reconciliation of non-GAAP measures to their most directly comparable GAAP measures as presented in this press release.

Cautionary Note Regarding Forward-Looking Statements

This press release includes statements that may constitute "forward looking statements", including expectations regarding financial performance, rebuilding shareholder value, capital expenditures, growth, and other Akorn plans and strategy. When used in this document, the words “will,” “expect,” “continue," “believe,” “estimate,” “intend,” “could,” “strives” and similar expressions are generally intended to identify forward-looking statements. These statements are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. A number of important factors could cause actual results of Akorn and its subsidiaries to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to: (i) the effect of the Delaware court’s recent decision against Akorn on Akorn’s ability to retain and hire key personnel, its ability to maintain relationships with its customers, suppliers and others with whom it does business, or its operating results and business generally, (ii) the risk that ongoing or future litigation related to the court’s decision may result in significant costs of defense, indemnification and/or liability, (iii) the outcome of the investigation conducted by Akorn with the assistance of outside consultants, into alleged breaches of FDA data integrity requirements relating to product development at Akorn and any actions taken by Akorn, third parties or the FDA as a result of such investigations, (iv) the difficulty of predicting the timing or outcome of product development efforts, including FDA and other regulatory agency approvals and actions, if any, (v) the timing and success of product launches, (vi) difficulties or delays in manufacturing, and (vii) such other risks and uncertainties outlined in the risk factors detailed in Part I, Item 1A, “Risk Factors,” of Akorn’s Annual Report on Form 10-K and other risk factors identified from time to time in our filings with the SEC. Readers should carefully review these risk factors, and should not place undue reliance on our forward-looking statements. These forward-looking statements are based on information, plans and estimates at the date of this report. Akorn undertakes no obligation to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes.

AKORN, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME
(In Thousands, Except Per Share Data)

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
REVENUES	$ 153,386	$ 186,057	$ 694,018	$ 841,045
Cost of sales (exclusive of amortization of intangibles, included within operating expenses below)	128,139	103,152	448,002	408,839
GROSS PROFIT	25,247	82,905	246,016	432,206
Selling, general and administrative expenses	69,778	61,356	279,628	216,324
Acquisition-related costs	22	38	121	159
Research and development expenses	10,867	10,592	47,321	44,988
Amortization of intangibles	13,487	15,152	53,472	61,443
Impairment of intangible assets	118,088	112,449	231,086	128,127
Litigation rulings and settlements	8,870	4,919	22,814	4,049
TOTAL OPERATING EXPENSES	221,112	204,506	634,442	455,090
OPERATING (LOSS)	(195,865)	(121,601)	(388,426)	(22,884)
Amortization of deferred financing costs	(1,304)	(1,304)	(5,216)	(5,216)
Interest expense, net	(13,569)	(9,532)	(45,900)	(38,070)
Other non-operating income (expense), net	1,378	3,100	1,360	6,972
(LOSS) INCOME BEFORE INCOME TAXES	(209,360)	(129,337)	(438,182)	(59,198)
Income tax provision (benefit)	5,678	(64,120)	(36,273)	(34,648)
NET (LOSS)	$ (215,038)	$ (65,217)	$ (401,909)	$ (24,550)
NET (LOSS) PER COMMON SHARE:				
NET (LOSS), BASIC	$ (1.71)	$ (0.52)	$ (3.21)	$ (0.20)
NET (LOSS), DILUTED	$ (1.71)	$ (0.52)	$ (3.21)	$ (0.20)
SHARES USED IN COMPUTING NET (LOSS) PER COMMON SHARE:				
BASIC	125,492	125,083	125,383	124,790
DILUTED	125,492	125,083	125,383	124,790

COMPREHENSIVE (LOSS):				
Net (loss)	$(215,038)	$ (65,217)	$(401,909)	$ (24,550)
Unrealized holding (loss) gain on available-for-sale securities, net of tax of $6 and ($157) for the years ended December 31, 2018 and 2017, respectively.	(12)	—	(21)	267
Foreign currency translation gain (loss) for the years ended December 31, 2018 and 2017, respectively.	3,866	2,022	(8,001)	6,150
Pension liability adjustment, net of tax of $389 and ($403) for the year ended December 31, 2018 and 2017, respectively.	(1,541)	1,311	(1,529)	1,582
COMPREHENSIVE (LOSS)	$(212,725)	$ (61,884)	$(411,460)	$ (16,551)

AKORN, INC.
CONSOLIDATED BALANCE SHEETS
(In Thousands,
Except Share Data)

	December 31,	
	2018	**2017**
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 224,868	$ 368,119
Trade accounts receivable, net	153,126	141,383
Inventories, net	173,645	183,568
Prepaid expenses and other current assets	32,180	37,081
TOTAL CURRENT ASSETS	583,819	730,151
PROPERTY, PLANT AND EQUIPMENT, NET	334,853	313,418
OTHER LONG-TERM ASSETS		
Goodwill	283,879	285,310
Intangible assets, net	284,976	569,484
Deferred tax assets	—	6,521
Other non-current assets	7,730	4,627
TOTAL OTHER LONG-TERM ASSETS	576,585	865,942
TOTAL ASSETS	$1,495,257	$1,909,511
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Trade accounts payable	$ 39,570	$ 51,976
Purchase consideration payable	—	3,901
Income taxes payable	—	15,775
Accrued royalties	6,786	5,902
Accrued compensation	19,745	12,286
Accrued administrative fees	36,767	38,598
Accrued legal fees and contingencies	52,413	28,293
Accrued expenses and other liabilities	15,542	14,358
TOTAL CURRENT LIABILITIES	170,823	171,089
LONG-TERM LIABILITIES		
Long-term debt (net of non-current deferred financing costs)	820,411	815,195
Deferred tax liability	566	43,404
FIN 48 reserve	49,990	40,300
Other long-term liabilities	9,601	8,278
TOTAL LONG-TERM LIABILITIES	880,568	907,177

TOTAL LIABILITIES	1,051,391	1,078,266
SHAREHOLDERS' EQUITY		
Preferred stock, $1 par value —5,000,000 shares authorized; no shares issued or outstanding at December 31, 2018 and 2017	—	—
Common stock, no par value — 150,000,000 shares authorized; 125,492,373 and 125,090,522 shares issued and outstanding at December 31, 2018 and 2017	574,553	550,472
(Accumulated deficit) Retained earnings	(107,168)	294,741
Accumulated other comprehensive loss	(23,519)	(13,968)
TOTAL SHAREHOLDERS' EQUITY	443,866	831,245
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$1,495,257	$1,909,511

AKORN, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In Thousands)

	Year ended December 31,	
	2018	**2017**
OPERATING ACTIVITIES:		
Net (loss)	$ (401,909)	$ (24,550)
Depreciation and amortization	82,805	85,173
Impairment of intangible assets	231,086	128,127
Fixed asset impairment	6,135	—
Amortization of deferred financing fees	5,216	5,216
Non-cash stock compensation expense	21,503	21,018
Non-cash interest expense	—	—
Income from available-for-sale securities	—	(3,032)
Deferred income taxes, net	(37,396)	(115,249)
Gain on sale of available-for-sale security	—	199
Other	421	(307)
Changes in operating assets and liabilities:		
Trade accounts receivable, net	(11,627)	141,979
Inventories, net	9,694	(8,367)
Prepaid expenses and other current assets	3,847	(12,232)
Other non-current assets	(3,120)	(3,519)
Trade accounts payable	(5,002)	(9,223)
Accrued legal fees and contingencies	24,120	21,492
FIN48 Reserve	9,690	38,999
Accrued expenses and other liabilities	(4,357)	(18,091)
NET CASH (USED IN) PROVIDED BY OPERATING ACTIVITIES	(68,894)	247,633
INVESTING ACTIVITIES:		
Proceeds from disposal of assets	30	4,815
Payments for other intangible assets	(50)	(200)
Purchases of property, plant and equipment	(69,111)	(95,170)
NET CASH USED IN INVESTING ACTIVITIES	(69,131)	(90,555)
FINANCING ACTIVITIES:		
Proceeds under stock option and stock purchase plans	546	9,320
Stock compensation plan withholdings from employee taxes	(777)	(1,726)
Payments of contingent acquisition liabilities	(4,793)	—
Lease Payments	(14)	—

NET CASH (USED IN) PROVIDED BY FINANCING ACTIVITIES	(5,038)	7,594
Effect of changes in exchange rates on cash and cash equivalents	(1,032)	1,183
(DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(144,095)	165,855
CASH AND CASH EQUIVALENTS, AND RESTRICTED CASH AT BEGINNING OF YEAR	369,889	204,034
CASH AND CASH EQUIVALENTS, AND RESTRICTED CASH AT END OF YEAR	$ 225,794	$ 369,889

AKORN, INC.
Reconciliation of GAAP Net (LOSS) to Non-GAAP EBITDA and Adjusted EBITDA
(In Thousands)

	Three Months Ended December 31,		Year Ended December 31,	
	2018	**2017**	**2018**	**2017**
NET (LOSS)	$(215,038)	$(65,217)	$(401,909)	$ (24,550)
ADJUSTMENTS TO ARRIVE AT EBITDA:				
Depreciation expense	8,217	6,228	29,333	23,730
Amortization expense	13,487	15,152	53,472	61,443
Interest expense, net	13,569	9,532	45,900	38,070
Income tax provision (benefit)	5,678	(64,120)	(36,273)	(34,648)
EBITDA	$(174,087)	$(98,425)	$(309,477)	$ 64,045
NON-CASH AND OTHER NON-RECURRING INCOME AND EXPENSES				
Data Integrity investigations & assessment	6,021	514	28,420	514
Fresenius transaction & litigation	8,303	—	43,305	7,354
Non-cash stock compensation expense	4,304	5,392	21,503	21,018
Impairment of intangible assets	118,088	112,449	231,086	128,127
Loss (Gain) from asset sales	—	3	(201)	(2,802)
Amortization of deferred financing costs	1,304	1,304	5,216	5,216
Restatement expenses	(273)	1,555	(1,018)	17,311
Executive termination payments	6,455	—	6,455	—
Fixed asset impairment	6,081	533	6,058	481
Litigation rulings and settlements	3,870	4,919	17,814	4,049
Merger and Acquisition-related expenses	22	38	121	159
ADJUSTED EBITDA	$ (19,912)	$ 28,282	$ 49,282	$245,472

The table below sets forth expenses included in Net (loss) that have not been included as adjustments to arrive at EBITDA and Adjusted EBITDA in the preceding table.

	($ in thousands)			
	Three Months Ended December 31,		Year Ended December 31,	
	2018	**2017**	**2018**	**2017**
FDA compliance related expenses	12,517	—	22,251	—
Failure to supply penalties (recorded as a contra-revenue)	7,462	4,446	22,453	18,231
TheraTears® direct-to-consumer advertising campaign	6,219	13,118	17,393	14,070

AKORN, INC.
Reconciliation of GAAP Net (Loss) to Non-GAAP Adjusted Net (Loss) Income and Adjusted Diluted (Loss) Earnings Per Share
(In Thousands, Except Per Share Data)

	Three Months Ended December 31,		Year Ended December 31,	
	2018	**2017**	**2018**	**2017**
NET (LOSS)	$ (215,038)	$ (65,217)	$ (401,909)	$ (24,550)
Income tax provision (benefit)	5,678	(64,120)	(36,273)	(34,648)
(LOSS) BEFORE INCOME TAXES	$ (209,360)	$ (129,337)	$ (438,182)	$ (59,198)
ADJUSTMENTS TO ARRIVE AT ADJUSTED NET (LOSS) INCOME:				
Acquisition-related costs (1)	22	38	121	159
Data Integrity investigations & assessment (2)	6,021	514	28,420	514
Fresenius transaction & litigation (2, 9)	8,303	—	43,305	7,354
Restatement expenses (2)	(273)	1,555	(1,018)	17,311
Non-cash stock compensation expense (2, 3, 4)	4,304	5,392	21,503	21,018
Amortization expense (5)	13,487	15,152	53,472	61,443
Loss from asset sales (6)	—	3	(201)	(2,802)
Impairment of intangible assets (7)	118,088	112,449	231,086	128,127
Amortization of deferred financing costs (8)	1,304	1,304	5,216	5,216
Executive termination payments (2, 3)	6,455	—	6,455	—
Fixed asset impairment (2)	6,081	533	6,058	481
Litigation rulings and settlements (9)	3,870	4,919	17,814	4,049
ADJUSTED (LOSS) INCOME BEFORE INCOME TAX	$ (41,698)	$ 12,522	$ (25,951)	$ 183,672
Option exercise and RSU vesting tax impact (10)	(332)	11,705	(2,748)	12,994
ADJUSTMENTS TO INCOME TAX PROVISION (BENEFIT)	(5,547)	(16,403)	466	54,191
TOTAL ADJUSTED INCOME TAX PROVISION (BENEFIT)	$ (5,879)	$ (4,698)	$ (2,282)	$ 67,185
ADJUSTED NET (LOSS) INCOME	$ (35,819)	$ 17,220	$ (23,669)	$ 116,487
ADJUSTED DILUTED (LOSS) EARNINGS PER SHARE (10)	$ (0.29)	$ 0.14	$ (0.19)	$ 0.93

(1) - Excluded from Acquisition-related costs
(2) - Excluded from SG&A expenses
(3) - Excluded from R&D expenses
(4) - Excluded from Cost of sales
(5) - Excluded from Amortization of intangibles
(6) - Excluded from Other non-operating (expense) income, net
(7) - Excluded from Impairment of intangible assets
(8) - Excluded from Amortization of deferred financing costs
(9) - Excluded from Litigation rulings and settlements
(10) - Included in Income tax expense

AKORN, INC.
Reconciliation of GAAP Debt to Non-GAAP Net Debt and Net Debt to Adjusted EBITDA Ratio
(In Thousands, Except Net Debt to Adjusted EBITDA Ratio)

		December 31, 2018
GAAP Debt	$	820,411
Deferred financing costs		11,527
Total term loans outstanding	$	831,938
Cash and cash equivalents		224,868
Net debt (1)	$	607,070
Adjusted EBITDA, year ended	$	49,282
Net debt to adjusted EBITDA ratio (2)		12.3

(1) **Net debt,** as defined by the Company, is gross debt including Akorn's term loan and revolving debt balances (if applicable) less cash and cash equivalents.

(2) **Net debt to Adjusted EBITDA ratio,** as defined by the Company, is net debt divided by the trailing twelve months Adjusted EBITDA.

Investors/Media:
(847) 279-6162
Investor.relations@akorn.com

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	1/23/2019-2/13/2019* FEI NUMBER 2433247

NAME AND TITLE OF INDIVIDUALTO WHOM REPORT ISSUED	
Eyal Mares, Vice President and General Manager Amityville Operations	
FIRM NAME Hi-Tech Pharmacal Co. Inc., An AKORN Company	STREET ADDRESS 369 Bayview Ave
CITY, STATE, ZIP CODE, COUNTRY Amityville, NY 11701-2801	TYPE ESTABLISHMENT INSPECTED Human Sterile and Non-Sterile Drug Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:
OBSERVATION 1

Records are not kept for the maintenance, cleaning, sanitizing and inspection of equipment.

Specifically, you did not have any records to adequately demonstrate that the transfer hose connected between the tote and the filling machine was maintained, cleaned, sanitized, and inspected prior to the filling of the finished drug product. The transfer hose is the final step where the finished drug product is transferred from the tote to the filling machine for final fill.

OBSERVATION 2
Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically, during review of the media fill for [redacted] in Room S3-104 and in Room 101, on January 31, 2019, I observed sterile pump parts, initially opened from their autoclave pouches, underneath a metal cart, shielded from the HEPA filtered vertical air flow within the ISO 5 environment. In Room 101, the pump was put together by a Sterile Mechanic inside an ISO 5 Laminar Air Flow Tent, and the pump is required to maintain the suspension as it flows through the pump and kettle during the final fill process in Room S3-104 with the Cozzoli Filler.

OBSERVATION 3

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jay T Wong, Investigator	X Jay T Wong Investigator Signed By: 2000720057 Date Signed: 02-13-2019 00:01:05	2/13/2019

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER 158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	DATE(S) OF INSPECTION 1/23/2019-2/13/2019* FEI NUMBER 2433247
NAME AND TITLE OF INDIVIDUALTO WHOM REPORT ISSUED Eyal Mares, Vice President and General Manager Amityville Operations	
FIRM NAME Hi-Tech Pharmacal Co. Inc., An AKORN Company	STREET ADDRESS 369 Bayview Ave
CTTY, STATE, ZIP CODE, COUN'TRY Amityville, NY 11701-2801	TYPE ESTABLISHMENT INSPECTED Human Sterile and Non-Sterile Drug Manufacturer

The written stability testing program is not followed.

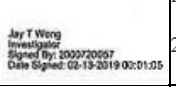
Specifically, you did not perform analysis within the time frame described in your written procedures *Stability Program for Pharmaceutical Drug Products,* QC-093-05, effective October 8, 2018, section 10.1.1, page 14, for the following US commercial finished drug products including, but not limited to:

- Cysteamine Ophthalmic Solution 0.44%, Product Code #915, Lot #360254, Start Date September 29, 2017, 12 Month Pull Date September 4, 2018, 12 Month Test Date October 10, 2018, 36 Days after Pull Date
- Promethazine HCl Oral Solution USP, Product Code #801A, Lot #358514, Start Date July 18, 2017, 12 Month Pull Date July 18, 2018, 12 Month Test Date September 11, 2018, 55 Days after Pull Date
- Clobetasol Propionate Emollient Cream 0.05%, Product Code #270, Lot #356892, Start Date May 4, 2017, 9 Month Pull Date February 2, 2018, 9 Month Test Date April 18, 2018, 75 Days after Pull Date

OBSERVATION 4
Containers and closures are not tested for conformance with all appropriate written procedures.

Specifically, I observed that the visual inspection check and the tip & plug dimension control for the Incoming Tip and Plug Inspection Record do not adequately test or challenge the dropper tips. These tips are used as the container closure system for dorzolamide hydrochloride- and dorzolamide hydrochloride-timolol maleate ophthalmic solutions. I reviewed that there were at least 84 customer complaints in the three years prior to January 2018 for "spray/dropper malfunction" as identified by your firm's investigation PR#76724, and with at least more than 50 similar complaints from approximately January 2018 to January 2019.

***DATES OF INSPECTION**

	EMPLOYEE(S) SIGNATURE		DATE ISSUED
SEE REVERSE OF THIS PAGE	Jay T Wong, Investigator	X 	2/13/2019

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS ANO PHONE NUMBER 158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661'		DATE{S) OF INSPECTION 1/23/2019-2/13/2019*	
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1/23/2019(Wed), 1/24/2019(Thu), 1/25/2019(Fri), 1/29/2019(Tue), 1/30/2019(Wed), 1/31/2019(Thu), 2/01/2019(Fri), 2/04/2019(Mon), 2/11/2019(Mon), 2/13/2019(Wed)			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jay T Wong, Investigator	X Jay T Wong Investigator Signed By: 2000720057 Date Signed: 02-13-2019 00:01:05	DATE ISSUED 2/13/2019

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."