
**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): August 8, 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 August 8, 2018, Insys Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the second quarter ended June 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 August 8, 2018 Announcing Financial Results for Second 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: August 8, 2018

Insys Therapeutics, Inc.

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



NEWS RELEASE

INSYS Therapeutics Reports Second Quarter 2018 Results*Focus remains on advancing pipeline across cannabinoid and spray platforms*

PHOENIX—Aug. 8, 2018—INSYS Therapeutics, Inc. (NASDAQ: INSY), a leader in the development, manufacture and commercialization of pharmaceutical cannabinoids (CBD) and spray technology, today reported financial results for its second quarter ended June 30, 2018.

OVERALL HIGHLIGHTS

- Reached agreement in principle to settle Department of Justice investigation with financial terms that are consistent with previous public statements and disclosures.
- Achieved gross revenue of \$38.0 million and net revenue of \$23.5 million in the second quarter.
- Continued to advance prioritized R&D programs with \$16.5 million investment in the second quarter.
 - Reported encouraging results from pharmacokinetics (PK) study of epinephrine nasal spray as potential product candidate for treatment of anaphylaxis.
 - Commenced enrolling Phase 2 clinical trial of cannabidiol (CBD) oral solution as potential treatment for Prader-Willi syndrome.
 - Initiated Phase 3 clinical trial of CBD oral solution as potential treatment for infantile spasms.
 - Continued enrolling Phase 2 clinical trial of CBD oral solution as potential treatment for childhood *absence* epilepsy.
- Established collaboration partnership with University of California San Diego's Center for Medicinal Cannabis Research to study CBD oral solution in various disease states, starting with autism.
- Received Complete Response Letter from FDA regarding buprenorphine New Drug Application (NDA).
- Announced exclusive licensing partnership with Lunatus to commercialize SUBSYS® in the Middle East.

“Our continuing commitment to the potential of CBD and our nasal spray technology to significantly improve the lives of patients was highlighted by several important milestones in the

second quarter of 2018, as we continue to make progress against our strategic plan,” said Saeed Motahari, president and chief executive officer of INSYS Therapeutics. “We received encouraging results from our pharmacokinetics study of epinephrine nasal spray and initiated a Phase 2 study of CBD for Prader-Willi Syndrome. Furthermore, we believe we remain on track to submit an NDA for naloxone nasal spray by the end of 2018. These critical milestones are in keeping with our long-term goal to submit one NDA per year through 2021.”

Motahari continued, “Prescriptions for our primary commercial product, SUBSYS®, declined at a slower rate than the overall TIRF market in the second quarter. Our commercial efforts are showing signs of traction, as we gained prescription share in the TIRF market sequentially for the first time in seven quarters. These efforts include new managed care wins, patient education, upgrading the salesforce talent and optimizing territory alignment.”

Motahari added, “Albeit off a small base, prescriptions of SYNDROS® experienced a solid improvement in the second quarter as net revenue improved 56 percent sequentially, driven by the initial success of our patient access and educational programs. We remain resolute in our commitment to patients who rely on SYNDROS® and SUBSYS® and believe our product pipeline has the potential to significantly improve the lives of patients with unmet medical needs—particularly our two life-saving drug candidates, epinephrine and naloxone nasal sprays.”

Financial & Operating Highlights

- Gross revenue for the second quarter of 2018 of \$38.0 million, compared to \$58.2 million for the second quarter of 2017 driven primarily by declines in the TIRF market, but slightly offset by market share gains in the second quarter of 2018.
- Net revenue for the second quarter of 2018 was \$23.5 million, compared to \$42.6 million for the second quarter of 2017, as a result of lower gross revenue and returns of expired product.
- Gross margin was 84.7 percent for the second quarter of 2018, compared to 90.8 percent in the same period of 2017.
- Sales and marketing investment was \$9.1 million for the second quarter of 2018, compared to \$13.3 million for the second quarter of 2017.
- Research and development investment increased to \$16.5 million for the second quarter of 2018, compared to \$14.1 million for the second quarter of 2017.
- General and administrative expense of \$10.9 million for the second quarter of 2018, compared to \$10.6 million in the second quarter of 2017.
- Legal expense increased to \$11.1 million for the second quarter of 2018, compared to \$6.5 million in the second quarter of 2017.
- Income tax expense was \$0.1 million for the second quarter of 2018 compared to a benefit of \$1.7 million during the second quarter of 2017.
- Net loss for the second quarter of 2018 was (\$27.4 million), or (\$0.37) per basic and diluted share, compared to a net loss of (\$8.2 million), or (\$0.11) per basic and diluted share, for the

second quarter of 2017. Adjusted net loss for the quarter was (\$0.33) per basic and diluted share.

- Adjusted EBITDA loss for the second quarter of 2018 was (\$22.5 million), compared to Adjusted EBITDA of \$0.3 million in the prior-year quarter. The reconciliation of net income to Adjusted EBITDA is included at the end of this news release.
- The Company had \$123.5 million in cash, cash equivalents and short-term and long-term investments with no debt as of June 30, 2018.

Webcast Information

A conference call is scheduled for 5:00 p.m. Eastern Standard Time on Aug. 8, 2018, to discuss the financial and operational results for the second 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 2070039. 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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net revenue	\$ 23,466	\$ 42,576	\$ 47,377	\$ 78,538
Cost of revenue	3,596	3,921	5,800	8,560
Gross profit	<u>19,870</u>	<u>38,655</u>	<u>41,577</u>	<u>69,978</u>
Operating expenses:				
Sales and marketing	9,079	13,292	18,130	28,950
Research and development	16,473	14,103	28,733	27,037
General and administrative	10,875	10,643	20,427	20,573
Legal	11,148	6,483	21,485	11,595
Charges related to litigation award and settlements	-	4,450	740	4,450
Total operating expenses	<u>47,575</u>	<u>48,971</u>	<u>89,515</u>	<u>92,605</u>
Loss from operations	(27,705)	(10,316)	(47,938)	(22,627)
Interest income	484	465	987	900
Other income (expense),net	(3)	13	(472)	39
Loss before income taxes	(27,224)	(9,838)	(47,423)	(21,688)
Income tax expense (benefit)	126	(1,654)	297	(6,980)
Net loss	<u>\$ (27,350)</u>	<u>\$ (8,184)</u>	<u>\$ (47,720)</u>	<u>\$ (14,708)</u>
Net loss per common share:				
Basic	\$ (0.37)	\$ (0.11)	\$ (0.65)	\$ (0.20)
Diluted	\$ (0.37)	\$ (0.11)	\$ (0.65)	\$ (0.20)
Shares used in computing net loss per common share:				
Basic	73,920,645	72,169,361	73,832,924	72,057,552
Diluted	73,920,645	72,169,361	73,832,924	72,057,552
Percentage of Net revenue:				
Net revenue	100.0%	100.0%	100.0%	100.0%
Cost of revenue	15.3%	9.2%	12.2%	10.9%
Gross profit	<u>84.7%</u>	<u>90.8%</u>	<u>87.8%</u>	<u>89.1%</u>
Operating expenses:				
Sales and marketing	38.7%	31.2%	38.3%	36.9%
Research and development	70.2%	33.1%	60.6%	34.4%
General and administrative	46.4%	25.0%	43.2%	26.1%
Legal	47.6%	15.2%	45.3%	14.8%
Charges related to litigation award and settlements	0.0%	10.5%	1.6%	5.7%
Total operating expenses	<u>202.9%</u>	<u>115.0%</u>	<u>189.0%</u>	<u>117.9%</u>
Loss from operations	(118.2)%	(24.2)%	(101.2)%	(28.8)%
Interest income	2.1%	1.1%	2.1%	1.1%
Other income (expense),net	0.0%	0.0%	-1.0%	0.1%
Loss before income taxes	(116.1)%	(23.1)%	(100.1)%	(27.6)%
Income tax expense (benefit)	0.5%	(3.9)%	0.6%	-8.9%
Net loss	<u>(116.6)%</u>	<u>(19.2)%</u>	<u>(100.7)%</u>	<u>(18.7)%</u>

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

	June 30, 2018	December 31, 2017
ASSETS:		
Cash and cash equivalents	\$ 16,090	\$ 31,999
Short-term investments	88,813	85,189
Accounts receivable, net	20,067	21,513
Inventories	10,001	17,408
Prepaid expenses and other current assets	21,143	19,833
Long-term investments	18,605	46,733
Other non-current assets	60,426	56,405
Total assets	\$ 235,145	\$ 279,080
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Liabilities	\$ 210,508	\$ 215,798
Stockholders' equity	24,637	63,282
Total liabilities and stockholders' equity	\$ 235,145	\$ 279,080

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net loss	\$ (27,350)	\$ (8,184)	\$ (47,720)	\$ (14,708)
Adjustments to arrive at EBITDA:				
Interest income	(484)	(465)	(987)	(900)
Income tax expense (benefit)	126	(1,654)	297	(6,980)
Depreciation and amortization expense	1,813	1,914	3,751	3,688
EBITDA	(25,895)	(8,389)	(44,659)	(18,900)
Non-cash stock compensation expense	3,384	4,288	6,554	8,280
Charges related to litigation award and settlements	-	4,450	740	4,450
Adjusted EBITDA	<u>\$ (22,511)</u>	<u>\$ 349</u>	<u>\$ (37,365)</u>	<u>\$ (6,170)</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net loss	\$ (27,350)	\$ (8,184)	\$ (47,720)	\$ (14,708)
Income tax expense (benefit)	126	(1,654)	297	(6,980)
Loss before income taxes	(27,224)	(9,838)	(47,423)	(21,688)
Adjustments to arrive at Adjusted net loss:				
Non-cash stock compensation expense	3,384	4,288	6,554	8,280
Charges related to litigation award and settlements	-	4,450	740	4,450
Adjusted loss before income taxes	(23,840)	(1,100)	(40,129)	(8,958)
Less: Adjusted income tax provision	262	(2,965)	(1,828)	(4,060)
Adjusted net loss	<u>\$ (24,102)</u>	<u>\$ 1,865</u>	<u>\$ (38,301)</u>	<u>\$ (4,898)</u>
Adjusted net loss per diluted share	<u>\$ (0.33)</u>	<u>\$ 0.03</u>	<u>\$ (0.52)</u>	<u>\$ (0.07)</u>

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