
**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): November 5, 2018

Insys Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-35902
(Commission File Number)

51-0327886
(IRS Employer
Identification No.)

1333 S. Spectrum Blvd, Suite 100
Chandler, Arizona
(Address of Principal Executive Offices)

85286
(Zip Code)

Registrant's Telephone Number, Including Area Code: (602) 910-2617

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 (see General Instructions 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.

Item 2.02 Results of Operations and Financial Condition.

On November 5, 2018, Insys Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the third quarter ended September 30, 2018. A copy of this press release is attached hereto as Exhibit 99.1.

The information in this Item 2.02 and Exhibit 99.1 hereto are being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall they be deemed incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated November 5, 2018 Announcing Financial Results for Third Quarter of 2018.

SIGNATURES

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.

Date: November 5, 2018

Insys Therapeutics, Inc.

By: /s/ Andrew G. Long
Andrew G. Long
Chief Financial Officer



NEWS RELEASE

INSYS Therapeutics Reports Third Quarter 2018 Results*Company's Position as a Leader and Strategic Partner in Pharmaceutical Cannabinoids Strengthens with Involvement in Seven CBD Clinical Trials*

PHOENIX—Nov. 5, 2018—INSYS Therapeutics, Inc. (NASDAQ: INSY), a leader in the development, manufacture and commercialization of pharmaceutical cannabinoids and spray technology, today reported financial results for its third quarter ended Sept. 30, 2018.

OVERALL HIGHLIGHTS

- Commenced a strategic alternatives review process for the company's opioid-related assets
 - Expanded collaborative partnership with University of California San Diego's Center for Medicinal Cannabis Research (CMCR) to study the company's cannabidiol (CBD) oral solution in two additional disease states (early psychosis and anxiety in anorexia nervosa)
 - Achieved net revenue of \$18.3 million in the third quarter of 2018
 - Advanced R&D programs with a \$14.5 million investment in the third quarter of 2018:
 - Received "Fast Track" designation from the FDA for epinephrine nasal spray as an investigational treatment for anaphylaxis
 - Continued enrollment of three company-sponsored CBD clinical studies:
 - childhood *absence* epilepsy (Phase 2)
 - Prader-Willi syndrome (Phase 2)
 - infantile spasms (Phase 3)
 - Completed pharmacokinetic study of dronabinol inhalation
 - Signed definitive licensing agreement with Lunatus to commercialize SUBSYS® in the Middle East
 - Received FDA approval of supplemental NDA for SYNDROS® to expand label, enabling use of the product with feeding tubes for patients with cancer and AIDS
 - Appointed Elizabeth Bohlen to the Board of Directors and added Mark Nance to the management team as chief legal officer and general counsel
 - Announced settlement agreement in principle with Department of Justice consistent with previous public statement and disclosures
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- Optimized commercial organization and related support functions to control operating costs in line with lower revenue
- Received confirmation from the SEC that it concluded its investigation of the company, and does not intend to recommend an enforcement action

“Our commitment to further establish our position as a leader in pharmaceutical cannabinoids and spray technology was exemplified by the achievement of several milestones in the third quarter,” said Saeed Motahari, president and chief executive officer of INSYS Therapeutics. “We continued to make progress on our pipeline and expanded our collaborative partnerships with leading research institutions, increasing the number of CBD clinical studies in which we’re the sole sponsor or a key collaborator to seven. Furthermore, our 99.5 percent pure pharmaceutical-grade CBD oral solution allows INSYS to meet the needs of clinical study patients and become a strategic partner across our industry and in the medical community.”

Motahari concluded, “The decline in the overall TIRF market continues to impact sales of our primary commercial product, SUBSYS®. Our proactive efforts to expand managed care access and educate appropriate HCPs have enabled us to maintain our leading share of the branded TIRF market. However, this decline in revenue has required us to contain costs and as a result, we have taken actions to adjust our commercial organization to align with the realities of the market. We will continue to be disciplined with our cost structure, while appropriately investing in our pipeline, which is the key to transforming INSYS into a leader in pharmaceutical cannabinoids and spray technology.”

Financial & Operating Highlights

During the preparation of the consolidated financial statements as of and for the quarter ended Sept. 30, 2018, the company identified errors that impacted the 2017 financial information, which have been revised for the correction of this error.

- The company had \$113.0 million in cash, cash equivalents and short-term and long-term investments with no debt outstanding as of Sept. 30, 2018
- Net revenue for the third quarter of 2018 was \$18.3 million, compared to \$30.7 million for the third quarter of 2017, driven primarily by declines in the TIRF market
- Gross margin was 87.0 percent for the third quarter of 2018, compared to 75.6 percent in the same period of 2017
- Sales and marketing investment was \$7.4 million for the third quarter of 2018, compared to \$12.8 million for the third quarter of 2017, as the company took action to better align its commercial organization to the lower revenue base
- Research and development investment decreased to \$14.5 million for the third quarter of 2018, compared to \$19.6 million for the third quarter of 2017, primarily as a result of the timing of clinical trials
- General and administrative expense of \$8.9 million for the third quarter of 2018 declined compared to \$11.3 million in the third quarter of 2017, as the company continued to look for opportunities to level-set its cost base
- Legal expense increased to \$16.0 million for the third quarter of 2018, compared to \$4.4 million in the third quarter of 2017, as a result of the company’s legal proceedings, including

expenses associated with indemnification of former executives in connection with their pending trial, which constitutes approximately 60 percent of the total Q3 2018 expense. Management is disputing the reasonableness of certain of these indemnification-related expenses

- Income tax expense was \$240 thousand for the third quarter of 2018 compared to a benefit of (\$9.0 million) during the revised third quarter of 2017
- Net loss for the third quarter of 2018 was (\$30.6 million), or (\$0.41) per basic and diluted share, compared to a net loss of (\$166.3 million), or (\$2.28) per basic and diluted share, for the revised third quarter of 2017. Adjusted net loss for the third quarter of 2018 was (\$0.37) per basic and diluted share
- Adjusted EBITDA loss for the third quarter of 2018 was (\$26.0 million), compared to Adjusted EBITDA loss of (\$18.4 million) in the prior-year quarter. The reconciliation of net income to Adjusted EBITDA is included at the end of this news release

During the preparation of the consolidated financial statements as of and for the quarter ended Sept. 30, 2018, the company identified errors within the company's consolidated financial statements for the year ended Dec. 31, 2017, resulting from the company's adoption of ASU 2016-09 "Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting" on Jan. 1, 2017, which impacted the previously filed financial statements for the quarters ended March 31, June 30, and Sept. 30 of 2017 as well as the audited financial statements for the year ended Dec. 31, 2017. In addition, we identified an error in the calculation of our weighted average shares outstanding, which impacted the previously filed financial statements for the three and nine months ended Sept. 30, 2017, and the year ended Dec. 31, 2017. The company evaluated the errors and concluded that they were not material to the financial statements previously issued. Accordingly, the Dec. 31, 2017 financial information has been revised to include a cumulative adjustment of \$2.9 million to correctly present uncertain tax position liabilities and accumulated deficit, resulting in a reduction to total liabilities and an increase in stockholders' equity. These revisions will be reflected and disclosed in the company's Form 10-Q for the period ended Sept. 30, 2018 to be filed with the SEC on or before Nov. 9, 2018. Additionally, in order to correctly present income tax benefit and net loss in the appropriate periods for comparative purposes, the financial results for the three and nine months ended Sept. 30, 2017, have been revised to include adjustments of \$40,000 and \$120,000, respectively. These revisions resulted in net loss per share for the three and nine months ended Sept. 30, 2017, and the year ended Dec. 31, 2017, changing from \$2.30 to \$2.28, \$2.51 to \$2.50 and \$3.16 to \$3.12, respectively.

Webcast Information

A conference call is scheduled for 5:00 p.m. Eastern Standard Time on Nov. 5, 2018, to discuss the financial and operational results for the third quarter 2018. Interested parties can listen to the call live as it occurs via the company's website, <https://www.insysrx.com/>, on the Investors section's Presentations & Events page; or by dialing 844-263-8304 (from inside the U.S.) or 213-358-0958 (from outside the U.S.), and using the Conference ID 6149699. A webcasted replay of the call will be available on the site a few hours after the event.

About INSYS

INSYS Therapeutics is a specialty pharmaceutical company that develops and commercializes innovative drugs and novel drug delivery systems of therapeutic molecules that improve patients' quality of life. Using proprietary spray technology and capabilities to develop pharmaceutical cannabinoids, INSYS is developing a pipeline of products intended to address unmet medical needs and the clinical shortcomings of existing commercial products. INSYS is committed to developing medications for potentially treating anaphylaxis, epilepsy, Prader-Willi syndrome, opioid addiction and overdose, and other disease areas with a significant unmet need.

SUBSYS® and SYNDROS® are trademarks of INSYS Development Company, Inc., a subsidiary of INSYS Therapeutics, Inc.

NOTE: All trademarks and registered trademarks are the property of their respective owners.

Forward-Looking Statements

This news release contains forward-looking statements, including discussions about stabilizing and generating future revenue, our future leadership position in the use of cannabinoids to develop potential solutions for patients in need and expectation around research and clinical product development and our expectations around our pipeline products including timelines and results related thereto. These forward-looking statements are based on management's expectations and assumptions as of the date of this news release; actual results may differ materially from those in these forward-looking statements as a result of various factors, many of which are beyond our control. These factors include, but are not limited to, risk factors described in our filings with the United States Securities and Exchange Commission, including those factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended Dec. 31, 2017 and subsequent updates that may occur in our Quarterly Reports on Form 10-Q. Forward-looking statements speak only as of the date of this news release, and we undertake no obligation to publicly update or revise these statements, except as may be required by law.

Non-GAAP Financial Measures

In addition to reporting all financial information required in accordance with generally accepted accounting principles (GAAP), the company is also reporting Adjusted EBITDA, Adjusted net loss and Adjusted net loss per diluted share, which are non-GAAP financial measures. Since Adjusted EBITDA, Adjusted net loss and Adjusted net loss per diluted share are not GAAP financial measures, they should not be used in isolation or as a substitute for consolidated statements of comprehensive loss and cash flow data prepared in accordance with GAAP. In addition, the company's definitions of Adjusted EBITDA, Adjusted net loss and Adjusted net loss per diluted share may not be comparable to similarly titled non-GAAP financial measures reported by other companies. For a full reconciliation of Adjusted EBITDA and Adjusted net loss to GAAP net income, please see the attachments to this earnings release.

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

Net loss, plus:

- Interest income (expense), net;
- The recorded provision for income taxes;

- Depreciation and amortization; and
- Non-cash expenses, such as stock compensation expense and accruals for expected litigation settlements.

The company believes that Adjusted EBITDA can be a meaningful indicator, to both company management and investors, of the past and expected ongoing operating performance of the company. EBITDA is a commonly used and widely accepted measure of financial performance. Adjusted EBITDA is deemed by the company to be a useful performance indicator because it includes an add-back of non-cash and non-recurring operating expenses that may be subject to uncontrollable factors not reflective of the company's true operational performance.

Adjusted net loss, as defined by the company, is calculated as follows:

Net loss, plus:

- The recorded provision for income taxes;
- Non-cash expenses, such as stock compensation expense, non-cash interest, and non-cash other expense (i.e., accruals for expected litigation settlements); and;
- Less an estimated cash tax provision, net of the benefit from utilizing NOL carry-forwards and windfalls from employee stock option exercises.

Adjusted net loss per diluted share is equal to Adjusted net loss divided by the diluted share count for the applicable period.

The company believes that Adjusted net loss and Adjusted net loss per diluted share are meaningful financial indicators, to both company management and investors, in that they exclude non-cash income and expense items, as well as other income and expense items that are not expected to recur and therefore are not reflective of continuing operating performance.

While the company uses Adjusted EBITDA, Adjusted net loss and Adjusted net loss per diluted share in managing and analyzing its business and financial condition and believes these non-GAAP financial measures to be useful to investors in evaluating the company's performance, each of these financial measures has certain shortcomings. Adjusted EBITDA does not take into account the impact of capital expenditures on either the liquidity or the GAAP 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 loss does not take into account non-cash expenses that reflect the amortization of past expenditures, or include stock-based compensation, which is an important and material element of the company's compensation package for its directors, officers and other key employees. As a result of the inherent limitations of each of these non-GAAP financial measures, the company's management utilizes comparable GAAP financial measures to evaluate the business in conjunction with Adjusted EBITDA, Adjusted net loss and Adjusted net loss per diluted share and encourages investors to do likewise.

— *Financial tables follow* —

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017 (As Revised)	2018	2017 (As Revised)
Net revenue	\$ 18,346	\$ 30,670	\$ 65,723	\$ 109,208
Cost of revenue	2,379	7,472	8,179	16,032
Gross profit	<u>15,967</u>	<u>23,198</u>	<u>57,544</u>	<u>93,176</u>
Operating expenses:				
Sales and marketing	7,358	12,825	25,488	41,775
Research and development	14,483	19,552	43,216	46,589
General and administrative	8,906	11,310	29,333	31,883
Legal	16,009	4,404	37,494	15,999
Charges related to litigation award and settlements	30	150,850	770	155,300
Total operating expenses	<u>46,786</u>	<u>198,941</u>	<u>136,301</u>	<u>291,546</u>
Loss from operations	(30,819)	(175,743)	(78,757)	(198,370)
Interest income	483	510	1,470	1,410
Other income (expense),net	-	(83)	(472)	(44)
Loss before income taxes	<u>(30,336)</u>	<u>(175,316)</u>	<u>(77,759)</u>	<u>(197,004)</u>
Income tax expense (benefit)	240	(9,036)	537	(16,096)
Net loss	<u>\$ (30,576)</u>	<u>\$ (166,280)</u>	<u>\$ (78,296)</u>	<u>\$ (180,908)</u>
Net loss per common share:				
Basic	\$ (0.41)	\$ (2.28)	\$ (1.06)	\$ (2.50)
Diluted	\$ (0.41)	\$ (2.28)	\$ (1.06)	\$ (2.50)
Shares used in computing net loss per common share:				
Basic	74,254,177	72,810,827	73,997,016	72,366,618
Diluted	74,254,177	72,810,827	73,997,016	72,366,618
Percentage of Net revenue:				
Net revenue	100.0%	100.0%	100.0%	100.0%
Cost of revenue	<u>13.0%</u>	<u>24.4%</u>	<u>12.4%</u>	<u>14.7%</u>
Gross profit	87.0%	75.6%	87.6%	85.3%
Operating expenses:				
Sales and marketing	40.1%	41.8%	38.8%	38.3%
Research and development	78.9%	63.7%	65.8%	42.7%
General and administrative	48.5%	36.9%	44.6%	29.1%
Legal	87.3%	14.4%	57.0%	14.7%
Charges related to litigation award and settlements	0.2%	491.9%	1.2%	142.2%
Total operating expenses	<u>255.0%</u>	<u>648.7%</u>	<u>207.4%</u>	<u>267.0%</u>
Loss from operations	-168.0%	-573.1%	-119.8%	-181.7%
Interest income	2.6%	1.7%	2.2%	1.3%
Other income (expense),net	0.0%	-0.3%	-0.7%	0.0%
Loss before income taxes	<u>-165.4%</u>	<u>-571.7%</u>	<u>-118.3%</u>	<u>-180.4%</u>
Income tax expense (benefit)	1.3%	-29.5%	0.8%	-14.7%
Net loss	<u>-166.7%</u>	<u>-542.2%</u>	<u>-119.1%</u>	<u>-165.7%</u>

(a) 2017 amounts revised for the correction of immaterial errors as documented above.

INSYS THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(unaudited)

	September 30, 2018	December 31, 2017
		(As Revised)
ASSETS:		
Cash and cash equivalents	\$ 20,845	\$ 31,999
Short-term investments	79,719	85,189
Accounts receivable, net	12,717	21,513
Inventories	10,754	17,408
Prepaid expenses and other current assets	21,442	19,833
Long-term investments	12,451	46,733
Other non-current assets	59,563	56,405
Total assets	\$ 217,491	\$ 279,080
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Liabilities	\$ 217,353	\$ 212,871
Stockholders' equity	138	66,209
Total liabilities and stockholders' equity	\$ 217,491	\$ 279,080

(a) 2017 amounts revised for the correction of immaterial errors as documented above.

INSYS THERAPEUTICS, INC.
RECONCILIATION OF NET LOSS TO NON-GAAP ADJUSTED EBITDA
(In thousands)
(unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
		(As Revised)		(As Revised)
Net loss	\$ (30,576)	\$ (166,280)	\$ (78,296)	\$ (180,908)
Adjustments to arrive at EBITDA:				
Interest income	(483)	(510)	(1,470)	(1,410)
Income tax expense (benefit)	240	(9,036)	537	(16,096)
Depreciation and amortization expense	1,938	1,817	5,689	5,505
EBITDA	(28,881)	(174,009)	(73,540)	(192,909)
Non-cash stock compensation expense	2,863	4,768	9,417	13,048
Charges related to litigation award and settlements	30	150,850	770	155,300
Adjusted EBITDA	<u>\$ (25,988)</u>	<u>\$ (18,391)</u>	<u>\$ (63,353)</u>	<u>\$ (24,561)</u>

(a) 2017 amounts revised for the correction of immaterial errors as documented above.

INSYS THERAPEUTICS, INC.
RECONCILIATION OF NET LOSS TO NON-GAAP ADJUSTED NET LOSS
(In thousands, except per share amounts)
(unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
		(As Revised)		(As Revised)
Net loss	\$ (30,576)	\$ (166,280)	\$ (78,296)	\$ (180,908)
Income tax expense (benefit)	240	(9,036)	537	(16,096)
Loss before income taxes	<u>(30,336)</u>	<u>(175,316)</u>	<u>(77,759)</u>	<u>(197,004)</u>
Adjustments to arrive at Adjusted net loss:				
Non-cash stock compensation expense	2,863	4,768	9,417	13,048
Charges related to litigation award and settlements	30	150,850	770	155,300
Adjusted loss before income taxes	<u>(27,443)</u>	<u>(19,698)</u>	<u>(67,572)</u>	<u>(28,656)</u>
Less: Adjusted income tax provision	300	(4,363)	(1,528)	(8,423)
Adjusted net loss	<u>\$ (27,743)</u>	<u>\$ (15,335)</u>	<u>\$ (66,044)</u>	<u>\$ (20,233)</u>
Adjusted net loss per diluted share	<u>\$ (0.37)</u>	<u>\$ (0.21)</u>	<u>\$ (0.89)</u>	<u>\$ (0.28)</u>

(a) 2017 amounts revised for the correction of immaterial errors as documented above.

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