

Insys Therapeutics, Inc.
Form 10-Q
May 10, 2018
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 001-35902

Insys Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of

incorporation or organization)

1333 S. Spectrum Blvd, Suite 100, Chandler, Arizona 85286

51-0327886
(IRS Employer

Identification No.)

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(Address of principal executive offices)

(Zip Code)

(480) 500-3127

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

(Do not check if a smaller reporting company)

Smaller reporting company

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. []

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

As of April 30, 2018, the registrant had 73,808,904 shares of Common Stock (\$0.01 par value) outstanding.

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GLOSSARY OF TERMS

The following glossary provides definitions for certain acronyms and terms used in our periodic filings with the United States Securities and Exchange Commission, including this Quarterly Report on Form 10-Q. These acronyms and terms are specific to our company, commonly used in our industry, or are otherwise frequently used throughout our filings, including this document.

Abbreviated Term	Defined Term
ANDA	Abbreviated New Drug Application
API	Active pharmaceutical ingredient
Aptar	AptarGroup, Inc.
ASC	Accounting Standards Codification
ASU	Accounting Standards Update
ATRA	American Taxpayer Relief Act of 2012
AUC	Area under the curve
AVC	Assurance of Voluntary Compliance
BTCP	Breakthrough cancer pain
Catalent	Catalent Pharma Solutions, LLC
CBD	Synthetic cannabidiol
cGMP	Current Good Manufacturing Practices
CID	Civil Investigative Demand
CINV	Chemotherapy-induced nausea and vomiting
CMS	Centers for Medicare & Medicaid Services
CRO	Contract Research Organization
CSA	Federal Controlled Substances Act of 1970
DEA	U.S. Drug Enforcement Administration
DOJ	U.S. Department of Justice
DOJ Investigations	HHS and HIPAA investigations, collectively
ERP	Enterprise Resource Planning
ESI	Express Scripts, Inc.
FASB	Financial Accounting Standards Board
FDA	U.S. Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
FSS	Federal Supply Schedule
GAO	Government Accountability Office
GCP	Good Clinical Practices
GI	Gastrointestinal
GLP	Good Laboratory Practices
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HITECH	Health Information Technology for Economic and Clinical Health Act of 2009
IND	Investigational New Drug Application

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Insys Pharma	Insys Pharma, Inc.
Insys Therapeutics	Insys Therapeutics, Inc.
IPO	Initial public offering
IPR	Inter Partes Review
IQVIA	IQVIA Holdings Inc. (formerly IMS Health, or “IMS”)
IRB	Institutional Review Board
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
Mylan	Mylan Pharmaceuticals, Inc.
NDA	New Drug Application
NeoPharm	NeoPharm, Inc.

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NOL	Net operating loss carryforward
NRV	Net Realizable Value
NSAID	Non-steroidal anti-inflammatory drug
Orange Book	FDA's Approved Drug Products with Therapeutic Equivalence Evaluations
ODOJ	Oregon Department of Justice
PBM	Pharmacy Benefit Managers
PDEs	Prescription Drug Events
PDMA	Prescription Drug Marketing Act
PDUFA	Prescription Drug User Fee Act
PK	Pharmacokinetics
PPACA	Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010
QSR	FDA's Quality System Regulation
REMS	Risk Evaluation and Mitigation Strategy
Renaissance	Renaissance Acquisition Holdings, LLC (formerly DPT Lakewood, LLC, or "DPT")
RLD	Reference listed drug
SEC	U.S. Securities and Exchange Commission
THC	Delta-9-tetrahydrocannabinol
TIRF	Transmucosal immediate-release fentanyl
TIRF REMS	Transmucosal immediate release fentanyl risk evaluation and mitigation strategy
USAO	United States Attorney Office
U.S. GAAP	Accounting Principles Generally Accepted in the United States of America
USPTO	United States Patent and Trademark Office
VC	Vomiting center

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PART I: FINANCIAL INFORMATION

ITEM 1. UNAUDITED FINANCIAL STATEMENTS

INSYS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	March 31, 2018	December 31, 2017
	(unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 18,549	\$ 31,999
Short-term investments	95,895	85,189
Accounts receivable, net of allowances of \$4,005 and \$3,832 at March 31, 2018 and December 31, 2017, respectively	15,761	21,513
Inventories, net	16,300	17,408
Prepaid expenses and other current assets	20,189	19,833
Total current assets	166,694	175,942
Property and equipment, net	54,777	55,174
Long-term investments	31,633	46,733
Other assets	835	1,231
Total assets	\$ 253,939	\$ 279,080
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 29,440	\$ 30,438
Accrued compensation	4,014	8,808
Accrued sales allowances	12,833	16,290
Deferred revenue	—	1,109
Accrued litigation award and settlements	151,524	150,534
Total current liabilities	197,811	207,179
Uncertain income tax positions	8,765	8,619
Total liabilities	206,576	215,798
Commitments and contingencies (Note 6)		
Stockholders' Equity:		
Preferred stock (par value \$0.001 per share; 10,000,000 shares authorized; 0 shares issued and outstanding as of March 31, 2018 and December 31, 2017, respectively)	—	—
Common stock (par value \$0.01 per share; 100,000,000 shares authorized;	738	736

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73,808,821 and 73,612,052 shares issued and outstanding as of

March 31, 2018 and December 31, 2017, respectively)

Additional paid in capital	282,048	278,356
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