Insys Therapeutics, Inc.
Form 10-Q
August 09, 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 June 30, 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)	51-0327886 (IRS Employer Identification No.)
1333 S. Spectrum Blvd, Suite 100, Chandler, Arizona	85286

(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 Date 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 August 5, 2018, the registrant had 74,244,874 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
CODM	Chief Operating Decision Maker
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

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.
NOL	Net operating loss carryforward

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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)

	June 30, 2018 (unaudited)	December 31, 2017
Assets		
Current Assets:		
Cash and cash equivalents	$ 16,090	$ 31,999
Short-term investments	88,813	85,189
Accounts receivable, net of allowances of $2,626 and $3,832 at June 30, 2018 and December 31, 2017, respectively	20,067	21,513
Inventories, net	10,001	17,408
Prepaid expenses and other current assets	21,143	19,833
Total current assets	156,114	175,942
Property and equipment, net	52,892	55,174
Long-term investments	18,605	46,733
Other assets	7,534	1,231
Total assets	$ 235,145	$ 279,080
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 33,569	$ 30,438
Accrued compensation	5,322	8,808
Accrued sales allowances	12,582	16,290
Deferred revenue	—	1,109
Accrued litigation award and settlements	150,134	150,534
Total current liabilities	201,607	207,179
Uncertain income tax positions	8,901	8,619
Total liabilities	210,508	215,798
Commitments and Contingencies (Note 7)		
Stockholders' Equity:		
Preferred stock (par value $0.001 per share; 10,000,000 shares authorized; 0 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively)	—	—
Common stock (par value $0.01 per share; 100,000,000 shares authorized;	742	736

74,224,373 and 73,612,052 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively)		
Additional paid in capital	286,556	278,356
Unrealized loss on available-for-sale securities, net of tax	(438)	(438)
Notes receivable from stockholders	—	(21)
Accumulated deficit	(262,223)	(215,351)
Total stockholders' equity	24,637	63,282
Total liabilities and stockholders' equity	$ 235,145	$ 279,080

See accompanying notes to unaudited condensed consolidated financial statements.

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INSYS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

(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	19,870	38,655	41,577	69,978
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	47,575	48,971	89,515	92,605
Operating loss	(27,705)	(10,316)	(47,938)	(22,627)
Other income:				
Interest income	484	465	987	900
Other income (expense), net	(3)	13	(472)	39
Total other income	481	478	515	939
Loss before income taxes	(27,224)	(9,838)	(47,423)	(21,688)
Income tax expense (benefit)	126	(1,654)	297	(6,980)
Net loss	(27,350)	(8,184)	(47,720)	(14,708)
Unrealized gain (loss) on available-for-sale securities, net of tax	112	(24)	-	51
Total comprehensive loss	$(27,238)	$(8,208)	$(47,720)	$(14,657)
Net loss per common share:				
Basic	$(0.37)	$(0.11)	$(0.65)	$(0.20)
Diluted	$(0.37)	$(0.11)	$(0.65)	$(0.20)
Weighted average common shares outstanding				
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

See accompanying notes to unaudited condensed consolidated financial statements.

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INSYS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

(In thousands, except share data)

(unaudited)

	Common Stock Shares	Amount	Additional Paid in Capital	Unrealized Loss on Available-For-Sale Securities	Notes Receivable From Stockholders	Accumulated Deficit	Total
Balance at December 31, 2017	73,612,052	$ 736	$ 278,356	$ (438)	$ (21)	$ (215,351)	$ 63,282
Adoption of new accounting standard ASC 606	—	—	—	—	—	848	848
Exercise of stock options	409,129	4	912	—	—	—	916
Issuance of common stock-employee stock purchase plan	149,282	2	734	—	—	—	736
Stock-based compensation-stock options, awards, and restricted stock units	—	—	6,554	—	—	—	6,554
Vesting of restricted stock units	53,910	—	—	—	—	—	—
Write-off of notes receivable from stockholders	—	—	—	—	21	—	21
Net loss	—	—	—	—	—	(47,720)	(47,720)
Balance at June 30, 2018	74,224,373	$ 742	$ 286,556	$ (438)	$ —	$ (262,223)	$ 24,637

See accompanying notes to unaudited condensed consolidated financial statements.

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INSYS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Six Months Ended June 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(47,720)	$(14,708)
Adjustments to reconcile net loss to net cash used in operating activities:		
Inventory obsolescence reserve	1,005	2,959
Depreciation and amortization	3,751	3,688
Stock-based compensation	6,554	8,280
Deferred income tax benefit	—	(3,308)
Loss on disposal of property and equipment	108	—
Impairment on property and equipment	1,487	—
Write-off of notes receivable and other assets due from stockholders	26	—
Amortization of investment discount	114	676
Changes in operating assets and liabilities:		
Accounts receivable	1,446	(3,318)
Inventories	930	345
Prepaid expenses and other current assets	(2,087)	(5,921)
Accounts payable, accrued expenses and other current and noncurrent liabilities	(5,275)	(16,990)
Accrued litigation award and settlements	(400)	1,050
Net cash used in operating activities	(40,061)	(27,247)
Cash flows from investing activities:		
Purchase of investments	(35,889)	(72,060)
Proceeds from sales of investments	11,855	2,919
Proceeds from maturities of investments	48,424	47,422
Purchases of property and equipment	(1,890)	(9,013)
Net cash provided by (used in) investing activities	22,500	(30,732)
Cash flows from financing activities:		
Proceeds from issuance of common stock	736	836
Proceeds from exercise of stock options	916	2,331
Net cash provided by financing activities	1,652	3,167
Change in cash and cash equivalents	(15,909)	(54,812)
Cash and cash equivalents, beginning of period	31,999	104,642

Cash and cash equivalents, end of period	$16,090	$49,830
Supplemental cash flow disclosures:		
Cash paid (refunded) for income taxes, net	$(7)	$1,793
Non-cash capital expenditures	$1,174	$642

See accompanying notes to unaudited condensed consolidated financial statements.

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INSYS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Basis of Presentation

Insys Therapeutics, Inc., which was incorporated in Delaware in June 1990, and our subsidiaries (collectively, "we," "us," and "our") maintain headquarters in Chandler, Arizona.

We are a commercial-stage specialty pharmaceutical company that develops and commercializes innovative supportive care products. As of June 30, 2018, we have two marketed products: SUBSYS®, a proprietary sublingual fentanyl spray for BTCP in opioid-tolerant adult patients; and SYNDROS®, a proprietary, orally administered liquid formulation of dronabinol for the treatment of CINV and anorexia associated with weight loss in patients with AIDS.

The accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance with U.S. GAAP, pursuant to rules and regulations of the SEC. Certain information and footnote disclosures have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, the accompanying condensed consolidated financial statements include normal recurring adjustments that are necessary for a fair presentation of the results for the interim periods presented. These condensed consolidated financial statements should be read in conjunction with our audited consolidated financial statements and notes thereto for the fiscal year ended December 31, 2017, included in our Annual Report on Form 10-K. The results of operations for the three and six months ended June 30, 2018 and 2017, are not necessarily indicative of results to be expected for the full fiscal year or any other periods.

The preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires management to make a number of estimates and judgments that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expense during the reported period. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition (which are affected by prescriptions dispensed, wholesaler discounts, patient discount programs, rebates, returns, and chargebacks), inventories, fair value of investments, legal liabilities and settlements, stock-based compensation expense, impairment, uncertain tax positions, and deferred tax valuation allowances. We base our estimates on historical experience and on various other assumptions that are believed by management to be reasonable under the circumstances. Actual results could materially differ from these estimates.

Certain prior period amounts have been reclassified to conform with current period presentation.

All significant intercompany balances and transactions have been eliminated in the accompanying unaudited condensed consolidated financial statements.

Recently Adopted Accounting Pronouncements

Effective January 1, 2018, we adopted the requirements of ASU No. 2014-09, "Revenue from Contracts with Customers (ASC Topic 606)," and all the related amendments ("new revenue standard"). The new revenue standard aims to achieve a consistent application of revenue recognition within the United States, resulting in a single revenue model to be applied by reporting companies under U.S. GAAP. Under the new model, recognition of revenue occurs when a customer obtains control of promised goods or services in an amount that reflects the consideration to which the entity

expects to be entitled in exchange for those goods or services. In addition, the new revenue standard requires that reporting companies disclose the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. We used the modified retrospective transition method for all contracts that were not completed as of the adoption date. In addition, we have applied the practical expedient to contract modifications, as allowed by the SEC, but did not have any material contract modifications to be included in the initial adoption of ASC Topic 606. The comparative information in these condensed consolidated financial statements has not been restated and continues to be reported under ASC Topic 605, “Revenue Recognition.” We expect the impact of the adoption of the new standard to be immaterial to our net income (loss) on an ongoing basis. We recognize revenue when we transfer control of our products to our customers, as our contracts have a single performance obligation (delivery of our product to their preferred location). Our sales revenue from SUBSYS® continues to be recognized when product is delivered to wholesale pharmaceutical distributors and specialty retail pharmacies (collectively, our customers). In accordance with the new revenue standard, our sales revenue from SYNDROS® is now recognized when product is delivered to our customers, where revenue was previously deferred until the right of return no longer existed, which occurred at the earlier of the time SYNDROS® units were sold to health care facilities or dispensed through patient prescriptions, or the expiration of the right of return. It is common for our contracts to include product sales allowances that can decrease the transaction price and are

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therefore considered to be variable consideration. In accordance with the new revenue standard, we estimate the amount of variable consideration promised in the contract using the expected value (probability weighted estimate) method. We do not have any significant extended payment terms as payment is received shortly after the point of sale. See Note 2, Revenue Recognition, for additional discussion of our revenue recognition policy, variable consideration estimates, and the impact of adopting the new revenue standard on our condensed consolidated balance sheets and statements of operations and comprehensive loss for the three and six months ended June 30, 2018. Overall, the adoption of the new revenue standard did not have a material impact on the amounts reported in our condensed consolidated financial statements and there were no other significant changes impacting the timing or measurement of our revenue or our business processes and controls.

The cumulative effect of the changes made to our January 1, 2018 condensed consolidated balance sheets for the adoption of the new revenue standard was as follows (in thousands):

	Balance at December 31, 2017	Adjustments due to adoption of ASC Topic 606	Balance at January 1, 2018
Condensed Consolidated Balance Sheets:			
Inventories, net	17,408	(59)	17,349
Accrued sales allowances	16,290	320	16,610
Deferred revenue	1,109	(1,109)	—
Accumulated deficit	(215,351)	848	(214,503)

The impact of adopting the new revenue standard on our condensed consolidated statements of operations and comprehensive loss was as follows (in thousands):

	Three Months Ended June 30, 2018			Six Months Ended June 30, 2018		
	Balances without Adopting ASC Topic 606	Impact of Adopting ASC Topic 606	As Reported	Balances without Adopting ASC Topic 606	Impact of Adopting ASC Topic 606	As Reported
Condensed Consolidated						

Statements of Operations and Comprehensive Loss:						
Net revenue	$23,432	$ 34	$23,466	$47,178	199	$47,377
Cost of revenue	3,592	4	3,596	5,786	14	5,800
Gross profit	19,840	30	19,870	41,392	185	41,577
Operating loss	(27,735)	30	(27,705)	(48,123)	185	(47,938)
Loss before income taxes	(27,254)	30	(27,224)	(47,608)	185	(47,423)
Net loss	(27,380)	30	(27,350)	(47,905)	185	(47,720)

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The impact of adopting the new revenue standard on our condensed consolidated balance sheets was as follows (in thousands):

	June 30, 2018		
	Balances without Adopting ASC Topic 606	Impact of Adopting ASC Topic 606	As Reported
Condensed Consolidated Balance Sheets:			
Inventories, net	$9,928	73	$10,001
Total current assets	156,041	73	156,114
Total assets	235,072	73	235,145
Accrued sales allowances	12,353	229	12,582
Deferred revenue	1,537	(1,537)	—
Total liabilities	211,816	(1,308)	210,508
Accumulated deficit	(262,408)	185	(262,223)
Total stockholders' equity	24,452	185	24,637

Effective January 1, 2018, we adopted ASU No. 2016-01, “Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities,” and ASU No. 2018-03, “Technical Corrections and Improvements to Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities.” These standards amended the Financial Instruments topic of the ASC to address certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. The standard requires that unrealized gains and losses on investments in equity securities to be recognized in net income (loss). The adoption of this guidance did not have a material impact on our condensed consolidated financial statements.

Effective January 1, 2018, we adopted ASU No. 2016-15, “Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments.” The guidance clarifies how certain cash flow transactions are classified in the statement of cash flows. The adoption of this guidance did not have a material impact on our condensed consolidated financial statements.

Effective January 1, 2018, we adopted ASU No. 2016-16, “Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory.” Prior to January 1, 2018, U. S. GAAP prohibited the recognition of current and deferred income taxes for an intra-entity asset transfer until the asset was sold to an outside party, which was an exception to the principle of comprehensive recognition of current and deferred income taxes in U. S. GAAP. This guidance eliminates the exception for an intra-entity transfer of an asset other than inventory. The adoption of this guidance did not have a material impact on our condensed consolidated financial statements.

Effective January 1, 2018, we adopted ASU No. 2017-09, “Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting.” The ASU requires modification accounting to a share-based payment award unless all of

the following are the same immediately before and after the change: the award’s fair value; the award’s vesting conditions; and the award’s classification as an equity instrument or a liability instrument. The adoption of this guidance did not have a material impact on our condensed consolidated financial statements.

Effective January 1, 2018, we adopted ASU No. 2018-05, “Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118 (SEC Update).” The standard addresses any uncertainty or diversity of views in practice regarding the application of ASC Topic 740 in situations where a registrant did not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting under ASC Topic 740 for certain income tax effects of the 2017 Tax Cuts and Jobs Act (the “Act”) for the reporting period in which the Act was enacted. The Company recognized the provisional tax impacts of the Act in the fourth quarter of 2017. During the first quarter of 2018, the Company did not identify any additional information regarding these provisional calculations. As a result, the Company continues to anticipate finalizing its analysis in connection with the completion of the Company's tax return for 2017 to be filed in 2018.

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In June 2018, the FASB issued ASU No. 2018-07, "Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting." The standard expands the scope of ASC Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees, and supersedes ASC Topic 505-50, "Equity – Equity Based Payments to Non-Employees." Previously, the fair value of share-based payment awards to nonemployees was determined by the measurement date, which was the earlier of the date at which a commitment for performance by the counterparty is reached or the date at which the counterparty's performance is complete. This concept caused significant differences in the accounting for share-based payment to nonemployees as compared to share-based payments to employees. Furthermore, the previous guidance required employers to revalue share-based payments to nonemployees at each reporting period if a measurement date could not be established, causing fluctuations in the resulting expense from period to period. The new standard eliminates the measurement date concept and requires the fair value of share-based payments to nonemployees to be measured on the grant date, consistent with share-based payments to employees. We early adopted the standard during the three months ended June 30, 2018. We remeasured the fair value of our equity-classified share-based payments to nonemployees for which a measurement date had not been established as of the adoption date of January 1, 2018. Because we had previously remeasured our share-based payments to nonemployees at each reporting period, the adoption did not result in a cumulative effect adjustment to opening retained earnings. The impact of this adoption on the condensed consolidated financial statements for the three months ended March 31, 2018 was an increase to stock-based compensation reported in general and administrative expenses of approximately $259,000, with an offset to additional paid-in capital.

Recent Accounting Pronouncements

In March 2017, the FASB issued ASU No. 2017-08, "Receivables—Nonrefundable Fees and Other Costs (Subtopic 310-20): Premium Amortization on Purchased Callable Debt Securities," to amend the amortization period for certain purchased callable debt securities held at a premium. The ASU shortens the amortization period for the premium to the earliest call date. Under current U.S. GAAP, entities generally amortize the premium as an adjustment of yield over the contractual life of the instrument. The amendments should be applied on a modified retrospective basis and are effective for fiscal years beginning after December 15, 2018. Early adoption is permitted, including adoption in an interim period. We are currently evaluating the impact of this amendment on our condensed consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments." The amendments effected by this ASU affect entities holding financial assets and net investment in leases that are not accounted for at fair value through net income and are effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, and early adoption is permitted. ASU 2016-13 amends the impairment model to utilize an expected loss methodology in place of the currently used incurred loss methodology, which will result in the timelier recognition of losses. We do not expect this amendment to have a material impact on our condensed consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, "Leases: (Topic 842)," to provide guidance on recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements, specifically differentiating between different types of leases. The core principle of Topic 842 is that a lessee should recognize the assets and liabilities that arise from all leases. The recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee have not significantly changed from previous U.S. GAAP guidance. There continues to be a differentiation between finance leases and operating leases. However, the principal difference from previous guidance is that the lease assets and lease liabilities arising from operating leases should be recognized in the balance sheet. The accounting applied by a lessor is largely unchanged from that applied under

previous U.S. GAAP guidance. The amendments will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, and early adoption is permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The modified retrospective approach includes a number of optional practical expedients that entities may elect to apply. These practical expedients relate to the identification and classification of leases that commenced before the effective date, initial direct costs for leases that commenced before the effective date, and the ability to use hindsight in evaluating lessee options to extend or terminate a lease or to purchase the underlying asset. An entity that elects to apply the practical expedients will, in effect, continue to account for leases that commenced before the effective date in accordance with previous U.S. GAAP guidance unless the lease is modified, except that lessees are required to recognize a right-of-use asset and a lease liability for all operating leases at each reporting date based on the present value of the remaining minimum rental payments that were tracked and disclosed under previous U.S. GAAP guidance. We currently expect that most of our operating lease commitments will be subject to the update and recognized as right-of-use assets and operating lease liabilities upon adoption. We expect the standard to have a material impact on our assets and liabilities for the addition of right-of-use assets and lease liabilities, but we do not expect it to have a material impact to our results of operations or liquidity.

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2. Revenue Recognition

To determine revenue recognition for contractual arrangements that we determine are within the scope of ASC Topic 606, we perform the following five steps: (i) identify each contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to our performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy the relevant performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods we transfer to the customer. We recognize revenue from the sale of our commercially approved products, SUBSYS® and SYNDROS®, when we transfer control of our products to our customers, as our contracts have a single performance obligation (delivery of our product to their preferred location). Revenue is measured as the amount of consideration we expect to receive in exchange for transferring goods. Any shipping and handling activities that we perform, whether before or after a customer has obtained control of the products, are considered activities to fulfill our obligation to transfer the products, and are recorded as incurred within sales and marketing expenses.

SUBSYS® was commercially launched in March 2012 and is monitored by an FDA-mandated REMS program known as the TIRF REMS. SYNDROS® was commercially launched in July 2017. We sell all of our products in the United States to wholesale pharmaceutical distributors and directly to specialty retail pharmacies (collectively, our customers). See Note 10, Product Lines, Concentration of Credit Risk and Significant Customers, for information on revenues disaggregated by product line and route to market.

As is customary in the pharmaceutical industry, it is common for our contracts to include product sales allowances that can decrease the transaction price and are therefore considered to be variable consideration. Product sales allowances are based on amounts owed or to be claimed on the related sales. We estimate variable consideration when determining the transaction price using the expected value method. We assess whether variable consideration is constrained and only include estimated amounts in the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved. Our estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on historical data, and take into consideration the terms of our agreements with customers and third-party payers and the levels of inventory within the distribution channels that may result in future discounts taken. In certain cases, such as patient assistance programs, our estimates are based on estimated utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on revenue in the period of adjustment. Our product sales allowances include:

Product Returns. We allow customers to return product for credit beginning six months prior to, and ending 12 months following, the product expiration date. SUBSYS® currently has a shelf life of 36 or 48 months from the date of manufacture, depending on the manufacture date, and SYNDROS® currently has a shelf life of 24 or 36 months from the date of manufacture, depending on the manufacture date. We have monitored actual return history since product launch, which provides us with a basis to reasonably estimate future product returns, taking into consideration the shelf life of product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels and consideration of the introduction of competitive products.

Because of the shelf life of our products and our return policy of issuing credits on returned product that is within six months before, and up to 12 months following, the product expiration date, there may be a significant period of time between when the product is shipped and when we issue credits on returned products. Accordingly, we may have to adjust these estimates, which could have an effect on net revenue and earnings in the period of adjustment. The allowance for product returns is included in accrued sales allowances.

Wholesaler and Retailer Discounts. We offer discounts to certain wholesale distributors and specialty retailers based on contractually determined rates. We accrue the discount as a reduction of receivables due from the wholesalers and retailers upon shipment to the respective wholesale distributors and retail pharmacies.

Prompt Pay Discounts. We offer cash discounts to our customers, generally 2% of the sales price, as an incentive for prompt payment. We account for cash discounts by reducing accounts receivable by the full amount of the discount.

Stocking Allowances. We may offer discounts and extended payment terms, generally in the month of the initial commercial launch of a new product and on the first order made by certain wholesale distributors and retail pharmacies based on contractually determined rates. We accrue the discount as a reduction of receivables due from the wholesalers and retailers upon shipment to the respective wholesale distributors and retail pharmacies. The extended payment terms are not greater than 12 months and therefore do not include a financing component.

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Patient Discount Programs. We offer discount card programs to patients, in which patients receive discounts on their prescriptions that are reimbursed by us to the retailer. We estimate the total amount that will be redeemed based on a percentage of actual redemptions applied to inventory in the distribution and retail channels. The allowance for patient discount programs is included in accrued sales allowances.

Rebates. We participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. We estimate and accrue these rebates based on current and estimated future contract prices, historical and estimated future percentages of products prescribed to qualified patients and estimated levels of inventory in the distribution channel. The allowance for rebates is included in accrued sales allowances.

Chargebacks. We provide discounts primarily to authorized users of the FSS of the General Services Administration under an FSS contract negotiated by the Department of Veterans Affairs and various organizations under Medicaid contracts and regulations. These organizations purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back to us the difference between the current retail price and the price the organization paid for the product. We estimate and accrue chargebacks based on estimated wholesaler inventory levels, current contract and estimated future prices and historical chargeback activity. Estimated chargebacks are recognized as a reduction of revenue in the same period the related revenue is recognized. The allowance for chargebacks is included as a reduction to accounts receivable.

As of June 30, 2018, the majority of our accounts receivables were related to product sales. For the three and six months ended June 30, 2018, the Company had no material bad-debt expense and there were no contract assets, contract liabilities or deferred contract costs recorded on the condensed consolidated balance sheets as of June 30, 2018.

3. Short-Term and Long-Term Investments

Our policy for short-term and long-term investments is to establish a high-quality portfolio that preserves principal, meets liquidity needs, avoids inappropriate concentrations, and delivers an appropriate yield in relationship to our investment guidelines and market conditions. Short-term and long-term investments consist of corporate and various government agency and municipal debt securities, commercial paper, as well as certificates of deposit that have maturity dates that are greater than 90 days. Certificates of deposit and commercial paper are carried at cost, which approximates fair value. We classify our marketable securities as available-for-sale in accordance with FASB ASC Topic 320, “Investments — Debt and Equity Securities.” Investments in debt securities that are classified as available-for-sale are carried at fair value with unrealized gains and losses reported in stockholders’ equity, net of related tax effects. There were no reclassifications on available-for-sale securities during the three and six months ended June 30, 2018 and 2017. A decline in the market value of any available-for-sale security below cost that is deemed to be other than temporary results in impairment of the fair value of the investment. If we had unrealized gains and losses and declines in value judged to be other than temporary, we would have been required to include those changes in other income (expense) in the condensed consolidated statements of operations and comprehensive loss. Premiums and discounts are amortized or accreted over the life of the related available-for-sale security. The cost of securities sold is calculated using the specific identification method. At June 30, 2018, our certificates of deposit and commercial paper as well as our marketable securities have been recorded at an estimated fair value of $599,000, $88,813,000, and $18,605,000 in cash and cash equivalents, short-term and long-term investments, respectively.

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Investments consisted of the following at June 30, 2018 (in thousands):

	Cost	Unrealized Gains	Unrealized Losses	Other-Than-Temporary Impairment Losses	Fair Value	Cash and Cash Equivalents	Short-term Investments	Long-term Investments
Cash and cash equivalents	$6,425	$ —	$ —	$ —	$6,425	$ 6,425	$ —	$ —
Money market securities	9,066	—	—	—	9,066	9,066	—	—
Marketable securities:								
Certificates of deposit	14,528	—	—	—	14,528	—	7,827	6,701
Commercial paper	15,228	—	—	—	15,228	599	14,629	—
Corporate securities	44,159	—	(222)	—	43,937	—	41,488	2,449
Federal agency securities	29,877	—	(205)	—	29,672	—	20,568	9,104
Municipal securities	4,663	—	(11)	—	4,652	—	4,301	351
Total marketable securities	108,455	—	(438)	—	108,017	599	88,813	18,605
	$123,946	$ —	$ (438)	$ —	$123,508	$ 16,090	$ 88,813	$ 18,605

Investments consisted of the following at December 31, 2017 (in thousands):

	Cost	Unrealized Gains	Unrealized Losses	Other-Than-Temporary Impairment Losses	Fair Value	Cash and Cash Equivalents	Short-term Investments	Long-term Investments
Cash and cash equivalents	$12,183	$ —	$ —	$ —	$12,183	$ 12,183	$ —	$ —
Money market securities	15,317	—	—	—	15,317	15,317	—	—
Marketable securities:								

Certificates of deposit	18,447	—	—	—	18,447	—	7,474	10,973
Commercial paper	10,560	—	—	—	10,560	1,499	9,061	—
Corporate securities	59,613	—	(206)	—	59,407	1,500	39,622	18,285
Federal agency securities	37,793	—	(203)	—	37,590	1,500	20,015	16,075
Municipal securities	10,446	—	(29)	—	10,417	—	9,017	1,400
Total marketable securities	136,859	—	(438)	—	136,421	4,499	85,189	46,733
	$164,359	$ —	$ (438)	$ —	$163,921	$ 31,999	$ 85,189	$ 46,733

The amortized cost and estimated fair value of the marketable securities by maturity, are shown below (in thousands):

	June 30, 2018		December 31, 2017	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Marketable securities:				
Due in one year or less	$89,618	$89,362	$90,071	$89,937
Due after one year through 5 years	18,537	18,355	46,788	46,484
Due after 5 years through 10 years	—	—	—	—
Due after 10 years	300	300	—	—
	$108,455	$108,017	$136,859	$136,421

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The following table shows the gross unrealized losses and the fair value of our investments, with unrealized losses that are not deemed to be other-than-temporarily impaired aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position (in thousands):

	June 30, 2018				December 31, 2017			
	Less Than 12 Months		Greater Than 12 Months		Less Than 12 Months		Greater Than 12 Months	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Marketable securities:								
Corporate securities	$28,904	$ (135)	$14,023	$ (87)	$245	$ (153)	$7,839	$ (52)
Federal agency securities	17,362	(113)	11,911	(92)	26,244	(89)	11,346	(114)
Municipal securities	2,358	(5)	1,030	(6)	50,537	(18)	1,145	(12)
	$48,624	$ (253)	$26,964	$ (185)	$77,026	$ (260)	$20,330	$ (178)

We did not have any unrealized gains or losses or decline in values judged to be other than temporary during the three and six months ended June 30, 2018 and 2017. This review includes an analysis of the facts and circumstances of each individual investment such as the severity of loss, the expectation for that security's performance and the creditworthiness of the issuer.

4. Fair Value Measurement

FASB ASC Topic 820, Fair Value Measurement, defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. It also establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;
Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and
Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

At June 30, 2018 and December 31, 2017, we held short-term and long-term investments, as discussed in Note 3, that are required to be measured at fair value on a recurring basis. Except as discussed in Note 6, we had no assets or liabilities measured at fair value on a nonrecurring basis at June 30, 2018 and December 31, 2017. Substantially all available-for-sale investments held by us at June 30, 2018 and December 31, 2017, have been valued based on Level 2 inputs. Available-for-sale securities classified within Level 2 of the fair value hierarchy are valued utilizing reports from an independent third-party public quotation service based on closing prices on the last business day of the period presented. In addition, we use the public quotation service to perform price testing by comparing quoted prices listed in reports provided by the asset managers that hold our investments to quotes listed through the public quotation service. These asset managers utilize an independent pricing source to obtain quotes for most fixed income securities and utilize internal procedures to validate the prices obtained. Our Level 3 asset represents an investment in

convertible preferred stock that is not listed on any security exchange. The fair value of the preferred stock approximates its carrying value at June 30, 2018 and December 31, 2017.

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Our assets and liabilities subject to the disclosure requirements of ASC Topic 820 at June 30, 2018, were as follows (in thousands):

	Fair Value Measurement at Reporting Date				
	Total	Quoted Prices in active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Gains (Losses)
Recurring fair value measurements					
Marketable securities:					
Certificates of deposit	$14,528	$ —	$ 14,528	$ —	
Commercial paper	15,228	—	15,228	—	
Corporate securities	43,937	—	43,419	518	
Federal agency securities	29,672	—	29,672	—	
Municipal securities	4,652	—	4,652	—	
Total recurring fair value measurements	$108,017	$ —	$ 107,499	$ 518	
Nonrecurring fair value measurements					
Property and equipment (see Note 6)	—	—	—	—	$(1,487)
Total nonrecurring fair value measurements	$—	$ —	$ —	$ —	$(1,487)

Our assets and liabilities subject to the disclosure requirements of ASC Topic 820 at December 31, 2017, were as follows (in thousands):

	Fair Value Measurement at Reporting Date			
	Total	Quoted Prices in active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)

		(Level 1)		
Recurring fair value measurements				
Marketable securities:				
Certificates of deposit	$18,447	$ —	$ 18,447	$ —
Commercial paper	10,560	—	10,560	—
Corporate securities	59,407	—	58,889	518
Federal agency securities	37,590	—	37,590	—
Municipal securities	10,417	—	10,417	—
Total recurring fair value measurements	$136,421	$ —	$ 135,903	$ 518

The following table presents additional information about assets measured at fair value on a recurring basis and for which we utilize Level 3 inputs to determine fair value for the three and six months ended June 30, 2018 and 2017 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Convertible preferred stock				
Balance, beginning of period	$518	$518	$518	$500
Change in fair value	—	—	—	18
Balance, end of period	$518	$518	$518	$518

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5. Inventories, net

Inventories are stated at lower of cost or NRV. Cost, which includes amounts related to materials and costs incurred by our contract manufacturers, is determined on a first-in, first-out basis. Inventories are reviewed periodically for potential excess, dated or obsolete status. Management evaluates the carrying value of inventories on a regular basis, taking into account such factors as historical and anticipated future sales compared to quantities on hand, the price we expect to obtain for products in their respective markets compared with historical cost and the remaining shelf life of goods on hand.

The components of inventories, net of allowances, are as follows (in thousands):

	June 30, 2018	December 31, 2017
Finished goods	$2,521	$ 4,709
Work-in-process	4,302	5,752
Raw materials and supplies	3,178	6,947
Total inventories	10,001	17,408
Plus: non-current raw materials and finished goods	6,358	826
	$16,359	$ 18,234

As of June 30, 2018 and December 31, 2017, raw materials inventories consisted of raw materials used in the manufacture of the dronabinol API for SYNDROS® in our U.S.-based, state-of-the-art dronabinol manufacturing facility, the fentanyl API for SUBSYS®, and component parts and packaging materials used in the manufacture of both SUBSYS® and SYNDROS®. Work-in-process consisted of actual production costs, including facility overhead and tooling costs of in-process dronabinol, SUBSYS® and SYNDROS® products. Finished goods inventories consisted of finished SUBSYS® and SYNDROS® products and deferred SYNDROS® cost of revenue of $0 and $59,000 as of June 30, 2018 and December 31, 2017, respectively. There was no deferred SYNDROS® cost of revenue as of June 30, 2018, due to the adoption of ASC Topic 606 on January 1, 2018. Non-current raw materials and finished goods represent those inventories not expected to be consumed or sold within 12 months of the balance sheet date and are included in other assets in our condensed consolidated balance sheets. As of June 30, 2018 and December 31, 2017, all work-in-process inventory is expected to be used within 12 months of the balance sheet date and, therefore, is classified as current assets in our condensed consolidated balance sheets. We maintain an allowance for excess and obsolete inventory, as well as inventory where its cost is in excess of its NRV. Inventories at June 30, 2018 and December 31, 2017, were reported net of these reserves of $9,599,000 and $13,664,000, respectively. During the three and six months ended June 30, 2018, we decreased these reserves by approximately $5,068,000 for the destruction of previously reserved product, partially offset by an increase to the reserves of approximately $1,005,000 and $477,000, respectively. During the three and six months ended June 30, 2017, we increased these reserves by approximately $2,959,000 and $1,185,000, respectively.

6. Property and Equipment, Net

Property and equipment are recorded at cost and depreciated using the straight-line method over their estimated useful lives; leasehold improvements are recorded at cost and depreciated using the straight-line method over the shorter of their estimated useful lives or remaining lease term. Maintenance and repairs that do not extend the life of assets are charged to expense when incurred. When property and equipment is disposed of, the related costs and accumulated depreciation are removed from the condensed consolidated balance sheets, and any gain or loss is reported in other

income (expense) in the period the transaction takes place. During the three and six months ended June 30, 2018, we recorded losses on the disposal of property and equipment of $0 and $108,000, respectively. There were no such charges during the three and six months ended June 30, 2017.

Property and equipment are reviewed for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted cash flows expected to be generated by the asset. If the carrying amount exceeds its estimated future undiscounted cash flows, an impairment charge is recognized by the amount by which the carrying amount exceeds the fair value of the asset. The fair value is measured on a nonrecurring basis using unobservable (Level 3) inputs. Impairment charges are reported in the period the impairment is identified. During the three and six months ended June 30, 2018, we recorded impairment charges in research and development of $1,487,000, as the result of a decision to abandon a partially constructed device manufacturing machine with a cost of $1,487,000 and no associated depreciation. There were no such charges during the three and six months ended June 30, 2017.

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7. Commitments and Contingencies

Legal Matters

Other than the matters that we have disclosed below, we from time to time become involved in various ordinary course legal and administrative proceedings, which include intellectual property, commercial, governmental and regulatory investigations, employee-related issues and private litigation, which we do not currently believe are either individually or collectively material.

We record accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. If the reasonable estimate of a probable loss is a range, and no amount within the range is a better estimate, the minimum amount in the range is accrued. If a loss is not probable or a probable loss cannot be reasonably estimated, no liability is recorded. We have established reserves for certain of our legal matters. Our loss estimates are generally developed in consultation with outside counsel and outside accounting experts and are based on analyses of potential outcomes. As legal and governmental proceedings, disputes and investigations are inherently unpredictable and in part, beyond our control, unless otherwise indicated, we cannot reasonably predict the outcome of these legal proceedings, nor can we estimate the amount of loss, or range of loss, if any, that may result from these proceedings. While our liability in connection with certain claims cannot be currently estimated, the resolution in any reporting period of one or more of these matters could have a significant impact on our consolidated financial condition, results of operations, liquidity, and cash flows for that future period, and could ultimately have a material adverse effect on our consolidated financial position and could cause the market value of our common shares to decline. While we believe we have valid defenses in these matters, litigation and governmental and regulatory investigations are inherently uncertain, and we may in the future incur material judgments or enter into material settlements of claims.

Government Proceedings

Like other companies in the pharmaceutical industry, we are subject to extensive regulation by national, state and local government agencies in the United States. As a result, interaction with government agencies occurs in the normal course of our operations. The following is a brief description of pending governmental investigations that we believe are potentially or actually material at this time. It is possible that criminal charges and substantial payments, fines and/or civil penalties or damages or exclusion from federal health care programs or other administrative actions, as well as a corporate integrity agreement, deferred prosecution agreement, or similar government mandated compliance document that institutes significant restrictions or obligations, could result for us from any government investigation or proceeding. In addition, even certain investigations that are not discussed below and which we do not deem to be material at this time could be determined to be material and could have a material adverse effect on our financial condition, results of operations and cash flows.

HHS Investigation. We received a subpoena, dated December 9, 2013, from the Office of Inspector General of the HHS in connection with an investigation of potential violations involving HHS programs. This subpoena was issued in connection with an investigation by the U.S. Attorney’s Office for the Central District of California and requested documents regarding our business, including the commercialization of SUBSYS®. We continue to cooperate with this investigation and have produced substantial documents in response to the subpoena and have provided other requested information.

On April 13, 2018, the United States intervened in part and declined to intervene in part in five lawsuits: United States ex rel. Guzman v. Insys Therapeutics, Inc. (CV 13-5861 JLS (AJWx)), United States ex rel Doe v. Insys Therapeutics,

Inc. (CV 14-3488 JLS (AJWx)), United States ex rel. Andersson v. Insys Therapeutics, Inc. (CV 14-9179 JLS (AJWx), United States ex rel. Erickson v. Insys Therapeutics, Inc. (CV 16-2956 JLS (AJWx), and United States ex rel. Doe v. Insys Therapeutics, Inc. (CV 16-7937 JLS (AJWx)). Qui tam lawsuits typically remain under seal (hence, usually unknown to the defendant) for some time while the government decides whether or not to intervene on behalf of a private qui tam plaintiff (known as a relator) and take the lead in the litigation. These lawsuits can involve significant monetary damages and penalties and award bounties to private plaintiffs who successfully bring the suits.

The States of California, Colorado, Indiana, Minnesota, New York, North Carolina, and Virginia (the "Plaintiff States") elected to intervene in part and declined to intervene in part in United States ex rel. Guzman v. Insys Therapeutics, Inc. (CV 13-5861 JLS (AJWx)) and United States ex rel. Doe v. Insys Therapeutics, Inc. (CV 16-7937 JLS (AJWx)). The States of Connecticut, Delaware, District of Columbia, Florida, Georgia, Illinois, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, and Washington declined to intervene.

The United States' Complaint in Intervention, which was ordered unsealed on May 11, 2018, brings claims for False Claims Act: Presentation of False Claims pursuant to 31 U.S.C. § 3729(a)(1)(A), False Claims Act: Using False Statements to Get False Claims Paid pursuant to 31 U.S.C. § 3729(a)(1)(B), Payment by Mistake, and Unjust Enrichment. This case is currently stayed and we continue to have ongoing discussion with respect to the DOJ Investigation (as discussed below). The qui tam plaintiffs may pursue the claims in which either the United States or the above-mentioned states declined to intervene.

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HIPAA Investigation. On September 8, 2014, we received a subpoena issued pursuant to HIPAA from the U.S. Attorney's Office for the District of Massachusetts. The subpoena requested documents regarding SUBSYS®, including our sales and marketing practices related to this product. This investigation also relates to activities in our patient services hub. We continue to cooperate with this investigation and have produced a substantial number of documents in response to the subpoena and have provided other requested information.

DOJ Investigation and Agreement in Principle. We collectively refer to the HHS and HIPAA investigations discussed above as the "DOJ Investigation". In connection with our cooperation, we have been engaged in discussions with the DOJ about these matters, including a resolution of potential liability exposure.

Management accrued, as of September 30, 2017, an aggregate of $150,000,000, which represented our best estimate of the minimum liability exposure that we expected to be paid out over five years in connection with the DOJ Investigation. This estimate reflected a minimum exposure at which management had determined a willingness to settle these matters. The accrual was recorded in accrued litigation award and settlements on our condensed consolidated balance sheets and as an operating expense on our condensed consolidated statements of operations and comprehensive loss.

On August 8, 2018, we announced that we reached an agreement in principle with the DOJ to settle the DOJ's civil and criminal investigation into inappropriate sales and commercial practices by some former company employees. Our initial estimate of the minimum liability exposure we previously accrued in connection with the DOJ Investigation of $150,000,000 expected to be paid over five years remains unchanged as of June 30, 2018, with the potential for contingency-based payments associated with certain events that, if they were to occur, management estimates would require additional payments ranging from $0 to $75,000,000. This agreement in principle is subject to the negotiation of final settlement documents with the government. We expect that a final settlement would include other material non-financial terms and conditions which will also be subject to negotiation.

Because other material, non-financial terms and conditions remain subject to the negotiation of final settlement documents, we cannot provide assurances as to the timing of the execution of final documentation and, like any pending negotiation, there is uncertainty as to the outcome. Moreover, any such final settlement is likely to involve entry into final agreements, which will impose significant costs and burdens and obligations on our business operations and could materially and adversely affect our results of operations and financial conditions as we implement and adhere to such requirements.

At this time, the aforementioned accrual does not currently meet the more likely than not standard for tax deductibility; therefore, we have recognized no tax benefit for it in the condensed consolidated financial statements. It is possible that some or all of this accrual may meet the more likely than not standard in the future, at which time the benefit would be recognized.

SEC Investigation. On January 11, 2018, the SEC's Los Angeles Regional office requested that the Company voluntarily provide information on the Company's: (1) restatement of the Company's interim unaudited condensed consolidated financial statements as of and for the quarters ended September 30, June 30, and March 31, 2016 and 2015, filed on April 7, 2017; (2) sales and marketing practices; and (3) compliance program, internal controls and enhancements thereto. The Company has provided such information and continues to cooperate with the SEC's investigation, including by responding to requests or demands for documents and other information.

Health Care Professionals and Former Employees Related Investigations.

Investigations of Health Care Professionals. A number of health care practitioners who formerly interacted with our company are under investigation or have been charged in criminal proceedings. In addition to the below investigations that are specifically directed at us, we have received governmental agency requests for information, including subpoenas, from at least the following governmental bodies: the USAO and/or HHS OIG of California (Los Angeles), Central District of California, Colorado, Connecticut, Eastern District of Michigan, Eastern District of New York, Florida (Jacksonville), Kansas, Middle District of Florida, Middle District of Pennsylvania, New Hampshire, New Jersey, Northern District of California, Northern District of Texas, Rhode Island, Southern District of Alabama, Southern District of New York, Southern District of Ohio, Western District of New York, and the states of Arizona, Delaware, Maryland and New York, regarding specific health care professionals with which we have interacted with in those states. In addition, at least the following health care practitioners formerly interacting with our company have been charged as follows:

On or about June 23, 2015, a nurse practitioner located in Connecticut, who served on our speaker bureau in connection with our speaker programs designed to educate and promote product awareness and safety for external health care providers, pled guilty to violating the federal Anti-Kickback Statute in connection with payments of approximately $83,000 from us.

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On or about November 7, 2016, a health care professional located in Michigan who served on our speaker bureau pled guilty to healthcare fraud in connection, in part, with receiving payments from us.

On February 23, 2017, two Alabama health care professionals who served on our speaker bureau were convicted on 19 of 20 counts brought against them, which included charges related to distribution of a controlled substance, drug conspiracy, health care fraud conspiracy and money laundering.

On or about March 22, 2017, the U.S. Attorney's Office for the District of New Hampshire filed an indictment against a physician assistant, who served on our speaker bureau, charging him with violating the federal Anti-Kickback Statute and conspiring to violate the federal Anti-Kickback Statute in connection with payments received for serving as an Insys promotional speaker. The physician assistant pled not guilty.

On or about October 20, 2017, a health care professional in Rhode Island, who served on our speaker bureau pled guilty to health care fraud and conspiracy to receive kickbacks in connection with payments of approximately $188,000 from us.

On or about March 14, 2018, the U.S. Attorney's Office for the Southern District of New York filed an indictment against five health care professionals who served on our speaker bureau, charging them with conspiracy to violate the federal Anti-Kickback Statute, violation of the federal Anti-Kickback Statute, and conspiracy to commit honest services fraud, and charged certain of them with aggravated identity theft, false statements, and wrongful disclosure of individually identifiable health information.

On or about June 4, 2018, a Florida health care professional who served on our speaker bureau pled guilty to conspiracy to receive healthcare kickbacks in connection, in part, with receiving payments from us.

On or about June 28, 2018, an Ohio health care professional who served on our speaker bureau was indicted for violating the federal Anti-Kickback Statute in connection with receiving payments of more than $103,000 from us.

Investigations of Former Employees. A number of our former employees have been charged in criminal proceedings related to our federal investigations and the following is certain information related thereto.

On or about February 18, 2016, one of our former sales employees located in Alabama pled guilty to a conspiracy to violate the federal Anti-Kickback Statute in connection with two convicted Alabama health care professionals mentioned above. On or about April 23, 2018, the former sales employee was sentenced to six months home confinement.

On or about June 19, 2016, a former district sales manager in New York and a former sales representative in New Jersey were charged in a federal court in Manhattan, New York, with violating the federal Anti-Kickback Statute in connection with interacting with health care professionals who prescribed our product and served on our speaker bureau.

On June 1, 2017, the former district sales manager was charged in a superseding indictment with additional charges of honest services wire fraud and aggravated identity theft in connection with falsifying sign-in sheets for our speaker programs. On or about March 16, 2018, records were unsealed indicating that the two former employees each pled guilty to conspiracy to violate the Anti-Kickback Statue, violation of the Anti-Kickback Statue, violation of HIPAA, conspiracy to commit honest services wire fraud, and aggravated identity theft, and that the former sales representative also pled guilty to health care fraud.

On or about December 8, 2016, the U.S. Attorney's Office for the District of Massachusetts issued an indictment against six former employees, including Michael L. Babich, our former President, CEO and director, on charges including racketeering conspiracy, conspiracy to commit mail fraud, conspiracy to commit wire fraud, conspiracy to violate the Anti-Kickback Statute and forfeiture (the "Original Indictment"). On or about October 26, 2017, the U.S. Attorney's Office for the District of Massachusetts issued a superseding indictment in connection with the Original Indictment and added charges against our former President, CEO and director, Dr. John N. Kapoor. After Dr. Kapoor's indictment, he agreed to put his ownership in our common stock in a trust to be controlled independently, which was executed on February 27, 2018 and filed with the Securities and Exchange Commission on a Current Report on Form 8-K on March 1, 2018.

On or about February 8, 2017, a former district sales manager in the Northeast was charged in federal court in New Haven, Connecticut, with violating the federal Anti-Kickback Statute in connection with interacting with health care professionals who prescribed our product and served on our speaker bureau.

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On April 5, 2017, the U.S. Attorney's Office for the District of Massachusetts filed an information charging a former prior authorization specialist and manager of our patient services hub with one count of wire fraud conspiracy; the former employee pled guilty to that information on June 19, 2017.

On or about July 11, 2017, a former district sales manager pled guilty to conspiring to violate the federal Anti-Kickback Statute related to her activities in the Southern District of Alabama, as well as the Middle and Southern Districts of Florida, including in connection with the two convicted Alabama health care professionals mentioned above.

On or about May 30, 2018, a former specialty sales professional pled guilty to a second-degree charge of conspiracy to commit commercial bribery related to her activities in New Jersey.

Except as otherwise indicated, we understand that each of these indicted individuals have entered pleas of not guilty to the charges against them.

Given the ongoing investigations related to our company and our current and former employees, as well as other individuals associated with our company, including health care professionals, it is possible that additional individual or company criminal charges and convictions and pleas could result from our ongoing federal and state government investigations and related proceedings and the foregoing disclosure and the disclosure below is merely intended to provide general insight into the comprehensive nature of the scope and breadth of investigations that are being conducted related to our company and is not, nor is it intended to be, an exhaustive listing of every charge, conviction or pleading in connection with our company. We continue to assess these matters to ensure we have an effective compliance program.

Ongoing State-Related Investigations. We have received CIDs or subpoenas, as the case may be, from at least each of the following state's Office of the Attorney General (or similarly named and authorized office) which have ongoing investigations directed at our company: Arizona, Colorado, Florida, Kansas, Kentucky, Maryland, Minnesota, Missouri, New Jersey, New York, North Carolina, Pennsylvania, Rhode Island, Virginia and Washington. Moreover, we have received an administrative subpoena from the California Insurance Commissioner. In addition, we understand that numerous physicians practicing within several of the aforementioned states have received subpoenas from certain state Attorney General or Department of Justice offices in connection with interactions with us. Generally, these CIDs and subpoenas request documents regarding SUBSYS®, including our sales and marketing practices related to SUBSYS® in the applicable state, as well as our patient services hub. We are cooperating with each of these investigations and have produced, or anticipate producing, documents in response to these CIDs, subpoenas and related requests for information from each office.

Resolved State-Related Investigations. Our company has resolved investigations conducted by certain states' Office of the Attorney General (or similarly named and authorized office) as follows:

In connection with the investigation by the ODOJ, we entered into a settlement agreement with the ODOJ, referred to as an AVC, and made monetary payments totaling approximately $1,100,000. The AVC requires us to maintain certain controls and processes around our promotional and sales activity related to SUBSYS® in Oregon. This AVC expressly provides that we do not admit any violation of law or regulation. This settlement was reached as a result of our cooperation with the ODOJ's investigation and after producing documents in response to certain CIDs and related requests for information from the ODOJ. All monetary payments in connection with this settlement were made prior to December 31, 2015.

In connection with the investigation by the Illinois Office of the Attorney General, such office filed a complaint against us on behalf of the State of Illinois on August 25, 2016, in the Circuit Court of Cook County, Illinois, Chancery Division, asserting a claim for violation of the Illinois Consumer Fraud and Deceptive Business Practices Act in connection with the sales and marketing of SUBSYS®. On August 18, 2017, the Circuit Court of Cook County entered a Final Judgment and Consent Decree, which, among other things, provided for a monetary payment of $4,450,000 by Insys and requires us to maintain certain controls and processes around our promotional and sales activity related to SUBSYS® in Illinois. The Final Judgment and Consent Decree expressly provides that we do not admit any violation of law or regulation. All monetary payments in connection with this Final Judgment and Consent Decree were accrued in the consolidated balance sheets as of June 30, 2017 and the payments in connection with this settlement were made prior to September 30, 2017.

In connection with the investigation by the State of New Hampshire, we entered into a settlement agreement with the State of New Hampshire referred to as an assurance of discontinuance, and made monetary payments totaling approximately $2,900,000 to the State of New Hampshire and a charitable contribution of $500,000 to be used by a New Hampshire charitable foundation in preventing or remediating problems related to abuse, misuse or misprescribing of opioid drugs. The assurance of discontinuance expressly provides that we do not admit any violation of law or regulation and requires us to maintain certain controls and processes around our promotional and sales activity related to SUBSYS® in New Hampshire. This settlement was reached as a result of our cooperation with the State of New Hampshire investigation and after producing documents in

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response to certain requests for information by the State of New Hampshire. These amounts were accrued in the consolidated balance sheets as of December 31, 2016 and the payments in connection with this settlement were made during the three months ended March 31, 2017.

In connection with the investigation by the State of Massachusetts, we entered into a settlement with the State of Massachusetts, which was entered by the Superior Court of the Commonwealth of Massachusetts in a Final Judgment by Consent on October 5, 2017. The Final Judgment by Consent provided for a monetary payment of $500,000 and requires us to maintain certain controls and processes around our promotional and sales activity related to Massachusetts. The Final Judgment by Consent expressly provides that we do not admit any liability or wrongdoing. The amount of the monetary payment was accrued in the consolidated balance sheets as of September 30, 2017 and the payments in connection with this settlement were made during the three months ended December 31, 2017.

Ongoing Complaints filed in connection with State AG Investigations. Our Company has several ongoing legal proceedings related to complaints filed in connection with investigations conducted by certain states' Office of the Attorney General (or similarly named and authorized office) as follows:

In connection with the investigation by the State of Arizona, on August 30, 2017, the Arizona Attorney General filed a complaint on behalf of the State of Arizona against us in the Maricopa County, Arizona Superior Court. The complaint asserts claims for violations of the Arizona Consumer Fraud Act in connection with the sales and marketing of SUBSYS® in Arizona and in connection with our patient services hub. The complaint seeks a permanent injunction preventing us from engaging in practices in violation of the Arizona Consumer Fraud Act, restitution to consumers and other persons, disgorgement of profits, civil penalties, and investigative costs. On or about November 10, 2017, we filed a motion to dismiss. On January 17, 2018, the Court dismissed, based upon preemption by the federal Sunshine Act, the State's claim to the extent related to remedies that are based upon the payment and disclosure of speaker fees, but did not dismiss the rest of the complaint. The State filed a motion for leave to amend its complaint, which the Court granted. We filed our answer to the amended complaint on April 5, 2018.

In connection with the investigation by the State of New Jersey, on October 5, 2017, the New Jersey Attorney General, on behalf of the State of New Jersey, and the Acting Director of the New Jersey Division of Consumer Affairs filed a complaint against us in the Superior Court of New Jersey, Chancery Division, Middlesex Vicinage. The complaint asserts claims for violations of the New Jersey Consumer Fraud Act and for violations of the New Jersey False Claims Act in connection with the sales and marketing of SUBSYS® in New Jersey and in connection with our patient services hub. The complaint seeks a permanent injunction preventing us from engaging in practices in violation of the New Jersey Consumer Fraud Act, disgorgement of profits, civil penalties, treble damages for alleged violations of the New Jersey False Claims Act, and costs and attorneys' fees.

On November 16, 2017, the New Jersey Attorney General filed an Amended Complaint, which we moved to dismiss on January 8, 2018. The New Jersey Attorney General opposed our motion on March 28, 2018, and we replied. The Court held oral argument on the motion on June 18, 2018.

On December 21, 2017, Attorney General of the State of North Carolina filed a complaint in Wake County, North Carolina Superior Court against us. The complaint asserts claims related to alleged violations of the North Carolina Consumer Protection Act. Our response to this complaint is due on September 27, 2018.

On February 1, 2018, the Attorney General of the State of New York, filed a complaint against us in the Supreme Court of the State of New York, County of New York. The complaint asserts claims related to alleged deceptive acts and practices. We moved to dismiss the complaint on April 18, 2018. In response, on May 25, 2018, the New York

Attorney General opposed our motion to dismiss and filed a cross-motion for partial summary judgment related to the State's commercial bribery claim. On June 29, 2018, we filed a reply in support of our motion to dismiss and opposed the State's motion for partial summary judgment. Oral argument on the motions currently scheduled for August 23, 2018.

On February 5, 2018, the Consumer Protection Division, Office of the Attorney General of Maryland, filed a petition to enforce an administrative subpoena against us. Our response to this petition was filed on April 2, 2018. On April 23, 2018, the Maryland Attorney General filed a motion to strike our response and for judgment on the pleadings, and on April 27, 2018, filed a renewed motion to strike and for judgment on the pleadings. On May 8, 2018, we filed a response to the Maryland Attorney General's initial motion to strike our response and for judgment on the pleadings, arguing that the motion was moot. On May 10, 2018, the Court issued an order confirming that the motion was moot. On May 14, 2018, we filed our response to the renewed motion to strike and for judgment on the pleadings, and on May 18, 2018, the Maryland Attorney General filed its reply. On July 25, 2018, the Court held a hearing on the Maryland Attorney General's renewed motion to strike and for judgment on the pleadings. On July 26, 2018, the Court denied the motion. The Court also scheduled a pretrial conference for September 7, 2018.

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On May 30, 2018, the Attorney General of the State of Minnesota and the Minnesota Board of Pharmacy filed a complaint against us in the Hennepin County District Court, State of Minnesota. The complaint asserts claims related to alleged deceptive acts and practices and consumer fraud, as well as claims under the Minnesota Wholesale Drug Distribution Licensing Act (Minn. Stat. § 151.461). On the same day, the Minnesota Board of Pharmacy filed an administrative action against us before the State of Minnesota Office of Administrative Hearings for the Board of Pharmacy, which seeks a determination regarding whether certain alleged conduct by Insys constitutes grounds for disciplinary action. We have not yet responded to either action.

Multi-District Prescription Opioid Litigation. We have been named along with various other opioid manufacturers, opioid distributors, prescribers, pharmacies, and others in complaints focused on the national opioid epidemic filed by various cities, counties, states, Native American tribes, and third-party payers in many state and federal courts in Alabama, Arizona, Arkansas, California, Connecticut, Florida, Georgia, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, New Mexico, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah and West Virginia. We are involved in approximately 500 of these cases, the majority of which have been consolidated into multi-district litigation (No. 2804) in the Northern District of Ohio. Most of the cases in the multi-district litigation are presently stayed while the Court seeks to facilitate a resolution. On April 2, 2018, the United States filed a motion to participate in settlement discussions and as a friend of the court. Additionally, the Court set certain cases for a litigation track, and those cases will move forward toward trial, which is scheduled to commence on March 18, 2019.

Putative Class Action Litigation. We have been named, along with various other opioid manufacturers and distributors, in putative class action complaints that seek to assert claims allegedly related to the national opioid epidemic on behalf of purchasers of health insurance between 1996 and the present in the states of California, Illinois, Massachusetts, New Jersey, and New York.

Congressional and Other Inquiries. Many federal agencies and branches are focused on the abuse of opioids in the United States and agencies such as the HHS have expressed their belief that the United States is in the midst of a prescription opioid abuse epidemic. Moreover, President Trump has declared the opioid crisis to be a public health emergency and has made it a priority to address this crisis.

Members of our U.S. Congress have been conducting hearings and other inquiries into causes and solutions to the national opioid epidemic that have involved inquiries into our Company’s practices. For example, on March 28, 2017, the Ranking Member of the Committee on Homeland Security and Governmental Affairs of the United States Senate distributed a letter to five manufacturers of opioid products, including us, requesting documents and information intended to aid such committee in understanding the challenges industry practices pose to efforts to curb opioid addiction and stem rising prescription drug costs for the federal government. This letter requested documents regarding our business, including the commercialization of SUBSYS®. This inquiry continues and has resulted in at least three reports that mention or address our Company. We continue to cooperate with this inquiry.

Similarly, on August 2, 2018, bipartisan leaders of the House of Representatives Committee on Energy and Commerce sent letters to three manufacturers of opioid products, including us, requesting documents and information intended to aid such committee in investigating potential breakdowns in the controlled substances supply chain which may have contributed to the nation’s opioid epidemic. This letter requested documents regarding our business, sales practices, and speaker programs. We intend to cooperate with this inquiry.

With the exception of the investigations by the ODOJ, the State of New Hampshire, the State of Illinois, the State of Massachusetts, and the DOJ, which we have quantified above, we believe a loss from an unfavorable outcome of these

federal and state governmental proceedings is reasonably possible and an estimate of the amount or range of loss from an unfavorable outcome is not determinable at these stages. We believe we have meritorious legal positions and will continue to represent our interests vigorously in these matters. However, responding to government investigations has and could continue to burden us with substantial legal costs in connection with defending any claims raised. Any potential resulting fines, restitution, damages and penalties, settlement payments, pleas or exclusion from federal health care programs or other administrative actions, as well as any related actions brought by stockholders or other third parties, could have a material adverse effect on our financial position, results of operations or cash flows. Additionally, these matters could also have a negative impact on our reputation and divert the attention of our management from operating our business.

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Federal Securities Litigation and Derivative Complaints

Federal Securities Litigation. On or about February 2, 2016, a complaint (captioned Richard Di Donato v. Insys Therapeutics, Inc., et al., Case 2:16-cv-00302-NVW) was filed in the United States District Court for the District of Arizona against us and certain of our current and former officers. The complaint was brought as a purported class action on behalf of purchasers of our common stock between March 3, 2015 and January 25, 2016. In general, the plaintiffs allege that the defendants violated the anti-fraud provisions of the federal securities laws by making materially false and misleading statements regarding our business, operations and compliance with laws during the class period, thereby artificially inflating the price of our common stock. On June 3, 2016, the Court appointed Clark Miller to serve as lead plaintiff. On June 24, 2016, the plaintiff filed a first amended complaint naming a former employee of Insys Therapeutics, Inc. as an additional defendant and extending the class period. On December 22, 2016, the plaintiff filed a second amended complaint, primarily to add allegations relating to an indictment of Michael L. Babich and certain of our former employees announced on December 8, 2016, and to extend the class period from August 12, 2014 through December 8, 2016. On January 12, 2017, the defendants moved to dismiss the second amended complaint. Oral arguments were heard by the Court on July 28, 2017, and the Court granted the motion in part and denied it in part. The plaintiff subsequently moved for leave to further amend the complaint, which we opposed. The Court denied Plaintiff's motion on March 31, 2018, and Insys filed its answer on April 13, 2018. The plaintiff seeks unspecified monetary damages and other relief. We continue to vigorously defend this matter.

On or about March 17, 2017, a complaint (captioned Kayd Currier v. Insys Therapeutics, Inc., et al., Case 1:17-cv-01954-PAC) was filed in United States District Court for the Southern District of New York against us and certain of our current and former officers. The complaint was brought as a purported class action on behalf of purchasers of our securities between February 23, 2016, and March 15, 2017. In general, the plaintiffs allege that the defendants violated the anti-fraud provisions of the federal securities laws by making materially false and misleading statements regarding our business and financial results during the class period, thereby artificially inflating the price of our securities. On or about March 28, 2017, a second complaint making similar allegations (captioned Hans E. Erdmann v. Insys Therapeutics, Inc., et al., Case 1:17-cv-02225-PAC) was filed in the same Court. On May 31, 2017, the Court consolidated the first and second complaint and appointed lead counsel in the consolidated action. On July 31, 2017, the lead counsel filed a consolidated complaint. On October 11, 2017, the Court held a pre-motion conference, at which the Court granted leave to plaintiffs to again amend the complaint. The amendment was filed on October 27, 2017, and we moved to dismiss. The Court subsequently dismissed the complaint as to Santosh Vetticaden and otherwise denied our motion to dismiss. Insys filed its answer on June 26, 2018. The plaintiffs in both actions seek unspecified monetary damages and other relief. We continue to vigorously defend this matter.

Derivative Litigation. On or about August 26, 2016, Gary Hirt and Precieux Art Jewelers Inc. filed a derivative complaint in the Court of Chancery of Delaware against members of our Board of Directors and Michael L. Babich. The plaintiffs allege, among other things, that the defendants breached their fiduciary duties by (a) knowingly overseeing the implementation of an illegal sales and marketing program, (b) consciously disregarding their duty of oversight of our compliance with laws and (c) trading on the basis of material non-public information. On November 8, 2016, the plaintiffs filed an amended derivative complaint, and on January 26, 2017, the plaintiffs supplemented the amended derivative complaint, primarily to add allegations relating to the indictment of Michael L. Babich and certain of our former employees announced on December 8, 2016. On November 22, 2016, the defendants moved to dismiss the action.

On or about February 2, 2017, Michael Bourque filed a derivative complaint in the Court of Chancery against members of our Board of Directors; Michael L. Babich; Franc Del Fosse, our General Counsel; and Sanga Emmanuel, our Vice President and Chief Compliance Officer. The Bourque derivative complaint contains similar claims as the

other derivative complaint. All parties stipulated to consolidate the two actions, and the consolidated action is captioned In re Insys Therapeutics, Inc. Derivative Litigation, C.A. No. 12696-VCMR. Following the submission of motions for appointment as lead counsel, the Court held a hearing on March 23, 2017, and appointed counsel for Gary Hirt and Precieux Art Jewelers Inc. as lead counsel. Lead counsel is required to designate an operative complaint or file a consolidated complaint. The plaintiffs seek unspecified monetary damages and other relief derivatively on behalf of Insys Therapeutics, Inc.

On or about April 28, 2017, lead counsel filed a consolidated and amended complaint which maintained the original defendants this lead counsel had included in its original complaint and did not include any additional defendants included in the Bourque complaint. On May 31, 2017, we subsequently moved to stay or to dismiss the complaint and, on or about July 28, 2017, lead counsel filed an answering brief in opposition to our motion to stay or dismiss. On November 30, 2017, the Court granted our motion to stay but has required us to provide certain discovery to the plaintiffs. On February 8, 2018, in response to the plaintiffs' motion to alter or clarify judgment, the Court ordered us to provide additional discovery to the plaintiffs. On March 16, 2018, the Court entered the parties' stipulated proposed order implementing the Court's ruling of February 8, 2018. We continue to vigorously defend this matter.

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On or about June 5, 2018, Jim Soltau filed a derivative complaint ("the Soltau complaint") in the United States District Court, District of Arizona, against members of our Board of Directors, John Kapoor, Michael Babich, Darryl Baker, Patrick Forteau, Brian Tambi, the Estate of Dr. Theodore Stanley, and Santosh Vetticaden. The plaintiff alleged, among other things, that these individuals breached their fiduciary duties as our officers and/or directors and are liable for unjust enrichment, waste of corporate assets, abuse of control, gross mismanagement, and violations of Sections 14(a), 10(b) and 20(a) of the Securities Exchange Act of 1934. On July 20, 2018, Insys filed its answer. On the same day, the parties also filed a joint motion to stay the case. The motion remains pending. We continue to vigorously defend this matter.

On or about June 10, 2018, David Bennett filed a derivative complaint in the United States District Court, District of Arizona, against members of our Board of Directors, John Kapoor, Michael Babich, Darryl Baker, Patrick Forteau, Brian Tambi, the Estate of Dr. Theodore Stanley, and Santosh Vetticaden. This complaint contains similar claims as the Soltau complaint. We intend to vigorously defend this matter

Paragraph IV Challenges

On June 26, 2017, we received a Paragraph IV Notice Letter from Par Pharmaceutical related to SYNDROS®. The letter asserts that (i) the FDA received an ANDA from Par Pharmaceutical, and (ii) that Par Pharmaceutical's formulation does not infringe SYNDROS® patents and/or that our patents for SYNDROS® are invalid. On August 3, 2017, we filed suit in United States District Court for the District of Delaware, in which we claim the ANDA was not sufficiently complete and allege patent infringement. On September 1, 2017, Par Pharmaceutical filed an answer and counterclaims, to which we have replied. On March 6, 2018, we provided to Par Pharmaceutical a covenant not to sue. The parties agreed to dismiss the case without prejudice.

On November 7, 2017, we submitted to the FDA a citizen petition under sections 505(j) and 505(q) of the Federal Food, Drug, and Cosmetic Act ("FDC Act") and the related regulations, 21 C.F.R. §§ 10.30-31, to request that the Commissioner of Food and Drugs (i) decline to receive or approve any ANDA application for generic dronabinol oral solution that relies on SYNDROS® as the Reference Listed Drug if the ANDA relies on a waiver in lieu of establishing in vivo bioequivalence to SYNDROS® and (ii) require that ANDA applicants for generic versions of SYNDROS® include federal and fasted state bioequivalence studies. On April 6, 2018, the FDA denied our citizen petition.

On or about August 2, 2017, we received a Paragraph IV Notice Letter from counsel for TEVA Pharmaceuticals USA ("TEVA USA") related to SUBSYS® 0.4mg. The letter asserts that (i) the FDA received an ANDA from TEVA USA and (ii) that TEVA USA's formulation does not infringe SUBSYS® patents and/or that our patents for SUBSYS® are invalid. On September 13, 2017, we filed suit in United States District Court for the District of Delaware, in which we allege patent infringement. On January 15, 2018, TEVA USA filed an answer and counterclaims, to which we have replied. We intend to represent our interests vigorously in this matter.

On or about August 31, 2017, we received a Paragraph IV Notice Letter from counsel for Alkem Pharmaceuticals ("Alkem") related to SYNDROS®. The letter asserts that (i) the FDA received an ANDA from Alkem Pharmaceuticals and (ii) Alkem Pharmaceuticals' formulation does not infringe SYNDROS® patents and/or that our patents for SYNDROS® are invalid. On October 10, 2017, we filed suit in the United States District Court for the District of Delaware, in which we allege patent infringement. On November 22, 2017, Alkem Pharmaceuticals filed a motion to dismiss Insys's complaint, which the Court subsequently denied. Alkem filed its answer and counterclaims, and Insys filed its answer to Alkem's counterclaims on February 27, 2018. We subsequently provided to Alkem a covenant not to sue and the parties agreed to dismiss the case without prejudice.

On or about January 31, 2018, we received a Paragraph IV Notice Letter from counsel for TEVA Pharmaceuticals USA ("TEVA USA") related to SUBSYS® 0.1mg, 0.2mg, 0.6mg, 1.2mg and 1.6mg. The letter asserts that (i) the FDA received an ANDA from TEVA USA and (ii) that TEVA USA's formulation does not infringe SUBSYS® patents and/or that our patents for SUBSYS® are invalid. We filed a patent infringement lawsuit against TEVA USA on March 16, 2018. TEVA USA filed its answer to our complaint and counterclaims, to which we have replied. We intend to represent our interests vigorously in this matter.

On or about July 10, 2018, we received a Paragraph IV Notice Letter from counsel for TEVA Pharmaceuticals USA ("TEVA USA") for related to SUBSYS® 0.8mg. The letter asserts that (i) the FDA received an ANDA from TEVA USA and (ii) that TEVA USA's formulation does not infringe SUBSYS® patents and/or that our patents for SUBSYS® are invalid. We intend to represent our interests vigorously in this matter.

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General Litigation and Disputes

Kottayil vs. Insys Pharma, Inc. On September 29, 2009, Insys Pharma, Inc., our wholly owned subsidiary, and certain of our officers and the five directors who comprised the Insys Pharma board of directors as of June 2009, as well as their spouses, were named as defendants in a lawsuit in the Superior Court of the State of Arizona, Maricopa County, or the Arizona Superior Court, brought by Santosh Kottayil, Ph.D., certain of his family members and a trust of which Dr. Kottayil is the trustee. Dr. Kottayil formerly served as President, Chief Scientific Officer and a director of Insys Pharma, among other positions.

In February 2010, Insys Pharma and the other defendants answered and filed counter-claims to Dr. Kottayil's amended complaint. The counter-claims include actions for breach of fiduciary duty, fraud and negligent misrepresentations and omissions with respect to the time during which Dr. Kottayil was employed at Insys Pharma. The counter-claims, among other relief, sought compensatory and punitive damages.

The trial commenced on December 1, 2014, with the evidence phase of the trial completed on January 29, 2015.

On June 8, 2015, the Court issued findings of fact and conclusions of law in its final trial ruling, which included a finding in favor of Kottayil and against Insys Pharma on Insys Pharma's counterclaims of breach of fiduciary duty, fraud, and negligent misrepresentation.

On October 2, 2015, the Court denied Kottayil's request to submit an application for attorneys' fees for his defense of the Insys Pharma counterclaims, finding that the request was premature.

On or around November 1, 2015, we received a notice from Dr. Kottayil's attorneys demanding indemnification for legal and other defense costs alleged to have been incurred in connection with Dr. Kottayil's defense of the Insys Pharma counterclaims in the amount of $3,630,000. We responded to these demands by, among other things, requesting supporting documents and information from the plaintiffs' counsel, which we have not received. On June 1, 2018, Dr. Kottayil filed a complaint in Superior Court in the State of Arizona in and for the County of Maricopa against Insys Pharma, Inc., our wholly owned subsidiary. The complaint seeks indemnification in the amount of $3,630,000, plus interest. On July 26, 2018, Insys moved to dismiss the complaint. Because of the uncertainty surrounding the ultimate outcome, we have not accrued for this claim at this time; however, we believe that that it is reasonably possible that there may be a material loss associated with this claim and we currently estimate the range of the reasonably possible loss to be between $0 and the $3,630,000 claimed.

Insurance Litigation. On June 23, 2017, Aetna, Inc. and a subsidiary filed an action against us and a number of former employees in the Pennsylvania Court of Common Pleas, Philadelphia County (captioned Aetna Inc. v. Insys Therapeutics, Inc., Case No. 170602779). Plaintiffs bring claims against us for: (1) insurance fraud; (2) civil conspiracy; (3) common law fraud; (4) unjust enrichment; (5) negligent misrepresentation; and (6) negligence. Through all of the claims, Aetna seeks recovery of millions of dollars paid for SUBSYS® prescriptions that, allegedly, were not properly covered. It also seeks punitive damages, investigative expenses and costs of suit, reasonable attorneys' fees and expenses, and prejudgment and post-judgment interest. Plaintiffs served their complaint on September 25, 2017. On October 25, 2017, we removed this matter to federal court. Aetna subsequently moved to remand the case to state court. On January 6, 2018, the district court denied Aetna's motion to remand. We moved to dismiss Aetna's claims and the motion has been fully briefed since November 30, 2017. We intend to vigorously defend this matter.

On July 12, 2017, numerous subsidiaries of Anthem, Inc. filed a complaint in the U.S. District Court for the District Court for the District Court for the District of Arizona against us (captioned Blue Cross of California, Inc. d/b/a Anthem Blue Cross of California v. Insys Therapeutics, Inc., Case No. 2:17-cv-02286-DLR). Plaintiffs brought claims against us for: (1) violation of various state laws prohibiting deceptive, unfair, and unlawful business practices (i.e., consumer fraud); (2) fraud; (3) negligent misrepresentation; (4) unjust enrichment; and (5) civil conspiracy to commit fraud and unfair business practices. Through all of the claims, Anthem seeks recovery of more than $19,000,000 paid for SUBSYS® prescriptions that, allegedly, were not properly covered. It also seeks punitive damages and an injunction to prevent Insys from continuing to engage in the conduct underlying its claims. Plaintiffs served their complaint on July 14, 2017. On August 4, 2017, we filed an answer to such complaint. On February 2, 2018, Plaintiffs filed a motion for leave to file a second amended complaint and on February 16, 2018, we filed (i) an opposition to Plaintiff's motion to file a second amended complaint and (ii) a motion to stay the case. On or about July 23, 2018, the Court granted Plaintiff's motion to file a second amended complaint. The motion to stay remains pending and discovery is ongoing. We intend to vigorously defend this matter.

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On October 31, 2017, we received correspondence from Horizon Blue Cross Blue Shield of New Jersey requesting reimbursement for allegedly fraudulently induced off-label purchases of SUBSYS® in connection with alleged claim value of approximately $4,400,000. We intend to vigorously defend this matter.

On May 21, 2018, MSPA Claims I, LLC, MAO-MSO Recovery II, LLC, and MSP Recovery Claims, Series LLC filed a complaint in the United States District Court, Northern District of Ohio, against Insys Therapeutics, Inc. Plaintiffs bring claims for violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), common law fraud, and unjust enrichment. Insys currently has an extension to respond to the complaint. We intend to vigorously defend this matter.

Markland. On July 1, 2016, Robert N. Markland, as the Personal Representative of the Estate of Carolyn S. Markland filed a complaint in the Circuit Court, Fourth Judicial Circuit, in and for Duval County, Florida, against Insys Therapeutics, Inc. The complaint states that it is a wrongful death products liability action brought pursuant to Section 768.16, et seq. under Florida law in connection with a death occurring in July 2014 and includes a claim of negligent marketing. The lawsuit seeks unspecified damages for past expenses and costs, pain and suffering and loss of consortium and earnings. On August 4, 2016, we removed this case to U.S. District Court in the Middle District of Florida. On September 2, 2016, we filed a motion to dismiss. The Court granted our motion on September 15, 2017. The plaintiff subsequently filed a notice of appeal, and the opening brief on appeal was filed on March 9, 2018. We filed our answering brief on May 24, 2018, and the reply brief was filed on July 9, 2018. We continue to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter, when taken individually, will have a material adverse effect on our business, financial position, or future results of operations.

Buchalter. On September 9, 2016, Jeffrey Buchalter filed a complaint in the Circuit Court for Anne Arundel County, Maryland, Case No. C-02-cv-16-002718, against Dr. William Tham, Physical Medicine & Pain Management Associates, Maryland Neurological Institute, various physician assistants, and Insys Therapeutics, Inc. Plaintiff's complaint states it is a personal injury action against Insys related to negligent misrepresentation, failure to warn and fraud under state laws. The lawsuit seeks unspecified compensatory and punitive damages. We filed a motion to dismiss and on or about May 6, 2017, the Court denied the motion to dismiss. On March 22, 2018, Plaintiff filed a motion to file a second amended complaint, which, among other things, sought to add as defendants certain former Insys officers and employees. The motion to file a second amended complaint was subsequently granted. Insys filed its answer to the second amended complaint on June 20, 2018. We continue to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter, when taken individually, will have a material adverse effect on our business, financial position, or future results of operations.

Fuller. On or about March 23, 2017, Deborah Fuller & David Fuller, as Administrators Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, individually, filed a complaint in the Superior Court of New Jersey Law Division, Middlesex County, Case No. L1859-17, against Vivienne Matalon, M.D., TLC Healthcare 2, LLC, Linden Care and Insys Therapeutics, Inc. The plaintiff's complaint alleges negligence violations under the Wrongful Death Act pursuant to N.J.S.A 2A:31, et seq. and also brings claims for fraud and negligent misrepresentation. We filed a motion to dismiss the complaint on May 19, 2017, and the Court held oral argument on the motion on June 29, 2017. On July 27, 2017, the Court issued a ruling on the multi-party motion to dismiss. The Court dismissed some claims but denied the motion to dismiss on certain of plaintiffs' claims. We answered the complaint, and, after plaintiffs dismissed the treating physician, on October 4, 2017, we removed the case to U.S. District Court for the District of New Jersey. Plaintiffs subsequently filed a motion to remand the case to state court on October 11, 2017. On January 19, 2018, the Magistrate Judge issued a Report and Recommendation, recommending that the District Court deny plaintiffs' motion to remand. On February 5, 2018, the District Court

adopted the Report and Recommendation. On February 6, 2018, plaintiffs filed a motion for leave to amend, seeking to add as defendants certain former Insys officers and a former employee. Insys filed its opposition to the motion for leave to amend on February 21, 2018. Consistent with our opposition, the Court denied plaintiffs' motion as to the former employee and granted the motion as to the former officers. Plaintiffs filed their first amended complaint on June 12, 2018. On June 26, 2018, Insys moved to dismiss, in part, plaintiffs' first amended complaint. Plaintiffs filed a response in opposition to the motion on July 18, 2018, and the Court set a return date of August 6, 2018. Plaintiffs subsequently stipulated to dismiss certain allegations and claims against Insys, and the motion to dismiss was withdrawn. We continue to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter, when taken individually, will have a material adverse effect on our business, financial position, or future results of operations.

Cantone. On or about June 15, 2017, we received service of a complaint filed by Angela Mistrulli Cantone and Philip L. Cantone in the State Court of South Carolina, County of Greenville, C.A. No.: 2017-CP-23 against Insys Therapeutics, Inc., Linden Care, LLC, Aathirayen Thiyagarajah, M.D. and Spine and Pain, LLC. The plaintiffs' complaint alleges medical negligence, negligence, negligent misrepresentation, unjust enrichment, common law fraud, unfair and deceptive trade practices, aiding and abetting and loss of consortium. We filed a motion to dismiss, which the Court denied. We filed our answer on November 14, 2017. We continue to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter, when taken individually, will have a material adverse effect on our business, financial position, or future results of operations.

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Ballou. On or about September 1, 2017, Carey Ballou filed a complaint in the circuit Court of Johnson County, Kansas, Case No. 17CV05004, against Insys Therapeutics, Inc., Insys Pharma, Inc., Torgny Andersson, Mid-America Physiatrist, P.A., Steven Simon M.D., Donna Ruck, Pharma Consultants KC, LLC, AmerisourceBergen Corporation, and Morris & Dickson Co., LLC. The plaintiffs bring claims against Insys for negligence, common law fraud, negligent misrepresentation, unfair and deceptive trade practices, unjust enrichment, conspiracy, and aiding and abetting. On December 26, 2017, Plaintiff filed a second amended complaint, which added as defendants certain former officers and employees. Insys moved to dismiss the second amended complaint on February 26, 2018. We intend to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter, when taken individually, will have a material adverse effect on our business, financial position, or future results of operations.

Whitham. On or about September 1, 2017, James “Mike” Whitham and Ashley Whitham filed a complaint in the Circuit Court of Johnson County, Kansas, Case No. 17CV05005, against Insys Therapeutics, Inc., Insys Pharma, Inc., Torgny Andersson, Mid-America Physiatrist, P.A., Steven Simon M.D., Donna Ruck, Pharma Consultants KC, LLC, AmerisourceBergen Corporation, and Morris & Dickson Co., LLC. The plaintiff brings claims against Insys for negligence, common law fraud, negligent misrepresentation, unfair and deceptive trade practices, unjust enrichment, loss of consortium, conspiracy, and aiding and abetting. On December 26, 2017, Plaintiff filed a second amended complaint, which added as defendants certain former officers and employees. Insys moved to dismiss the second amended complaint on February 26, 2018. We intend to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter, when taken individually, will have a material adverse effect on our business, financial position, or future results of operations.

Hartsfield. On or about October 4, 2017, Cheryl Hartsfield filed a complaint in the Circuit Court of Pulaski County, Arkansas, Case No. 60CV-17-5581, against Insys Therapeutics, Inc., Linden Care, LLC, Mahmood Ahmad, and United Pain Care, Ltd. The plaintiff brings claims against Insys for common law fraud and deceit, breach of fiduciary duty, violations of the Arkansas deceptive trade practices act, civil conspiracy, acting in concert, and negligence. Insys filed its answer to the complaint on November 27, 2017. We intend to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter, when taken individually, will have a material adverse effect on our business, financial position, or future results of operations.

Jordan. On January 5, 2018, Bobby Ray Jordan, individually and as Special Administrator of the Estate of Doris L. Jordan, deceased, filed a complaint in the District Court of Leavensworth County, Kansas against Insys Therapeutics, Inc., Insys Pharma, Inc., Torgny Andersson, Mid-America Physiatrist, P.A., Steven Simon, M.D., Donna Ruck, Pharma Consultants KC, LLC, John N. Kapoor, Michael L. Babich, and Alec Burlakoff. The plaintiff brings claims against Insys for negligence, conspiracy to commit fraud and breach of fiduciary duty, negligent misrepresentation, unfair and deceptive trade practices, unjust enrichment, survival action, and wrongful death action. On January 31, 2018, Insys moved to consolidate this case with the Ballou and Witham actions, which the Court denied. On April 16, 2018, we moved to transfer venue to Johnson County, Kansas. The motion remains pending. We intend to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter, when taken individually, will have a material adverse effect on our business, financial position, or future results of operations.

Mencucci. On February 23, 2018, Lisa Mencucci and Angelo Mencucci filed a complaint in the Superior Court of Providence, Rhode Island against Insys Therapeutics, Inc. and Jerrold Rosenberg, M.D. Plaintiffs bring claims against Insys for common law fraud, common law fraud and misrepresentation – punitive damages, conscious misrepresentation involving risk of physical harm, conscious misrepresentation involving risk of physical harm – punitive damages, Rhode Island General Law 9-1-2, Rhode Island General Law 9-1-2 – punitive damages, negligent

misrepresentation, negligent misrepresentation involving risk of physical harm, negligence, and violation of the Rhode Island Deceptive trade practices act. Our answer to the Complaint was filed on April 26, 2018. We intend to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter, when taken individually, will have a material adverse effect on our business, financial position, or future results of operations.

Hemmings. On March 21, 2018, William Hemmings filed a complaint in the United States District Court for the Northern District of Illinois against Insys Therapeutics, Inc. Plaintiff brings claims against Insys for negligence, fraud, and consumer fraud. On May 16, 2018, we filed an answer and a motion to dismiss. The motion to dismiss is fully briefed and remains pending. We intend to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter, when taken individually, will have a material adverse effect on our business, financial position, or future results of operations.

Hampton. On March 8, 2018, Scott Hampton, as Heir, Executor and Personal Representative of the Estate of Diana Hampton, individually and on behalf of his minor children I.S. and S.M., filed a complaint in Clark County, Nevada District Court against Steven A. Holper and Insys Therapeutics, Inc. Plaintiffs bring claims against Insys for wrongful death: negligence, survivor action: negligence, wrongful death: intentional/reckless conduct, survivor’s action: intentional/reckless conduct, negligence, strict liability – defect in design – product liability, strict liability – failure to warn, and punitive damages.

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On April 16, 2018, Insys removed this case to the United States District Court for the District of Nevada. On April 17, 2018, the District Judge entered an Order to Show Cause why the case should not be remanded to state court, and subsequently remanded the case to state court. On June 26, 2018, Insys moved to dismiss the case. On June 29, 2018, plaintiffs sought leave to amend the complaint, which the court granted. Oral argument on the motion occurred on July 30, 2018. We intend to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter, when taken individually, will have a material adverse effect on our business, financial position, or future results of operations.

Munson. On April 4, 2018, Morgan Michelle Munson and Christopher Edward Munson filed a complaint in Duval County, Florida Circuit Court against Insys Therapeutics, Inc. and Linden Care, LLC. Plaintiffs bring claims against Insys for civil conspiracy, negligence, and aiding and abetting. On May 21, 2018, Insys removed the case to the United States District Court for the Middle District of Florida. On June 12, 2018, plaintiffs filed a motion for leave to file amended complaint and to remand. We filed our response in opposition on July 10, 2018. We intend to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter, when taken individually, will have a material adverse effect on our business, financial position, or future results of operations.

Tisher/Starling. On May 4, 2018, Herbert Tisher and Jane Tisher filed a complaint in the Superior Court of the State of Delaware against Insys Therapeutics, Inc., Compassionate Pain Management, LLC, Compassionate Diagnostics, LLC d/b/a Cutting Edge Treatment Center, and Eva C. Dickinson, M.D. On July 3, 2018, the Complaint was amended to add as Plaintiffs James Starling, Jr. and Pamela Starling, and to remove as a Plaintiff Jane Tisher. The Amended Complaint also added as defendants Michael J. Babich, Alec Burlakoff, Michael J. Gurry, Richard Simon, Sunrise Lee, Joseph A. Rowan, John N. Kapoor, Rodney Village Pharmacy LLC, Hometown Drug LLC, and Sanjana Company, LLC. Plaintiffs bring claims against Insys for general negligence, negligent misrepresentation, common law fraud, aiding and abetting, unjust enrichment, and civil conspiracy. Insys was served with the complaint on May 30, 2018, and currently has an extension to respond to the amended complaint. We continue to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter, when taken individually, will have a material adverse effect on our business, financial position, or future results of operations.

Kyle. On May 10, 2018, Jeffrey A. Kyle and Polly Kyle filed a complaint in the State of New Hampshire Superior Court, Stratford, SS, against Christopher Clough, PA, Dr. John J. Schermerhorn, Dr. O'Connell's Pain Care Centers, Inc., and Insys Therapeutics, Inc. Plaintiffs bring claims against Insys for negligence and loss of consortium. Insys filed its answer to the complaint on July 13, 2018. The parties are in the discovery phase of the case. We continue to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter, when taken individually, will have a material adverse effect on our business, financial position, or future results of operations.

Gruenspecht. On June 14, 2018, Mark Gruenspecht filed a complaint in the Supreme Court of the State of New York, County of New York, against Upper East Side Pain Medicine, P.C., Gordon Freedman, M.D., and Insys Therapeutics, Inc. Plaintiff brings a single untitled claim against Insys, asserting, among other things, that Insys's conduct constituted fraud, deception, misrepresentation, wantonness, negligence, and gross negligence. The complaint was served on June 28, 2018. We continue to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter, when taken individually, will have a material adverse effect on our business, financial position, or future results of operations.

Hanson. On July 10, 2018, Cynthia L. Hanson filed a complaint in the Circuit Court of Johnson County, Kansas against Insys Therapeutics, Inc., Insys Pharma, Inc., Torgny Andersson, Mid-America Physiatrist, P.A., Steven

Simon, M.D., Donna Ruck, Pharma Consultants KC, LLC, AmerisourceBergen Corporation, and Morris & Dickson Co., LLC. Plaintiff brings bring claims against Insys for negligence, conspiracy to commit fraud and breach of fiduciary duty, negligent misrepresentation, unfair and deceptive trade practices, unjust enrichment, survival action, and wrongful death action. On July 23, 2018, we accepted service and our response to the complaint is due on September 21, 2018. We continue to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter, when taken individually, will have a material adverse effect on our business, financial position, or future results of operations.

Kelly. On July 18, 2018, Michael and Julie Kelly filed a complaint in the Common Pleas Court of Erie County, Ohio against Insys Therapeutics, Inc., Insys Pharma, Inc., and Insys Manufacturing, LLC. Plaintiffs bring claims against Insys for negligence, negligent misrepresentation, strict products liability due to inadequate warning, strict products liability defective due to inadequate warning pursuant to Ohio Revised Code Section 2307.76, strict products liability defect due to design defect, strict products liability defective pursuant to Ohio Revised Code Section 2307.75, fraud, Ohio Consume Sales Practices Act pursuant to Ohio Revised Code Chapter 1345, false advertising, unjust enrichment, loss of consortium, negligent infliction of emotional distress, and punitive damages. Insys was served with the complaint on July 30, 2018.

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Except as it pertains to (i) the final settlements addressed above, (ii) the accrual of $150,000,000 related to the DOJ Investigation, and (iii) the potential for damages in the federal securities litigation and derivative action that we believe could be covered by in whole or part our director and officers insurance policies (once we have met any applicable retainage requirement under the applicable policy), we believe that the probability of unfavorable outcome or loss related to all of the above litigation matters and an estimate of the amount or range of loss, if any, from an unfavorable outcome are not determinable at this time. We believe we have meritorious legal positions and will continue to represent our interests vigorously in these matters but the range of possible outcomes on these matters is very broad and, unless otherwise provided above, we are not able to provide a reasonable estimate of our potential liability, if any, nor are we able to predict the outcome of each litigation matter.

The expense and time required to respond to each of these litigation matters and legal proceedings and related actions, defending any claims raised, and any resulting fines, restitution, damages and penalties, or settlement payments, as well as any related actions brought by shareholders or other third parties, could have a material impact on our reputation, business and financial condition and divert the attention of our management from operating our business.

Material Agreements

Aptar

In October 2015, we entered into an amended and restated supply, development and exclusive licensing agreement with Aptargroup, Inc. (“Aptar”), which, among other things, extended our exclusive supply rights to the current sublingual spray device currently utilized by SUBSYS®, as well any new device(s) jointly developed by the two companies for a period of seven years. In addition to extending the term, this amendment added certain minimum purchase commitments and requires certain tiered royalties as a percentage of net revenue to be paid by us ranging from less than one percent to the low single digits, commencing in March 2016 through the term of this agreement, from our sales of SUBSYS® and future products that use the Aptar spray device technology.

In January 2016, we assigned our rights, title, duties and obligations of supply, development and exclusive licensing agreement with Aptar from our parent to our manufacturing subsidiary as part of a corporate restructuring.

In April 2017, we, through our manufacturing subsidiary, entered into a further amendment to our Aptar supply, development and exclusive licensing agreement. This amendment effectively eliminates any prior minimum purchase obligations that had been set forth in the amendment dated October 30, 2015, and beginning in 2019, replaces them with a new annual flat fee of up to $500,000 if the quantity of devices purchased in a calendar year is less than one million devices. As a result, the cumulative effect related to this amendment reduces our aggregated purchase commitment with Aptar from $20,790,000 to $9,000,000 through December 21, 2022.

As of June 30, 2018, our remaining estimated annual contractual obligation under our agreement with Aptar was $7,500,000.

Renaissance

In April 2015, we entered into an amendment to our Renaissance manufacturing and supply agreement dated May 24, 2011, as amended, which extends our existing manufacturing and supply agreement to produce SUBSYS® until the end of 2020. In addition to extending the term, this amendment added certain minimum purchase commitments.

In January 2016, we assigned our rights, title, duties and obligations under our manufacturing and supply agreement with Renaissance from our parent to our manufacturing subsidiary as part of a corporate restructuring.

In April 2018, we, through our manufacturing subsidiary, entered into a further amendment to our Renaissance manufacturing and supply agreement. This amendment effectively eliminates any prior minimum purchase (and batch) obligations that had been set forth in the amendment dated July 2016 and replaces them with a new annual purchase commitment of $3,000,000 for the calendar year ended December 31, 2018, and $2,000,000 for the calendar years ending December 31, 2019 and 2020. As a result, the cumulative effect related to this amendment reduces our aggregated purchase commitment with Renaissance from $12,000,000 to $7,000,000 through December 31, 2020. During the three months ended June 30, 2018, we recorded a loss of $1,195,000 in cost of revenue in these condensed consolidated statements of operations and comprehensive loss for a portion of this commitment which represented firm, non-cancellable and unconditional purchase commitments for quantities in excess of our current forecasts for future demand.

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As of June 30, 2018, our remaining estimated annual contractual obligation under our agreement with Renaissance was $4,870,000.

The following table sets forth our aggregate minimum purchase commitments and exclusive supply rights with Renaissance and Aptar under these agreements (in thousands):

Years ending December 31,	
Remainder of 2018	$2,370
2019	4,000
2020	4,000
2021	2,000
2022	—
Thereafter	—
Total	$12,370

8. Stock-based Compensation

Amounts recognized in the condensed consolidated statements of operations and comprehensive loss with respect to our stock-based compensation plans were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Research and development	$736	$784	$1,583	$1,817
General and administrative	2,648	3,504	4,971	6,463
Total cost of stock-based compensation	$3,384	$4,288	$6,554	$8,280

The following table summarizes stock option activity during the six months ended June 30, 2018:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in millions)
Vested and exercisable as of December 31, 2017	3,499,957	$ 11.43		
Outstanding as of December 31, 2017	6,332,415	$ 12.10		
Granted	1,305,700	$ 7.88		
Cancelled	(605,506)	$ 14.03		

Exercised	(409,129)	$ 2.30		
Outstanding as of June 30, 2018	6,623,480	$ 11.69	7.6	$ 5.5
Vested and exercisable as of June 30, 2018	3,412,459	$ 12.47	6.3	$ 4.8

As of June 30, 2018, we expected to recognize $20,394,000 of stock-based compensation for outstanding options over a weighted-average period of 2.6 years.

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From time to time we grant restricted stock units to certain employees and directors. Restricted stock units are valued at the closing market price of our common stock on the day of grant and the total value of the units is recognized as expense ratably over the vesting period of the grants. The following table summarizes restricted stock unit activity during the six months ended June 30, 2018:

	Number of Units	Weighted Average Grant-Date Fair Value Per Unit
Outstanding as of December 31, 2017	381,900	$ 10.27
Granted	283,770	$ 8.04
Exercised	(53,910)	$ 12.65
Cancelled	(35,637)	$ 8.86
Outstanding as of June 30, 2018	576,123	$ 9.04

As of June 30, 2018, we expected to recognize $3,925,000 of stock-based compensation for outstanding restricted stock units over a weighted-average period of 2.0 years.

Cash received from option exercises under all stock-based payment arrangements for the six months ended June 30, 2018 and 2017 was $916,000 and $2,331,000, respectively. For the six months ended June 30, 2018 and 2017, we recorded net reductions of $2,210,000 and $108,000, respectively, of our federal and state income tax liability, with an offsetting credit within income tax expense, resulting from the excess tax benefits of stock options. A full valuation allowance was recorded against these reductions during the six months ended June 30, 2018.

9. Net Loss per Share

Basic net loss per common share is computed by dividing the net loss allocable to the common stockholders by the weighted average number of common shares outstanding during the period. The diluted income per share further includes any common shares available to be issued upon exercise of outstanding stock options if such inclusion would be dilutive.

The following table sets forth the computation of basic and diluted net loss per common share (dollars in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Historical net loss per share - Basic				
Numerator:				

Net loss	$(27,350)	$(8,184)	$(47,720)	$(14,708)
Denominator:				
Weighted average number of common shares outstanding	73,920,645	72,169,361	73,832,924	72,057,552
Basic net loss per common share	$(0.37)	$(0.11)	$(0.65)	$(0.20)
Historical net loss per share - Diluted				
Numerator:				
Net loss	$(27,350)	$(8,184)	$(47,720)	$(14,708)
Denominator:				
Weighted average number of common shares outstanding	73,920,645	72,169,361	73,832,924	72,057,552
Effect of dilutive stock options	—	—	—	—
Weighted average number of common shares outstanding	73,920,645	72,169,361	73,832,924	72,057,552
Diluted net loss per common share	$(0.37)	$(0.11)	$(0.65)	$(0.20)

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As we have incurred a net loss for the six months ended June 30, 2018 and 2017, basic and diluted per share amounts are the same, since the effect of potential common share equivalents is anti-dilutive. Anti-dilutive share equivalents included 5,632,270 and 5,559,590 outstanding stock options as of June 30, 2018 and 2017, respectively.

10. Product Lines, Concentration of Credit Risk and Significant Customers

We are engaged in the business of developing and selling pharmaceutical products. During the three and six months ended June 30, 2018, we had two product lines, SUBSYS® and SYNDROS®. Our CODM evaluates revenues based on product lines.

The following tables summarizes our net revenue by product line, as well as the percentage of revenue by route to market (in thousands):

	Net Revenue by Product Line			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
SUBSYS®	$22,470	$42,576	$45,744	$78,538
SYNDROS®	996	—	1,633	—
Total net revenue	$23,466	$42,576	$47,377	$78,538

	Percent of Revenue by Route to Market			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Pharmaceutical wholesalers	59 %	59 %	60 %	62 %
Specialty pharmaceutical retailers	41 %	41 %	40 %	38 %
	100 %	100 %	100 %	100 %

All our products are sold in the United States of America.

Product shipments to our three largest pharmaceutical wholesalers accounted for 31%, 15% and 11% of total shipments and product shipments to our two largest specialty pharmaceutical retailers accounted for 22% and 17% of total shipments for the six months ended June 30, 2018. Product shipments to our three largest pharmaceutical wholesalers accounted for 24%, 18%, and 11% of total shipments and product shipments to our two largest specialty

pharmaceutical retailers accounted for 27% and 11% of total shipments for the six months ended June 30, 2017. Our three largest pharmaceutical wholesalers' accounts receivable balances accounted for 43%, 12%, and 11% of gross accounts receivable and our two largest specialty pharmaceutical retailers' accounts receivable balances accounted for 22% and 15% of gross accounts receivable balance as of June 30, 2018. Three pharmaceutical wholesalers' accounts receivable balances accounted for 44%, 18%, and 10% of gross accounts receivable balance as of December 31, 2017, and two specialty pharmaceutical retailers' accounts receivable balances accounted for 13% and 12% of gross accounts receivable as of December 31, 2017.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto as of and for the year ended December 31, 2017, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2017.

Forward-Looking Statements

The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to:

- statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management;
- PBM formulary changes relative to SUBSYS® or SYNDROS® that may have a material impact on future net revenue;
- our intent to file an IND application for the treatment of epilepsy with cannabidiol;
- the sufficiency of our manufacturing capacity;
- the beneficial attributes of our dronabinol product candidates and delivery mechanisms;
- that our suppliers are equipped to supply us with our current and future chemical needs;
- that pending dronabinol candidates will default to Schedule II classification;
- that changes in health care laws will result in reduced Medicaid and Medicare payments for prescription drugs;
- that sales and marketing and research and development costs will be our largest categories of expenses;
- that sales and marketing expenses will fluctuate based on changes in SUBSYS® or SYNDROS® net revenue;
- our development of different dronabinol delivery systems;
- that we can maintain or even grow market share and net revenue for SUBSYS® and SYNDROS® and our strategies relating thereto;
- our sales and marketing strategy for future products and delivery systems;
- that we may pursue strategic transactions such as acquisitions of other companies, asset purchase, out- or in-licensing of products, strategic partnerships, joint ventures, divestitures, business combinations and investments;
- our ability to obtain foundation materials and manufacture dronabinol in light of government quotas;
- our strategy of using Marinol as a reference drug in future drug approval applications;
- the expected pathway of drug applications we expect to file in the future; that physicians and payers will continue to gain familiarity about and accept the features of SUBSYS® and SYNDROS®;
- our plans and strategies for obtaining future international approvals;
- our plans and strategies to protect our intellectual property;
- our intention of not paying dividends;
- possible capital raising transactions we may pursue;
-

that we may avail ourselves of certain Nasdaq governance provisions because of our potential status as a controlled company;

- that research and development and operating costs will fluctuate;
- that any investments in our sales and research and development infrastructure could result in increased sales;
- that reductions in our sales and marketing force could result in decreased sales;

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- accounting estimates and the impact of new or recently issued accounting pronouncements;
- that cash flows from operations will fluctuate as a result of sales of SUBSYS® and SYNDROS®;
- the source and sufficiency of our liquidity and capital resources to fund our operations;
- trends in restrictions and impediments relating to reimbursement policies imposed by PBMs;
- the impact of pending litigation and our strategy relating thereto;
- that we will not recognize revenue in the near term from current research and development initiatives;
- our exposure to interest rate changes and market risks related to our investments;
- and the potential impact of Section 382 limitations on our NOLs.

The words “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “will,” “would” and similar are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements. All forward-looking statements in this Form 10-Q are made based on our current expectations, forecasts, estimates and assumptions, and involve risks, uncertainties and other factors that could cause results or events to differ materially from those expressed in the forward-looking statements. In evaluating these statements, you should specifically consider various factors, uncertainties and risks that could affect our future results or operations as described from time to time in our SEC reports, including those risks outlined under “Risk Factors” in Item 1A of our Form 10-K for the year ended December 31, 2017. These factors, uncertainties and risks may cause our actual results to differ materially from any forward-looking statement set forth in this Form 10-Q. You should carefully consider these risks and uncertainties described and other information contained in the reports we file with or furnish to the SEC before making any investment decision with respect to our securities. All forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by this cautionary statement. Some of the important factors that could cause our actual results to differ materially from those projected in any forward-looking statements include, but are not limited to, the following:

- the impact of ongoing regulatory review of SUBSYS®, SYNDROS® and other product candidates that receive regulatory approval;
- our dependence on sales of SUBSYS® and SYNDROS®;
- market acceptance, including by third-party payers, of our products;
- the unpredictability and regulation surrounding the reimbursement of SUBSYS® and SYNDROS® by third-party payers;
- the success of our sales and marketing strategies;
- the success of our cost savings initiatives;
- our ability to manage change in our business;
- manufacturing failures;
- challenges relating to our operation of a second dronabinol manufacturing facility;
- our limited manufacturing capabilities and our reliance on third parties in our product supply chain;
- delays in manufacturing or interruption of our sublingual spray delivery system;
- competition;
- our ability to achieve and maintain adequate levels of third-party payer and reimbursement coverage for sales of our products;
- our reliance on wholesale pharmaceutical distributors for sales of our products through to the retail distribution channel;

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- our reliance on third parties for the performance of services relating to SUBSYS® and SYNDROS®, including invoicing, storage and transportation;
- our ability to develop a pipeline of product candidates;
- any failure of our clinical trials to demonstrate acceptable levels of safety and efficacy;
- expenses, delays, changes and terminations that could adversely affect the design and implementation of our clinical trials;
- reliance on third parties to conduct and oversee our clinical trials;
- acceptance by the FDA of our data from our clinical trials conducted outside the United States;
- risks and uncertainties associated with starting materials sourced from India;
- our ability to meet Section 505(b)(2) regulatory approval pathways or requirements for our product candidates;
- annual DEA quotas on the amount of dronabinol allowed to be produced in the United States;
- our failure to successfully acquire, develop or market additional product candidates;
- our ability to retain key management and other personnel;
- misconduct and improper activities by our former and current employees, prescribing physicians and other persons involved in the marketing and distribution of our products;
- our ability to utilize our net operating loss and research and development tax credit carryforwards;
- the adoption of new tax legislation or exposure to additional tax liabilities could affect our financial performance;
- the adverse impacts of strategic transactions;
- our exposure to product and other liability claims;
- our ability to comply with environmental laws relating to our use of hazardous materials;
- system failures, accidents, or security breaches;
- natural disasters;
- our significant operating expenses and need for potential additional funding;
- our failure to comply with federal and state health care laws, including fraud and abuse and health information privacy and security laws;
- undesirable side effects of our products and the potential for post-approval regulatory action relating to such side effects;
- the impact of changes in policies and funding resulting from health care reform measures, including the impact on the funding, staffing and leadership of the FDA and other agencies;
- heightened attention on the use of opioids, including government litigation, changes in policies, and legislation at the federal and local level;
- our ability to obtain and enforce patent rights or other intellectual property rights that cover our products and product candidates;
- costs of litigation and our ability to protect our intellectual property rights;
- our exposure to litigation relating to infringement suits against us;
- our exposure to claims that our employees or independent contractors have wrongfully used or disclosed to us trade secrets of their other clients or former employers;
- our compliance with the procedural, document submission, fee payment and other requirements needed to apply for patents;
- our ability to obtain adequate insurance coverage;

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- our stockholder's perception of the decisions made by the voting committee associated with the independent trust that controls the shares owned by our principal stockholder;
- challenges related to the indictment of our principal stockholder;
- fluctuation in the price of our common stock;
    - substantial future sales of shares by existing shareholders, or the perception that such sales may occur, could cause our stock price to decline;
- our ability to maintain and improve our financial controls and related compliance with SEC and stock exchange listing standards;
- lack of, or inaccurate, published research about us;
- the impact of future sales of our common stock or securities convertible into our common stock;
- the effect of anti-takeover provisions in our charter documents and under Delaware law;
- the impact of exemptions from certain Nasdaq independence rules because of our potential status as a "controlled company";
- our ability to obtain additional financing, or that, if obtained, that terms would be favourable to us or our stockholders; and
- our intention to not pay dividends in the foreseeable future.

Additionally, there may be other risks that are otherwise described from time to time in the reports that we file with the SEC. Any forward-looking statements in this report should be considered in light of various important factors, including the risks and uncertainties listed above, as well as others.

Overview

We are a commercial-stage specialty pharmaceutical company that develops and commercializes innovative supportive care products. As of June 30, 2018, we have two commercially marketed products:

- SUBSYS® — a proprietary, single-use product that delivers fentanyl, an opioid analgesic, for transmucosal absorption underneath the tongue, offered in 100, 200, 400, 600, 800, 1,200 and 1,600 mcg dosages. SUBSYS® is approved for the treatment of BTCP in opioid-tolerant patients. We received FDA approval for SUBSYS® in January 2012 and commercially launched SUBSYS® in March 2012.
- SYNDROS® — a dronabinol oral solution that is equivalent to Marinol, an approved second-line treatment for CINV and anorexia associated with weight loss in patients with AIDS, offered in multi-dose 30-mL bottles. We received FDA approval for SYNDROS® in July 2016. In March 2017, the DEA issued an interim final ruling that would result in SYNDROS® being placed in Schedule II of the CSA. We received final labeling approval by the FDA in May 2017 and commercially launched SYNDROS® in July 2017.

We market SUBSYS® and SYNDROS® through our U.S.-based field sales force focused on oncologists and supportive care physicians. Consistent with most pharmaceutical manufacturing companies, we sell SUBSYS® and SYNDROS® primarily to pharmaceutical wholesalers and collect sales proceeds from those wholesalers. For the six months ended June 30, 2018, sales to our three largest wholesale customers accounted for 57% of gross revenue. We also sell SUBSYS® and SYNDROS® directly to certain specialty pharmaceutical retailers who distribute our product. For the six months ended June 30, 2018, direct sales to our two largest specialty pharmaceutical retailers accounted for 39% of gross revenue.

All wholesaler and specialty pharmacies that fulfill SUBSYS® and SYNDROS® prescriptions are fully independent from us. For instance, we do not own or have any ownership stake in any pharmaceutical wholesaler or specialty pharmacy, nor do we have an option to acquire any wholesaler or specialty pharmacy. In addition, our relationships with every pharmacy that fulfills SUBSYS® and SYNDROS® prescriptions are non-exclusive in that each of these pharmacies may also fulfill prescriptions for other pharmaceutical manufacturers, including our competitors. For the

six months ended June 30, 2018, over 252 independent pharmacies have fulfilled at least one SUBSYS® prescription.

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Our sales of, and revenue from, SUBSYS® and SYNDROS® depend in significant part on the coverage and reimbursement policies of third-party payers, including government payers, such as Medicare and Medicaid, and private health insurers. All third-party payers are sensitive to the cost of drugs, including our products, and consistently implement efforts to control these costs, which efforts include, but are not limited to, establishing excluded or preferred drug lists. SUBSYS® and SYNDROS® have been, and will continue to be, subject to these restrictions and impediments from third-party payers, particularly PBMs and private health insurers. We have in the past, either directly or through the use of qualified third-party entities such as large service providers or specialty pharmacies, facilitated assistance to patients in connection with obtaining insurance coverage for our products.

We focus a significant portion of our resources on our research and development efforts. In particular, we are developing product candidates in both cannabinoids and sublingual and intranasal sprays. Our most advanced product candidate is buprenorphine sublingual spray. We believe this product candidate possesses unique pharmacological properties that may make it a safe and efficacious alternative to traditional opioids, especially outside of a hospital setting. On September 29, 2017, we filed an NDA with the FDA for this product candidate, and on December 6, 2017, the FDA accepted the filing. On July 27, 2018, we received a Complete Response Letter from the FDA, indicating that, although the clinical development program demonstrated all three proposed doses of the product candidate were statistically significantly different than placebo in providing pain relief, some of the data suggested potential safety concerns. Given the attributes of our proprietary buprenorphine formulation for sublingual delivery, we continue to believe that this drug-device combination could bring value to the management of pain and will assess the next steps for this product. Additionally, we continue to progress with our Cannabidiol Oral Solution, a CBD, and currently have four clinical development programs underway, including two Phase 2 and one Phase 3 clinical trials.

We produce the dronabinol API for SYNDROS® at our U.S.-based, state-of-the-art dronabinol manufacturing facility. While we believe that this facility has the capacity to supply sufficient commercial quantities of dronabinol API for SYNDROS® and support the continued development of our other dronabinol product candidates in the near-term, we have opened and expanded a second dronabinol manufacturing facility, which we anticipate will enable us to supply sufficient commercial quantities of dronabinol API for the anticipated commercialization of our proprietary dronabinol product candidates, if approved.

We have the capability to manufacture pharmaceutical CBD, an over 99.5% pure form of cannabidiol, in our Round Rock, Texas manufacturing facility.

Factors Affecting Our Performance

We believe that our performance and future success are dependent upon a number of factors, including our approved product sales, investments in our infrastructure and growth, our ability to successfully develop product candidates, and complete related regulatory processes. While each of these areas presents significant opportunities for us, they also pose significant risks and challenges that we must successfully address. In addition, our ability to ensure that our products, policies and practices adhere to the extensive national, state, and local regulations applicable to our industry is critical to our success. Finally, we believe that as our ongoing federal and state investigations and litigation proceedings have continued to accumulate, these challenges in the aggregate have led to significant legal costs and pressure on our business with respect to factors like reputational damage in the healthcare community and industry.

Approved Product Sales. Our operating results will depend significantly upon sales of approved products. During the six months ended June 30, 2018, substantially all of our net revenues were generated from the sale of our approved

product, SUBSYS®. We generated minimal revenues from the sale of SYNDROS® during the six months ended June 30, 2018. Our results depend on prescription volume generally, which we believe is driven primarily by achievement of broad market acceptance and coverage by third-party payers, and effectiveness of the marketing and selling efforts with respect to SUBSYS® and SYNDROS®. Moreover, our gross margins improve on a unit-by-unit basis as we sell higher dosage strengths of our products. Importantly, the proportion of prescriptions written for repeat SUBSYS® patients was approximately 91% of prescriptions as of June 30, 2018. Generally, repeat SUBSYS® patients receive significantly higher doses of SUBSYS® on average than first-time patients, as patients are titrated from a starter dose of SUBSYS® to their effective dose in accordance with the TIRF REMS protocol.

According to IQVIA, a worldwide integrated information and technology health care service provider, the total market for TIRF products for the three months ended June 30, 2018, was approximately 6,506 prescriptions and we estimate SUBSYS® prescriptions were approximately 29% of the TIRF market in this period, compared to a total market for TIRF products of approximately 11,300 prescriptions and approximately 34% SUBSYS® market share for the three months ended June 30, 2017.

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As management seeks to continue to provide insight into known material trends and uncertainties related to our net revenue, we note that the macro trend of the continuing and heightened publicity surrounding the national opioid epidemic continues to result in sensitivity by many health care professionals to prescribe, and pharmacies to dispense, opioids. In part, this sensitivity by health care professionals and pharmacies is the result of third-party payers, such as insurance companies, and regulatory and government agencies increasingly scrutinizing the indications and uses for which health care professionals are prescribing, and pharmacies are dispensing, opioids. Other high-profile initiatives, such as President Trump's declaration of the opioid crisis as a public health emergency, are likely adding to this sensitivity. Furthermore, widespread litigation focused on opioids, including multi-district litigation, has focused an enormous amount of scrutiny on the prescribing of opioids. Consequently, these current and potential future events have affected and will likely continue to affect, the manner in which, and the situations when, opioids, including SUBSYS®, are being prescribed, dispensed and approved for coverage.

Finally, the nature of the pricing on branded products such as SUBSYS® and SYNDROS® has adversely affected our revenue and may have likely been one driver in our decrease in overall market share for SUBSYS®. Pharmaceutical product pricing has received significant governmental and media attention and we believe that migration to lower-cost generics has resulted from this focus.

In addition to the macro trends discussed above, our company continues to have issues more specific to our business that have affected, and will likely continue to adversely affect, our net revenue and may be causing the decrease in overall market share for SUBSYS®. For instance, our company has significant reputational issues primarily driven by ongoing state and federal investigations into our sales, marketing and other commercial practices, as well as and criminal developments related thereto, and media reports covering such activity. We have had numerous former employees that have either been charged with or have pled guilty to criminal activity in connection with our sales, marketing, and other commercial practices. In addition, we had various health care professionals that previously interacted with our company, either through our speaker bureau, as a prescriber, or both, that have either been charged with, or have pled guilty to or been convicted of, criminal activity in connection with our sales, marketing and other commercial practices. These developments, which may continue to worsen, have significantly and adversely affected our reputation within the healthcare industry and with governmental entities.

On July 12, 2018, we eliminated 45 positions through headcount reduction and role consolidation. The headcount reduction included 30 employees, the majority of which were sales and marketing employees, and represented approximately 9% of our workforce. These reductions in our sales and marketing force may adversely affect the sales performance of the products.

While we continue to sell directly into wholesalers and retail pharmacies for our revenue, the direct pressures discussed above related to the retail demand-side components of our business will likely result in our inability to grow full-year 2018 SUBSYS® revenue. In addition, for the same reasons, we anticipate that we will likely continue to experience future declines in SUBSYS® revenue for the remainder of 2018 when compared to prior quarters in 2017.

Third-Party Payer Interactions and Government Programs Associated with Reimbursement. Acceptance of our products by third-party payers is critical to the success of our business and financial condition. Our relationships with these third-party payers evolves on a regular basis and is often difficult to predict, but may be affected by the reputational issues discussed above. By way of example, from time to time, third-party payers modify which drugs they choose to reimburse. For instance, on or around August 1, 2014, ESI officially released its exclusion list of drugs which included SUBSYS®, effective January 1, 2015, in connection with its national preferred formulary. While SUBSYS® was removed from this list in 2017, other PBMs may take similar actions as a result of a number of factors, including migration to lower-cost generics, and these actions may have a material impact on our net revenue

in the future. As we have in the past, we will continue working with PBMs to evaluate price increases and to communicate with managed care and health-system decision-makers to ensure a balanced approach, which takes into account the clinical performance and efficacy of our products.

In addition, from time to time, our business may be affected by evolving or new governmental programs in the reimbursement landscape. For instance, CMS, which is part of the HHS, has instituted The Recovery Audit Program. The program's mission is to identify and correct improper Medicare payments through the efficient detection and collection of overpayments made on claims of health care services provided to Medicare beneficiaries, and the identification of underpayments to providers so that CMS can implement actions that will prevent future improper payments in all 50 states. We are aware that in January 2016, certain specialty pharmacies received written correspondence from Humana indicating that as a result of a CMS audit, Humana was initiating a deletion of certain PDEs related to SUBSYS®, which will result in a reversal and recovery of identified claims paid to certain pharmacies. This audit by CMS may have been part of The Recovery Audit Program or a similar initiative of CMS. Based upon information available to us, all of these claims involve Medicare Part D patients whose prescriptions were in connection with off-label indications and related to approximately $5.6 million in SUBSYS® claims in the aggregate. Upon our inquiry for more information about these matters, Humana notified us that these deletions of certain PDEs resulting from the CMS audit also involve TIRF medications other than SUBSYS® and Humana intends to resolve these matters with the pharmacies. We believe that some affected pharmacies may alter their processes and or protocols related to dispensing off-label TIRF prescriptions to Medicare patients as a result of these and similar events.

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Investments in Our Infrastructure and Growth. Our ability to increase our sales and to further penetrate our target market segments is dependent in part on our ability to invest in our infrastructure and in our sales and marketing efforts. In order to drive further growth, we may hire additional sales and marketing personnel and invest in marketing our products to our target physician prescriber base. While we would anticipate that any increase in sales force would result in increased product sales and net revenue, this would also lead to corresponding increases in our operating expenses. Conversely, a decrease in sales force may lead to decreased product sales, net revenue, and operating expenses. As of June 30, 2018, we had 153 full-time sales and marketing personnel. We have constructed a second dronabinol manufacturing facility, which we anticipate will supply us with sufficient commercial quantities of dronabinol API for the commercialization of our proprietary dronabinol product candidates, if approved. This second facility has, and will continue to, increase our operating expenses.

Product Development and Related Regulatory Processes. Our operating results will also depend significantly on our research and development activities and related regulatory developments. Our research and development expenses were $28.7 million and $27.0 million for the six months ended June 30, 2018 and 2017, respectively. As of June 30, 2018, we had 57 full-time research and development personnel. We expect research and development expenses to fluctuate with the timing of our planned preclinical studies and clinical trials for our product candidates, particularly our proprietary cannabinoid product candidates and sublingual spray product candidates. We do not expect to realize net revenues from all of these research and development initiatives in the near term and may never realize net revenues from these investments. Due to the risks inherent in conducting preclinical studies and clinical trials, the regulatory approval process and the costs of preparing, filing and prosecuting patent applications, our development completion dates and costs will vary significantly for each product candidate and are very difficult to estimate. The lengthy process of seeking regulatory approvals and the subsequent compliance with applicable regulations require the expenditure of substantial additional resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals or acceptable DEA classifications for our product candidates could cause our research and development expenditures to increase significantly and in turn, have a material adverse effect on our results of operations.

Cost Savings Initiatives. As of June 30, 2018, we had cash and cash equivalents and investments of $123.5 million. Management believes that our existing cash and cash equivalents and investments will be sufficient to sustain operations for at least the next 12 months from the issuance of these unaudited condensed consolidated financial statements, based on its current business plan. At June 30, 2018, we had an accumulated deficit of $(262.2) million and negative working capital of $(45.5) million. As a result of the declining TIRF market, combined with the DOJ Investigation and other legal matters, we have implemented a number of cost savings initiatives. Some of these initiatives include prioritizing research and development projects, reducing discretionary spending, and renegotiating long-term commitment contracts. Additionally, on July 12, 2018, we eliminated 45 positions through headcount reduction and role consolidation. The headcount reduction included 30 employees, the majority of which were sales and marketing employees, and represented approximately 9% of our workforce. The affected employees received certain severance benefits, for which we incurred a one-time severance-related charge totalling approximately $0.3 million recorded within sales and marketing expenses during the three and six months ended June 30, 2018. We may also incur other charges or cash expenditures not currently contemplated due to events that may occur as a result of, or associated with, the headcount reduction. We expect to continue to incur losses from operations, and we may take additional actions to reduce our immediate cash expenditures. Although management has been successful in renegotiating long-term contracts and reducing expenses, there can be no assurance that we will be successful or that any needed financing will be available in the future at terms acceptable to the Company.

Basis of Presentation

Net Revenue

We sell SUBSYS® and SYNDROS® in various dosing packages to wholesale pharmaceutical distributors and speciality retail pharmacies (collectively, our customers), on a wholesale basis. Sales to our customers are subject to specified rights of return. We recognize revenue when we transfer control of our products to our customers, as our contracts have a single performance obligation (delivery of our product to their preferred location).

Cost of Revenue, Gross Profit and Gross Margin

Cost of revenue consists primarily of materials, third-party manufacturing costs, freight in, direct and indirect personnel costs, and other overhead costs based on units dispensed through patient prescriptions. Also, included in cost of revenue are charges for reserves for excess, dated, or obsolete commercial inventories and production manufacturing variances.

Gross profit is net revenue less cost of revenue. Gross margin is gross profit expressed as a percentage of net revenue.

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Sales and Marketing Expenses

Our sales and marketing expenses consist primarily of salaries, commissions, benefits, travel, consulting fees, costs of obtaining prescription and market data, and market research studies related to SUBSYS® and SYNDROS®. As of June 30, 2018, we had 153 full-time sales and marketing personnel. Because we use an incentive-based compensation model for our sales professionals, we expect our sales and marketing expenses to fluctuate from period to period based on changes in net revenue.

Research and Development Expenses

Research and development expenses consist of costs associated with our preclinical studies and clinical trials, and other expenses related to our drug development efforts. Our research and development expenses consist primarily of:

- external research and development expenses incurred under agreements with third-party CROs, investigative sites, manufacturers and consultants;
- employee-related expenses, which include salaries, benefits and stock-based compensation for the personnel involved in our drug development activities; and
- materials, facilities, equipment and laboratory supplies, depreciation, impairment and other allocated expenses.

To date, our research and development efforts have been focused primarily on our fentanyl, dronabinol, buprenorphine and cannabidiol programs. As of June 30, 2018, we had 57 full-time research and development personnel. We expect research and development expenses to fluctuate with the timing of our planned preclinical studies and clinical trials for our product candidates. We determine which research and development projects to pursue, as well as the level of funding available for each project, based on the scientific, preclinical and clinical results of each product candidate, as well as the related regulatory action and the risk adjusted economic benefit to the company.

The following table provides a breakdown of our research and development expenses during the six months ended June 30, 2018 and 2017 (in millions):

	Six Months Ended June 30,	
	2018	2017
Cannabidiol	$9.9	$4.5
Buprenorphine	0.4	2.2
Fentanyl	0.2	2.1
Epinephrine	0.6	0.2
Naloxone	1.0	0.6
Dronabinol	3.4	1.3
Buprenorphine/Naloxone	0.8	0.5
Internal research and development costs	11.9	14.0
Other	0.5	1.6
Total research and development expenses	$28.7	$27.0

General and Administrative Expenses

Our general and administrative expenses consist primarily of:

- salaries and related costs for personnel in executive, finance, accounting, human resources, information technology and business development;
- regulatory fees for commercialized products;
- insurance premiums;
- fees for investor relations service and internal support functions;
- facility costs not otherwise included in research and development expenses; and
- professional fees for consulting and accounting services.

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As of June 30, 2018, we had 52 full-time general and administrative personnel. We expect general and administrative expense to fluctuate with market changes.

Legal Expenses

Our legal expenses consist primarily of salaries and related costs for legal personnel and professional fees for legal services. We expect legal expense to fluctuate due to timing of litigation and legal defense activities. More specifically, as our ongoing federal and state investigations and litigation proceedings have continued to accumulate, these challenges have led to significant legal costs and expenses. It is difficult to predict such legal costs, and in many ways these costs are not within our control. For instance, consistent with the practice of many publicly-traded companies, we have entered into, and continue to enter into, indemnity agreements with our executive officers and a number of our board of directors which broadly provide for us to advance legal expenses and to hold such officer or director harmless in connection with matters related to their position. As has been previously disclosed, two of our former executive officers, who have indemnity agreements with us based upon their prior employment and membership on our board of directors, have been criminally charged. Our satisfaction of our obligations pursuant to these executives' indemnity agreements, as well as the payment of legal fees for other current and former employees in connection with these legal proceedings, has resulted in significant expense. Moreover, our board of directors has been subject to securities class action and derivative cases which has resulted, and may in the future result, in significant and continuing legal costs and expenses related to separate legal counsel for individuals.

Income Tax Expense (Benefit)

We account for income taxes based upon an asset and liability approach. Deferred tax assets and liabilities represent the future tax consequences of the differences between the financial statement carrying amounts of assets and liabilities versus the tax basis of assets and liabilities. Under this method, deferred tax assets are recognized for deductible temporary differences, and operating loss and tax credit carryforwards. Deferred tax liabilities are recognized for taxable temporary differences. Deferred tax assets are reduced by a valuation allowance when, in our opinion, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The impact of tax rate changes on deferred tax assets and liabilities is recognized in the year that the change is enacted. We also account for the uncertainty in income taxes by utilizing a comprehensive model for the recognition, measurement, presentation, and disclosure in financial statements of any uncertain tax positions that have been taken or are expected to be taken on an income tax return.

Significant Accounting Polices and Estimates

Significant changes to our accounting policies as a result of adopting ASC Topic 606 are discussed in Note 1 and Note 2 of the Notes to our Unaudited Condensed Consolidated Financial Statements. Significant changes to our accounting policies as a result of adopting ASU 2018-07 are discussed in Note 1. There were no other changes in our significant accounting policies and estimates during the six months ended June 30, 2018, from those set forth in "Note 2, Significant Accounting Policies" in our Annual Report on Form 10-K for the year ended December 31, 2017.

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Results of Operations

Comparison of Three Months Ended June 30, 2018 to Three Months Ended June 30, 2017

The following table presents certain selected consolidated financial data for the three months ended June 30, 2018 and 2017, expressed as a percentage of net revenue:

	Three Months Ended June 30,	
	2018	2017
Net revenue	100.0 %	100.0%
Cost of revenue	15.3	9.2
Gross profit	84.7	90.8
Operating expenses:		
Sales and marketing	38.7	31.2
Research and development	70.2	33.1
General and administrative	46.4	25.0
Legal	47.6	15.2
Charges related to litigation award and settlements	—	10.5
Total operating expenses	202.9	115.0
Operating loss	(118.2)	(24.2)
Other income:		
Interest income	2.1	1.1
Other income (expense), net	—	-
Total other income	2.1	1.1
Loss before income taxes	(116.1)	(23.1)
Income tax expense (benefit)	0.5	(3.9)
Net loss	(116.6)%	(19.2)%

Net Revenue. Net revenue decreased $19.1 million, or 44.9%, to $23.5 million for the three months ended June 30, 2018, compared to $42.6 million for the three months ended June 30, 2017. The decrease in net revenue was attributable to a 46.2% decrease in shipments to pharmaceutical wholesalers and specialty pharmaceutical retailers for the three months ended June 30, 2018 primarily due to reduced demand for SUBSYS®, as compared to the three months ended June 30, 2017, combined with a 1.0% decrease in net sales price due to changes in mix of prescribed dosages and changes in provisions for wholesaler discounts, patient discounts, rebates, and returns, partially offset by price increases in January 2017, August 2017, and January 2018. Provisions for patient discounts, wholesaler discounts, rebates, and returns were $1.1 million, $2.8 million, $5.8 million, and $4.8 million, respectively, or 38.2% on a combined basis of gross revenue for the three months ended June 30, 2018, compared to $2.4 million, $4.1 million, $7.8 million, and $1.3 million, respectively, or 26.9% on a combined basis of gross revenue for the three months ended June 30, 2017. The decrease in product sales allowances was primarily attributable to lower sales of SUBSYS® during the three months ended June 30, 2018 as compared to the three months ended June 30, 2017, partially offset by a $3.5 million increase in product returns. As described in “Factors Affecting Our Performance – Approved Product Sales”, the continuing sensitivity by some health care professionals to prescribe, and pharmacies to

dispense, opioids, scrutiny by third-party payers and governmental agencies, ongoing state and federal investigations, and media reports related thereto, will likely result in our inability to grow full-year SUBSYS® revenue for the remainder of 2018 when compared to 2017. In addition, for the same reasons, we anticipate that we will experience future declines in SUBSYS® revenue for the remainder of 2018 when compared to prior quarters in 2017.

Cost of Revenue, Gross Profit and Gross Margin. Cost of revenue decreased $0.3 million to $3.6 million for the three months ended June 30, 2018, compared to $3.9 million for the three months ended June 30, 2017. The decrease in cost of revenue was primarily attributable to the decrease in sales of SUBSYS® during the three months ended June 30, 2018. Gross profit decreased $18.8 million to $19.9 million for the three months ended June 30, 2018, compared to $38.7 million for the three months ended June 30, 2017, due primarily to the decrease in sales of SUBSYS®. Gross margin for the three months ended June 30, 2018 was approximately 85% compared to approximately 91% for the three months ended June 30, 2017. The decrease in gross margin was primarily due to an increase in product sales allowances as a percentage of gross revenue due to increased product returns, and the purchase commitment loss recorded in cost of revenue during the three months ended June 30, 2018.

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Sales and Marketing Expense. Sales and marketing expense decreased $4.2 million to $9.1 million for the three months ended June 30, 2018, compared to $13.3 million for the three months ended June 30, 2017. The decrease in sales and marketing expense was primarily due to lower sales of SUBSYS® and the resulting decrease in sales and marketing personnel costs.

Research and Development Expense. Research and development expense increased $2.4 million to $16.5 million for the three months ended June 30, 2018, compared to $14.1 million for the three months ended June 30, 2017. The increase in research and development expense was primarily due to an impairment of property and equipment of $1.5 million, as well as timing of clinical and development expenses.

General and Administrative Expense. General and administrative expense increased $0.3 to $10.9 million for the three months ended June 30, 2018, compared to $10.6 for three months ended June 30, 2017. The increase in general and administrative expense was primarily due to increases in professional fees, partially offset by decreases in stock based compensation costs.

Legal Expense. Legal expense increased $4.6 million to $11.1 million for the three months ended June 30, 2018, compared to $6.5 million for the three months ended June 30, 2017. The increase was due to increases in legal expense incurred in connection with various ongoing government investigations and prosecutions of our former employees, and other legal proceedings.

Charges Related to Litigation Award and Settlements. There were no charges related to litigation award and settlements for the three months ended June 30, 2018. Charges related to litigation award and settlements for the three months ended June 30, 2017 represent an accrual of $4.5 million in connection with the investigation by the State of Illinois.

Income Tax Expense (Benefit). Provision for income taxes was $0.1 million for the three months ended June 30, 2018, representing an effective tax rate of (0.5)%, as compared to $(1.7) million for the three months ended June 30, 2017, representing an effective tax rate of 16.8%. The change in the effective rate for the period ended June 30, 2018, compared with the same period in the previous year was primarily due to the increase in valuation allowance during the three months ended June 30, 2018. As of June 30, 2018, we had approximately $41.8 million of federal NOLs, and $253.8 million of state NOLs.

We record valuation allowances to reduce the book value of our deferred tax assets to amounts that are estimated on a more likely than not basis to be realized. We established a full valuation allowance for deferred taxes during the period ended December 31, 2017, and maintain a full valuation allowance as of the current quarter. The establishment of a valuation allowance does not impact cash, nor does it preclude us from using our tax credits, loss carryforwards and other deferred tax assets in the future.

We had unrecognized tax benefits of approximately $10.4 million as of June 30, 2018, primarily associated with tax positions taken in prior years. No significant penalties and approximately $1.6 million of interest are included in income taxes and accounted for on the balance sheet related to unrecognized tax positions.

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Comparison of Six Months Ended June 30, 2018 to Six Months Ended June 30, 2017

The following table presents certain selected consolidated financial data for the six months ended June 30, 2018 and 2017, expressed as a percentage of net revenue:

	Six Months Ended June 30,	
	2018	2017
Net revenue	100.0 %	100.0%
Cost of revenue	12.2	10.9
Gross profit	87.8	89.1
Operating expenses:		
Sales and marketing	38.3	36.9
Research and development	60.6	34.4
General and administrative	43.2	26.1
Legal	45.3	14.8
Charges related to litigation award and settlements	1.6	5.7
Total operating expenses	189.0	117.9
Operating income (loss)	(101.2)	(28.8)
Other income:		
Interest income	2.1	1.1
Other income (expense), net	(1.0)	0.1
Total other income	1.1	1.2
Income (loss) before income taxes	(100.1)	(27.6)
Income tax expense (benefit)	0.6	(8.9)
Net income (loss)	(100.7)%	(18.7)%

Net Revenue. Net revenue decreased $31.1 million, or 39.7%, to $47.4 million for the six months ended June 30, 2018, compared to $78.5 million for the six months ended June 30, 2017. The decrease in net revenue was attributable to a 40.4% decrease in shipments to pharmaceutical wholesalers and specialty pharmaceutical retailers for the six months ended June 30, 2018 primarily due to reduced demand for SUBSYS®, as compared to the six months ended June 30, 2017, combined with a 1.4% decrease in net sales price due to changes in mix of prescribed dosages and changes in provisions for wholesaler discounts, patient discounts, rebates, and returns, partially offset by price increases in January 2017, August 2017, and January 2018. Provisions for patient discounts, wholesaler discounts, rebates, and returns were $2.8 million, $5.7 million, $12.4 million, and $8.2 million, respectively, or 38.0% on a combined basis of gross revenue for the six months ended June 30, 2018, compared to $7.0 million, $7.7 million, $15.9 million, and $1.0 million, respectively, or 28.6% on a combined basis of gross revenue for the six months ended June 30, 2017. The decrease in product sales allowances was primarily attributable to lower sales of SUBSYS® during the six months ended June 30, 2018 as compared to the six months ended June 30, 2017, offset by a $7.2 million increase in product returns. As described in “Factors Affecting Our Performance – Approved Product Sales”, the continuing sensitivity by some health care professionals to prescribe, and pharmacies to dispense, opioids, scrutiny by third-party payers and governmental agencies, ongoing state and federal investigations, and media reports related thereto, will likely result in our inability to grow full-year SUBSYS® revenue for the remainder of 2018 when compared to 2017. In addition, for the same reasons, we anticipate that we will experience future declines in SUBSYS® revenue for the remainder of 2018 when compared to prior quarters in 2017.

Cost of Revenue, Gross Profit and Gross Margin. Cost of revenue decreased $2.8 million to $5.8 million for the six months ended June 30, 2018, compared to $8.6 million for the six months ended June 30, 2017. The decrease in cost of revenue was primarily attributable to the decrease in sales of SUBSYS® during the six months ended June 30, 2018. Gross profit decreased $28.4 million to $41.6 million for the six months ended June 30, 2018, compared to $70.0 million for the six months ended June 30, 2017, due primarily to the decrease in sales of SUBSYS®. Gross margin for the six months ended June 30, 2018 remained flat at approximately 88% compared to approximately 89% for the six months ended June 30, 2017.

Sales and Marketing Expense. Sales and marketing expense decreased $10.9 million to $18.1 million for the six months ended June 30, 2018, compared to $29.0 million for the six months ended June 30, 2017. The decrease in sales and marketing expense was primarily due to the decrease in sales of SUBSYS® and a decrease in sales and marketing personnel costs.

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Research and Development Expense. Research and development expense increased $1.7 million to $28.7 million for the six months ended June 30, 2018, compared to $27.0 million for the six months ended June 30, 2017. The increase in research and development expense was primarily due to an impairment of property and equipment of $1.5 million, as well as timing of clinical and development expenses.

General and Administrative Expense. General and administrative expense decreased $0.2 million to $20.4 million for the six months ended June 30, 2018, compared to $20.6 million for the six months ended June 30, 2017. The decrease in general and administrative expense was primarily due to decreases in stock based compensation costs, partially offset by increases in personnel costs.

Legal Expense. Legal expense increased $9.9 million to $21.5 million for the six months ended June 30, 2018, compared to $11.6 million for the six months ended June 30, 2017. The increase was due to increases in legal expense incurred in connection with various ongoing government investigations and prosecutions of our former employees, and other legal proceedings.

Charges Related to Litigation Award and Settlements. Charges related to litigation award and settlements for the six months ended June 30, 2018 were $0.7 million. Charges related to litigation award and settlements for the six months ended June 30, 2017 represent an accrual of $4.5 million in connection with the investigation by the State of Illinois.

Income Tax Expense (Benefit). Provision for income taxes was $0.3 million for the six months ended June 30, 2018, representing an effective tax rate of (0.6)%, as compared to $(7.0) million for the six months ended June 30, 2017, representing an effective tax rate of 32.2%. The change in the effective rate for the period ended June 30, 2018, compared with the same period in the previous year was primarily due to the increase in valuation allowance during the six months ended June 30, 2018. As of June 30, 2018, we had approximately $41.8 million of federal NOLs, and $253.8 million of state NOLs.

We record valuation allowances to reduce the book value of our deferred tax assets to amounts that are estimated on a more likely than not basis to be realized. We established a full valuation allowance for deferred taxes during the period ended December 31, 2017, and maintain a full valuation allowance as of the current quarter. The establishment of a valuation allowance does not impact cash, nor does it preclude us from using our tax credits, loss carryforwards and other deferred tax assets in the future.

We had unrecognized tax benefits of approximately $10.4 million as of June 30, 2018, primarily associated with tax positions taken in prior years. No significant penalties and approximately $1.6 million of interest are included in income taxes and accounted for on the balance sheet related to unrecognized tax positions.

Liquidity and Capital Resources

Sources of Liquidity

Current operations are financed principally with existing cash on hand, investments in marketable securities and cash flows from operations.

Cash Flows

The following table shows a summary of our cash flows for the periods indicated (in millions):

	Six Months Ended June 30,	
	2018	2017
Net cash used in operating activities	$(40.0)	$(27.2)
Net cash provided by (used in) investing activities	22.5	(30.7)
Net cash provided by financing activities	1.6	3.1
Net decrease in cash and cash equivalents	(15.9)	(54.8)
Cash and cash equivalents, beginning of period	32.0	104.6
Cash and cash equivalents, end of period	$16.1	$49.8

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Cash Flows from Operating Activities. Net cash used in operating activities was $40.0 million and $27.2 million for the six months ended June 30, 2018 and 2017, respectively. The net cash used during the six months ended June 30, 2018 primarily reflects the net loss for the period driven by a reduction in SUBSYS® net sales, adjusted in part by depreciation and amortization, stock-based compensation expense, and an impairment loss on property and equipment.

Cash Flows from Investing Activities. Net cash provided by investing activities was $22.5 million for the six months ended June 30, 2018, and consists primarily of the net sale and maturity of investments. Net cash used in investing activities of $30.7 million for the six months ended June 30, 2017 consists primarily of the purchase of investments and property and equipment.

Cash Flows from Financing Activities. Net cash provided by financing activities was $1.6 million and $3.1 million for the six months ended June 30, 2018 and 2017. During the six months ended June 30, 2018, we received proceeds from the exercise of stock options of $0.9 million and proceeds from shares issued under our employee stock purchase plan of $0.7 million. During the six months ended June 30, 2017, we received proceeds from the exercise of stock options of $2.3 million and proceeds from shares issued under our employee stock purchase plan of $0.8 million.

We invoice pharmaceutical wholesalers and specialty pharmaceutical retailers upon delivery of SUBSYS® and SYNDROS®. To date, our customers have typically paid us 30 to 60 days from their applicable invoice dates.

Our cash flows for 2018 and beyond will depend on a variety of factors, including sales of SUBSYS® and SYNDROS®, regulatory approvals, investments in manufacturing and production, capital equipment, research and development, and litigation settlements, and general and administrative expenses.

Funding Requirements

We believe that our cash and cash equivalents and investments, together with interest thereon, will be sufficient to fund our operations for at least the next 12 months from the issuance date of these unaudited condensed consolidated financial statements.

In the ordinary course of business, we are involved in litigation, claims, government inquiries, investigations, charges and proceedings. Refer to Note 7 to the Unaudited Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q. Our ability to successfully defend ourselves against pending and future litigation may impact cash flows. The uncertainty of the timing of a settlement with the DOJ, if any, could impact our liquidity and require us to sell investments before the recovery of their amortized cost basis, particularly when aggregated with other potential state investigation settlements that may occur in the future, as well as potential future settlements related to ongoing litigation with insurance payers or other third parties.

Because of the numerous risks and uncertainties associated with commercialization of SUBSYS®, SYNDROS® and the development of our other product candidates, we are unable to predict the amounts of increased capital outlays and operating expenditures associated with our current anticipated product introduction, clinical trials and preclinical studies. The timing and amounts of our funding requirements will depend on numerous factors, including but not limited to:

- the levels and mix of our product sales;
- the rates of progress, costs and outcomes of our clinical trials and other product development programs, including product candidates that we may develop, in-license or acquire;

- regulatory approvals, DEA classifications and other regulatory related events;
- personnel, facilities, equipment and other similar requirements;
- costs of operating as a public company;
- the effects of competing technological and market developments;
- costs associated with litigation and government investigations;

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- costs and judgements of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates;
- our ability to acquire or in-license products and product candidates, technologies or businesses; and
- terms and timing of any additional collaborative, licensing, co-promotion or other arrangements that we may establish.

We cannot be sure that our existing cash and cash equivalents or investments will continue to be adequate to fund our operations, or that additional financing will be available when needed, or that, if available, financing will be obtained on terms favorable to us or our stockholders. Having insufficient funds may require us to delay, scale back or eliminate some or all of our research or development programs or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. If we raise additional funds by issuing equity or convertible securities, substantial dilution to existing stockholders will likely result. If we raise additional funds by incurring new debt obligations, the terms of the debt will likely require significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

Contractual Obligations

In April 2018, we, through our manufacturing subsidiary, entered into a further amendment to our Renaissance manufacturing and supply agreement. This amendment effectively eliminates any prior minimum purchase (and batch) obligations that had been set forth in the amendment dated July 2016, and replaces them with a new annual purchase commitment of $3,000,000 for the calendar year ended December 31, 2018, and $2,000,000 for the calendar years ending December 31, 2019 and 2020. As a result, the cumulative effect related to this amendment reduces our aggregated purchase commitment with Renaissance from $12,000,000 to $7,000,000 through December 31, 2020.

Off-Balance Sheet Arrangements

During the six months ended June 30, 2018, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements.

Recently Adopted Accounting Pronouncements

Refer to Note 1 to the Unaudited Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

At June 30, 2018, $9.1 million of our cash equivalent investments was in money market securities that are reflected as cash equivalents because all original maturities are within 90 days. Money market securities may consist of commercial paper, Federal agency discount notes and money market funds. We believe our interest rate risk with respect to these investments is limited due to the short-term duration of these arrangements and the yields earned, which approximate current interest rates.

Our policy for our short-term and long-term investments is to establish a high-quality portfolio that preserves principal, meets liquidity needs, avoids inappropriate concentrations and delivers an appropriate yield in relationship to our investment guidelines and market conditions. Our investment portfolio, consisting of fixed income securities that we hold on an available-for-sale basis, was approximately $108.0 million as of June 30, 2018, and $136.4 million as of December 31, 2017. These securities, like all fixed income instruments, are subject to interest rate risk and would likely decline in value if market interest rates increase. We have the ability to hold our fixed income investments until maturity and, therefore, we would not expect to recognize any material adverse impact in income or cash flows if market interest rates increase.

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The following table provides information about our available-for-sale securities that are sensitive to changes in interest rates. We have aggregated our available-for-sale securities for presentation purposes since they are all very similar in nature (dollar amounts in millions):

Interest Rate Sensitivity

Principal Amount by Expected Maturity as of June 30, 2018

	Remainder of 2018	2019	2020	2021	2022	Thereafter
CD's and Available-for-sale securities	$ 57.9	$41.8	$8.0	$ —	$ —	$ 0.3
Weighted-average yield rate	1.17 %	0.86%	0.18%	—	—	0.00 %

We have not entered into derivative financial instruments. We do not have operations outside of the U.S. and accordingly, we have not been susceptible to significant risk from changes in foreign currencies.

During the normal course of business, we could be subjected to a variety of market risks, examples of which include, but are not limited to, interest rate movements and foreign currency fluctuations, as we discussed above, and collectability of accounts receivable. We continuously assess these risks and have established policies and procedures to protect against the adverse effects of these and other potential exposures. Although we do not anticipate any material losses in these risk areas, no assurance can be made that material losses will not be incurred in these areas in the future.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our President and Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the quarterly period ended June 30, 2018, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within any company have been detected.

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PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The information contained in Note 7 to the Unaudited Condensed Consolidated Financial Statements is incorporated herein by reference.

ITEM 1A. RISK FACTORS

You should carefully consider the risks described in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2017, as well as other factors discussed herein under “Forward-Looking Statements” in Part I, Item 2 “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our business, financial condition and results of operations could be adversely affected by any of the risks and uncertainties described therein. There have been no material changes from the risk factors disclosed in Part I, Item 1A, in our Annual Report on Form 10-K.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On August 7, 2018, the Board of Directors (the “Board”) of Insys Therapeutics, Inc. (the “Company”) appointed Elizabeth Bohlen, effective immediately, to serve as a member of the Board. Ms. Bohlen was appointed as a Class I director, with an initial term expiring at the Company’s 2020 annual meeting of stockholders.

Ms. Bohlen will receive cash compensation for her Board service in the amount of $50,000 as an annual board retainer. Ms. Bohlen shall also receive an initial equity grant in connection with her Board service as follows: (i) 24,000 stock options and (ii) 6,000 restricted stock units. Such equity award is subject to such other terms and conditions as set forth in the applicable equity plan and any relevant grant agreement accompanying such grant. The Company also expects to enter into the Company’s standard director indemnification agreement with Ms. Bohlen. Ms. Bohlen has not been appointed to any Board committees at this time, but the Board anticipates it will re-evaluate this matter in the future.

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ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation of Insys Therapeutics, Inc. (1)
3.2	Amended and Restated Bylaws of Insys Therapeutics, Inc. (2)
3.3	Certificate of Designation of Series A Junior Participating Preferred Stock (3)
4.1	Form of Common Stock Certificate of Registrant (4)
4.2	Rights Agreement, dated August 15, 2014 between Insys Therapeutics, Inc. and Computershare Trust Company, N.A. (5)
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 (filed herewith)
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 (filed herewith)
32	Certifications of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith)
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Previously filed as Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2014, and incorporated herein by reference.
(2) Previously filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 9, 2016, and incorporated herein by reference.
(3) Previously filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 18, 2014, and incorporated herein by reference.
(4)

Previously filed as Exhibit 4.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2014, and incorporated herein by reference.

(5) Previously filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 18, 2014, and incorporated herein by reference.

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INSYS THERAPEUTICS, INC.

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 thereunto duly authorized.

INSYS THERAPEUTICS, INC.

Dated: August 9, 2018 By: /s/ Saeed Motahari
Saeed Motahari
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Andrew G. Long
Andrew G. Long
Chief Financial Officer
(Principal Financial and Accounting Officer)