Insys Therapeutics, Inc.
Form 10-Q
August 07, 2017
Table of Contents

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, 2017

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 (Address of principal executive offices)	85286 (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 revisited 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 July 26, 2017, the registrant had 72,696,647 shares of Common Stock ($0.01 par value) outstanding.

Table of Contents

INSYS THERAPEUTICS, INC.

FORM 10-Q

TABLE OF CONTENTS

Table of Contents

FORM 10-Q

GLOSSARY OF TERMS

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

Abbreviated Term	Defined Term
ANDA	Abbreviated New Drug Application
API	Active pharmaceutical ingredient
Aptar	AptarGroup, Inc.
ASC	Accounting Standards Codification
ASU	Accounting Standards Update
ATRA	American Taxpayer Relief Act of 2012
AUC	Area under the curve
AVC	Assurance of Voluntary Compliance
BTCP	Breakthrough cancer pain
Catalent	Catalent Pharma Solutions, LLC
CBD	Synthetic cannabidiol
cGMP	Current Good Manufacturing Practices
CID	Civil Investigative Demand
CINV	Chemotherapy-induced nausea and vomiting
CMS	Centers for Medicare & Medicaid Services
CRO	Contract Research Organization
CSA	Federal Controlled Substances Act of 1970
DEA	U.S. Drug Enforcement Administration
DPT	DPT Lakewood, LLC
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
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
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

Table of Contents

Abbreviated

Term	Defined Term
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
QuintilesIMS	QuintilesIMS Holdings, Inc.
REMS	Risk Evaluation and Mitigation Strategy
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

Table of Contents

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, 2017 (unaudited)	December 31, 2016
Assets		
Current Assets:		
Cash and cash equivalents	$ 49,830	$ 104,642
Short-term investments	91,786	78,238
Accounts receivable, net of allowances of $3,636 and $6,144 at June 30, 2017 and December 31, 2016, respectively	23,972	20,654
Inventories, net	19,988	20,414
Prepaid expenses and other current assets	11,610	5,695
Total current assets	197,186	229,643
Property and equipment, net	49,139	43,172
Long-term investments	61,342	53,796
Deferred income tax assets, net	26,551	23,243
Other assets	3,410	6,282
Total assets	$ 337,628	$ 356,136
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 23,016	$ 27,359
Accrued compensation	5,443	8,833
Accrued sales allowances	20,085	28,955
Accrued litigation award and settlements	14,517	13,467
Total current liabilities	63,061	78,614
Uncertain income tax positions	8,188	7,933
Total liabilities	71,249	86,547
Commitments and contingencies (Note 6)		
Stockholders' Equity:		
Preferred stock (par value $0.01 per share; 10,000,000 shares authorized; 0 shares issued and outstanding as of June 30, 2017 and December 31, 2016, respectively)	—	—
Common stock (par value $0.01 per share; 100,000,000 shares authorized; 72,695,042 and 71,923,550 shares issued and outstanding as of	727	719

June 30, 2017 and December 31, 2016, respectively)		
Additional paid in capital	267,968	256,529
Unrealized loss on available-for-sale securities, net of tax	(251)	(302)
Notes receivable from stockholders	(21)	(21)
Retained earnings (accumulated deficit)	(2,044)	12,664
Total stockholders' equity	266,379	269,589
Total liabilities and stockholders' equity	$ 337,628	$ 356,136

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

INSYS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

(In thousands, except share and per share data)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net revenue	$42,576	$69,221	$78,538	$129,642
Cost of revenue	3,921	6,273	8,560	10,911
Gross profit	38,655	62,948	69,978	118,731
Operating expenses:				
Sales and marketing	13,292	19,691	28,950	39,491
Research and development	14,103	22,889	27,037	41,924
General and administrative	17,126	13,924	32,168	28,622
Charges related to litigation award and settlements	4,450	—	4,450	—
Total operating expenses	48,971	56,504	92,605	110,037
Operating income (loss)	(10,316)	6,444	(22,627)	8,694
Other income:				
Interest income	465	256	900	481
Other income (expense), net	13	(5)	39	44
Total other income	478	251	939	525
Income (loss) before income taxes	(9,838)	6,695	(21,688)	9,219
Income tax expense (benefit)	(1,654)	668	(6,980)	902
Net income (loss)	(8,184)	6,027	(14,708)	8,317
Unrealized gain (loss) on available-for-sale securities, net of tax	(24)	70	51	236
Total comprehensive income (loss)	$(8,208)	$6,097	$(14,657)	$8,553
Net income (loss) per common share:				
Basic	$(0.11)	$0.08	$(0.20)	$0.12
Diluted	$(0.11)	$0.08	$(0.20)	$0.11
Weighted average common shares outstanding				
Basic	72,169,361	71,543,809	72,057,552	71,567,949
Diluted	72,169,361	74,053,550	72,057,552	74,281,838

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

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	Retained Earnings (Accumulated Deficit)	Total
Balance at December 31, 2016	71,923,550	$ 719	$256,529	$ (302)	$ (21)	$ 12,664	$269,589
Exercise of stock options	663,690	7	2,324	—	—	—	2,331
Issuance of common stock- employee stock purchase plan	107,802	1	835	—	—	—	$836
Stock-based compensation- stock options and awards	—	—	8,280	—	—	—	8,280
Unrealized gain on available-for -sale securities, net of tax	—	—	—	51	—	—	51
Net loss	—	—	—	—	—	(14,708)	(14,708)
Balance at June 30, 2017	72,695,042	$ 727	$267,968	$ (251)	$ (21)	$ (2,044)	$266,379

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

INSYS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Six Months Ended June 30,	
	2017	2016
Cash flows from operating activities:		
Net income (loss)	$(14,708)	$8,317
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Inventory obsolescence reserve	2,959	638
Depreciation and amortization	3,688	3,023
Stock-based compensation	8,280	9,072
Deferred income tax benefit	(3,308)	(2,343)
Excess tax benefits on stock options and awards	—	(934)
Amortization of investment discount	676	1,123
Changes in operating assets and liabilities:		
Accounts receivable	(3,318)	7,873
Inventories	345	1,717
Prepaid expenses and other current assets	(5,921)	(2,083)
Accounts payable, accrued expenses and other current liabilities	(16,990)	(18,148)
Accrued litigation award and settlements	1,050	—
Net cash provided by (used in) operating activities	(27,247)	8,255
Cash flows from investing activities:		
Purchase of investments	(72,060)	(42,232)
Proceeds from sales of investments	2,919	4,324
Proceeds from maturities of investments	47,422	35,396
Purchases of property and equipment	(9,013)	(4,501)
Net cash used in investing activities	(30,732)	(7,013)
Cash flows from financing activities:		
Proceeds from issuance of common stock	836	1,576
Excess tax benefits on stock options and awards	—	934
Proceeds from exercise of stock options	2,331	2,123
Repurchase of common stock	—	(16,100)
Net cash provided by (used in) financing activities	3,167	(11,467)
Change in cash and cash equivalents	(54,812)	(10,225)
Cash and cash equivalents, beginning of period	104,642	79,515
Cash and cash equivalents, end of period	$49,830	$69,290
Supplemental cash flow disclosures:		
Cash paid for income taxes	$1,793	$6,624
Non-cash capital expenditures	$642	$70

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

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, 2017, we have one marketed product: SUBSYS®, a proprietary sublingual fentanyl spray for BTCP in opioid-tolerant adult patients; and one product: SYNDROS™, which received FDA approval in July 2016 and final labeling approval by the FDA in May 2017. We commercially launched SYNDROS™ in July 2017.

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, 2016, included in our Annual Report on Form 10-K. The results of operations for the three and six months ended June 30, 2017 and 2016 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, liabilities, revenues, expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to revenue recognition (which is affected by prescriptions dispensed, wholesaler discounts, patient discount programs, rebates, and chargebacks), inventories, legal liabilities, stock-based compensation expense, 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 may 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, 2017, we adopted ASU No. 2016-09, Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. Among other requirements, the new guidance requires all tax effects related to share-based payments at settlement (or expiration) to be recorded through the income statement. Previously, tax benefits in excess of compensation cost ("windfalls") were recorded in equity, and tax deficiencies ("shortfalls") were recorded in equity to the extent of previous windfalls, and then to the income statement. As required, this change was applied prospectively to all excess tax benefits and tax deficiencies resulting from settlements.

Under the new guidance, the windfall tax benefit is to be recorded when it arises, subject to normal valuation allowance considerations. Excess tax benefits that were not previously recognized because the related tax deduction had not reduced current taxes payable were recorded through a cumulative effect adjustment as of the date of the adoption. As required, upon adoption, this change was applied on a modified retrospective basis, with a cumulative effect adjustment of change in accounting principle of approximately $368,000 as a deferred tax asset with a corresponding valuation allowance of $368,000, which were offset in retained earnings. Additionally, our condensed consolidated statement of cash flows now presents excess tax benefits as an operating activity, adjusted prospectively with no adjustments made to prior periods.

Additionally, ASU No. 2016-09 addressed the presentation of employee taxes paid on the statement of cash flows. We are now required to present the cost of shares withheld from the employee to satisfy the employees' income tax liability as a financing activity on the statement of cash flows rather than as an operating cash flow. This change was applied on a retrospective basis, as required, but did not impact the condensed consolidated statement of cash flows for the six months ended June 30, 2016.

Table of Contents

ASU 2016-09 also permits entities to make an accounting policy election related to how forfeitures will impact the recognition of compensation cost for stock-based compensation to either estimate the total number of awards for which the requisite service period will not be rendered, as currently required, or to account for forfeitures as they occur. Upon adoption of ASU 2016-09, we elected to change our accounting policy to account for forfeitures as they occur. As required, this change was applied on a modified retrospective basis; however, as of December 31, 2016, we had estimated no forfeitures relating to the outstanding equity awards. As a result, no adjustment was required.

Going forward, the adoption of ASU 2016-09 could cause volatility in the effective tax rate, as the excess tax benefits associated with the exercise of stock options could generate a significant discrete income tax benefit in a particular interim period, potentially creating volatility in net income and net income per share period-to-period and period-over-period.

Effective January 1, 2017, we adopted ASU No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. Prior to January 1, 2017, we measured inventory at the lower of cost or market. This guidance requires us to measure inventory at the lower of cost and NRV, which eliminates the need to determine replacement cost and evaluate whether it is above the ceiling (NRV) or below the floor (NRV less a normal profit margin). The guidance defines NRV as the “estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation.” The adoption of this guidance did not have a material impact on our condensed consolidated financial statements.

Recent Accounting Pronouncements

In May 2017, the FASB issued ASU No. 2017-09, Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting, to provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. Specifically, 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 amendments should be applied prospectively to an award modified on or after the adoption date, and are effective for fiscal years beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period, for reporting periods for which financial statements have not yet been issued. We are currently evaluating the impact of this amendment on our consolidated financial statements.

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 consolidated financial statements.

In October 2016, the FASB issued ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory, to improve the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. Current U. S. GAAP prohibits the recognition of current and deferred income taxes for an intra-entity asset transfer until the asset has been sold to an outside party, which is an exception to the principle of comprehensive recognition of current and deferred income taxes in U. S. GAAP. The amendments in this update eliminate the exception for an intra-entity transfer of an asset other than inventory. The amendments should be applied on a modified retrospective transition basis, and are effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, and early adoption is permitted. We are currently evaluating the impact of these amendments on our consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. The amendments effected by this ASU affect entities required to present a statement of cash flows and provide specific guidance on a variety of cash flow issues to reduce current and potential future diversity in practice. The amendments are effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years, and early adoption is permitted. An entity that elects early adoption must adopt all of the amendments in the same period. The amendments should be applied using a retrospective transition method to each period presented. We are currently evaluating the impact of these amendments on our consolidated financial statements.

Table of Contents

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 are currently evaluating the impact of these amendments on our 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 are currently evaluating the impact of these amendments on our consolidated financial statements and related disclosures; however, based on our current operating leases, we do not expect that the adoption of this guidance will have a material impact on our consolidated financial statements. See Note 6, Commitments and Contingencies, for information about our lease commitments.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities, which amended the Financial Instruments topic of the ASC to address certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. The amendments will be effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, and early adoption is not permitted. These amendments should be applied by means of a cumulative-effect adjustment to the balance sheet as of the beginning of the fiscal year of adoption. The amendments related to equity securities without readily determinable fair values (including disclosure requirements) should be applied prospectively to equity investments that exist as of the date of adoption. We are currently evaluating the impact of these amendments on our consolidated financial statements

Table of Contents

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). The new 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 standard requires that reporting companies disclose the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The new standard is required to be applied either retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying it recognized at the date of initial application. In March 2016 and April 2016, the FASB issued ASU No. 2016-08 and ASU No. 2016-10, respectively, which further clarified the implementation guidance on principal versus agent considerations contained in ASU No. 2014-09 and the identification of performance obligations and licensing, respectively. In May 2016, the FASB issued ASU 2016-12, Narrow-Scope Improvements and Practical Expedients, which provides clarification on assessing the collectability criterion, presentation of sales taxes, measurement date for non-cash consideration and completed contracts at transition. These standards will be effective for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). Early adoption is permitted, but not before December 15, 2016, the original effective date of the standard. We are currently analyzing ASU 2014-09, and the related ASUs, to evaluate the impact of the new standard on existing contracts with our customers. We initiated a contract review process during 2016, including evaluation of our performance obligations and variable consideration. Our evaluation is still ongoing; however, based on the evaluation of our current contracts and revenue stream, most will be recorded consistently under both the current and new standard. We primarily sell products and recognize revenue upon delivery to customers, at which point the earnings process is deemed to be complete. Our performance obligations are clearly identifiable and we do not anticipate significant changes to the assessment of such performance obligations or the timing of our revenue recognition upon adoption of the new standard. Our primary business processes are consistent with the principles contained in the ASU, and we do not expect significant changes to those processes, our internal controls or systems. We continue to evaluate the impact of the new standard on our financial statement disclosures as well as our planned transition approach. Additionally, we will continue to monitor industry activities and any additional guidance provided by regulators, standards setters, or the accounting profession and adjust our assessment and implementation plans accordingly.

2. Revenue Recognition

We recognize revenue from the sale of SUBSYS®. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.

SUBSYS® was commercially launched in March 2012 and is monitored by an FDA-mandated REMS program known as the TIRF REMS. We sell SUBSYS® in the United States to wholesale pharmaceutical distributors and directly to retail pharmacies, collectively our customers, subject to rights of return within a period beginning six months prior to, and ending 12 months following, product expiration. SUBSYS® currently has a shelf life of 36 months from the date of manufacture. We record revenue for SUBSYS® at the time the customer receives the shipment.

We recognize estimated product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates 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, we recognize the cost of patient discounts as a reduction of revenue based on estimated

utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on product 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. The shelf life of SUBSYS® is currently 36 months from the date of manufacture. 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

Table of Contents

when the product is shipped and when we issue credits on returned product. Accordingly, we may have to adjust these estimates, which could have an effect on product sales 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 upon shipment to the respective wholesale distributors and retail pharmacies.

Patient Discount Programs. We offer discount card programs to patients for SUBSYS®, 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 sold 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.

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 No. 320, Investments — Debt and Equity Securities. Available-for-sale securities 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, 2017 and 2016. 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. 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, 2017 and 2016. 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 income (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, 2017, our certificates of deposit and commercial paper as well as our marketable securities have been recorded at an estimated fair value of $95,000, $91,786,000, and $61,342,000 in cash and cash equivalents, short-term and long-term investments, respectively.

Table of Contents

Investments consisted of the following at June 30, 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	$14,973	$ —	$ —	$ —	$14,973	$ 14,973	$ —	$ —
Money market securities	34,762	—	—	—	34,762	34,762	—	—
Marketable securities:								
Certificates of deposit	24,767	—	—	—	24,767	—	12,678	12,089
Commercial paper	10,472	—	—	—	10,472	—	10,472	—
Corporate securities	59,003	2	(116)	—	58,889	—	36,759	22,130
Federal agency securities	33,505	—	(119)	—	33,386	—	13,969	19,417
Municipal securities	25,727	5	(23)	—	25,709	95	17,908	7,706
Total marketable securities	153,474	7	(258)	—	153,223	95	91,786	61,342
	$203,209	$ 7	$ (258)	$ —	$202,958	$ 49,830	$ 91,786	$ 61,342

Investments consisted of the following at December 31, 2016 (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	$49,331	$ —	$ —	$ —	$49,331	$ 49,331	$ —	$ —
Money market securities	54,015	—	—	—	54,015	54,015	—	—
Marketable securities:								
Certificates of deposit	26,114	—	—	—	26,114	—	13,855	12,259
Commercial paper	1,485	—	—	—	1,485	—	1,485	—
Corporate securities	39,562	—	(135)	—	39,427	500	25,681	13,246
	30,660	4	(92)	—	30,572	—	10,854	19,718

Federal agency securities								
Municipal securities	35,811	2	(81)	—	35,732	796	26,363	8,573
Total marketable securities	133,632	6	(308)	—	133,330	1,296	78,238	53,796
	$236,978	$ 6	$ (308)	$ —	$236,676	$ 104,642	$ 78,238	$ 53,796

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

	June 30, 2017		December 31, 2016	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Marketable securities:				
Due in one year or less	$92,197	$92,130	$80,092	$80,027
Due after one year through 5 years	61,277	61,093	53,540	53,303
Due after 5 years through 10 years	—	—	—	—
Due after 10 years	—	—	—	—
	$153,474	$153,223	$133,632	$133,330

Table of Contents

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, 2017				December 31, 2016			
	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	$51,711	$ (115)	$1,350	$ (1)	$38,027	$ (134)	$401	$ (1)
Federal agency securities	33,386	(119)	—	—	26,449	(91)	1,217	(1)
Municipal securities	13,774	(23)	—	—	30,373	(81)	100	—
	$98,871	$ (257)	$1,350	$ (1)	$94,849	$ (306)	$1,718	$ (2)

As of June 30, 2017 and December 31, 2016, we have concluded that all the unrealized losses on our marketable securities are temporary in nature. Marketable securities are reviewed quarterly for possible other-than-temporary impairment. 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. Additionally, we do not intend to sell, and it is not probable that we will be required to sell, any of the securities before the recovery of their amortized cost basis.

Table of Contents

4. Fair Value Measurement

FASB ASC No. 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, 2017 and December 31, 2016, 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. Substantially all available-for-sale investments held by us at June 30, 2017 and December 31, 2016 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 our investment in a long-term corporate convertible promissory note and a warrant to purchase shares issued in connection with the convertible promissory note, which converted to convertible preferred stock on December 31, 2016. This stock is not listed on any security exchange. The fair value of the preferred stock approximates its carrying value at June 30, 2017 and December 31, 2016.

Our investments measured at fair value on a recurring basis subject to the disclosure requirements of ASC 820 at June 30, 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)
Marketable securities:				
Certificates of deposit	$24,767	$ —	$24,767	$ —
Commercial paper	10,472	—	10,472	—
Corporate securities	58,889	—	58,371	518
Federal agency securities	33,386	—	33,386	—
Municipal securities	25,709	—	25,709	—
Total assets measured at fair value	$153,223	$ —	$152,705	$ 518

Our investments measured at fair value on a recurring basis subject to the disclosure requirements of ASC 820 at December 31, 2016 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)
Marketable securities:				
Certificates of deposit	$26,114	$ —	$ 26,114	$ —
Commercial paper	1,485	—	1,485	—
Corporate securities	39,427	—	38,927	500
Federal agency securities	30,572	—	30,572	—
Municipal securities	35,732	—	35,732	—
Total assets measured at fair value	$133,330	$ —	$ 132,830	$ 500

Table of Contents

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, 2017 and 2016 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Convertible stock				
Balance, beginning of period	$518	$ —	$500	$ —
Change in fair value		—	18	—
Purchases	—	—		—
Balance, end of period	$518	$ —	$518	$ —

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, 2017	December 31, 2016
Finished goods	$6,046	$ 8,408
Work-in-process	6,652	6,183
Raw materials and supplies	7,290	5,823
Total inventories	19,988	20,414
Plus: non-current raw materials and supplies and finished goods	3,379	6,257
	$23,367	$ 26,671

As of June 30, 2017 and December 31, 2016, raw materials inventories consisted of raw materials used in the manufacture of the API in our U.S.-based, state-of-the-art dronabinol manufacturing facility and component parts and packaging materials used in the manufacture of SUBSYS® and SYNDROS™. Work-in-process consists of actual production costs, including facility overhead and tolling costs of in-process dronabinol, SUBSYS® and SYNDROS™ products. Finished goods inventories consisted of finished SUBSYS® and SYNDROS™ products. Non-current raw

materials and supplies 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, 2017 and December 31, 2016, all work-in-process inventory is expected to be used within 12 months of the balance sheet date and, therefore, is classified as current inventory. 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, 2017 and December 31, 2016 were reported net of these reserves of $9.8 million and $6.8 million, respectively. During the six months ended June 30, 2017 and 2016, we increased these reserves by $3.0 million and $0.6 million, respectively.

6. 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.

Table of Contents

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 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 and cash flows for that future period, 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 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.

Department of Health and Human Services 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. This subpoena requests documents regarding our business, including the commercialization of SUBSYS®. We are cooperating with this investigation and have produced documents in response to the subpoena and have provided other requested information. We believe a loss is probable with respect to this investigation, but we are not in a position to estimate a range of such loss or other scope and outcome associated with this investigation.

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 requests 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 are cooperating with this investigation and have produced documents in response to the subpoena and have provided other requested information. We believe a loss is probable with respect to this investigation, but we are not in a position to estimate a range of such loss or other scope and outcome associated with this investigation.

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.

A number of our former employees have been charged in criminal proceedings related to our federal investigations. 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 regard to two Alabama health care professionals who prescribed our product SUBSYS®. These two Alabama health care professionals, 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, were charged by the U.S. Attorney's Office for the Southern District of Alabama, and on or about February 23, 2017, 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 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 providers. Moreover, 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

Table of Contents

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. Both of these former employees in New York and New Jersey have pled not guilty. On or about October 13, 2016, a former prior authorization specialist and manager of our patient services hub was charged by the U.S. Attorney's Office for the District of Massachusetts with conspiracy to commit wire fraud in connection with our provision of prior authorization support related to our patient services hub. On April 5, 2017, the U.S. Attorney's Office for the District of Massachusetts filed an information charging this former employee with one count of wire fraud conspiracy; the former employee pled guilty to that information on June 19, 2017. 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. 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. Except as otherwise indicated, we understand that each of these indicted individuals have entered pleas of not guilty to the charges against them. On or about July 11, 2017, a former sales employee pled guilty in federal court in Connecticut to an Information charging her with one count of conspiring to violate the federal Anti-Kickback Statute.

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.

State Related Investigations. We have received CIDs or subpoenas, as the case may be, from each of the Office of the Attorney General (or similarly named and authorized office) of the State of Arizona, Colorado, Florida, Illinois, Kentucky, Massachusetts, Maryland, Minnesota, New Hampshire, New Jersey, New York, North Carolina, Oregon, Pennsylvania 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 each applicable state Attorney General or Department of Justice office 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 documents in response to these CIDs, subpoenas and related requests for information from each office.

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 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 State of Illinois, on August 25, 2016, the Illinois Office of the Attorney General filed a complaint on behalf of the State of Illinois against us in the Circuit Court of Cook County, Illinois,

Chancery Division. The complaint asserts a claim for violation of the Illinois Consumer Fraud and Deceptive Business Practices Act in connection with the sales and marketing of SUBSYS® in Illinois. The complaint seeks injunctive relief, including a permanent injunction preventing us from engaging in commerce in the State of Illinois, and civil penalties. The Circuit Court of Cook County extended the time for us to answer or otherwise respond to the complaint and the next status hearing is August 14, 2017. In connection with the investigation by the State of Illinois, we have made a reasonable estimate of a probable loss of approximately $4,450,000. This estimated amount was accrued in the consolidated balance sheet as of June 30, 2017. We continue to cooperate with this investigation and to engage in discussions with the Illinois Office of the Attorney General.

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

Table of Contents

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 response to certain requests for information by the State of New Hampshire. These amounts were accrued in the consolidated balance sheet 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 have made a reasonable estimate of a probable loss of approximately $500,000. This estimated amount was accrued in the consolidated balance sheet as of March 31, 2017. We continue to cooperate with the State of Massachusetts investigation, including producing documents in response to certain requests for information.

Investigations of Health Care Professionals. In addition to the above 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 of Connecticut, Eastern District of Michigan, Florida (Jacksonville), Kansas, New Hampshire, Rhode Island, Southern District of New York, Southern District of Ohio, Southern District of Alabama, Northern District of Texas and Western District of New York regarding specific health care professionals that we have interacted with in those states. 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.

Opioid Litigation and Broad Investigations by Governmental Authorities. Many federal and governmental agencies 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. Common prescription drugs that contain opioids are drugs such as oxycodone, hydrocodone and fentanyl. Our product, SUBSYS®, is a fentanyl-based product in the TIRF class. Certain stakeholders in the health care community, regulatory bodies and governmental agencies may associate us with, or determine that we are a part of, this perceived opioid abuse epidemic. Like all TIRF products, our product is part of the mandatory TIRF REMS program, which is designed "to ensure informed risk-benefit decisions before initiating treatment, and while patients are treated to ensure appropriate use of TIRF medicines" and "to mitigate the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors with the use of TIRF medicines." Nevertheless, from time to time, we may be included in litigation or investigations that are directed at the abuse of opioids in the United States.

For example, in May 2014, Santa Clara and Orange Counties in California filed a complaint in state court in Orange County, California against numerous pharmaceutical manufacturers alleging claims related to opioid marketing practices, including false advertising, unfair competition, and public nuisance. Despite the fact that we are not named specifically in the complaint and this lawsuit was recently stayed, we have received a preservation notice letter from the Office of the County Counsel for the County of Santa Clara. From time to time, we may be included in these types of litigations as a result of the fact that we market an opioid product.

In addition, 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 requests documents regarding our business, including the commercialization of SUBSYS®. We continue to cooperate with this inquiry.

With the exception of the investigations by the ODOJ, the State of New Hampshire and the State of Massachusetts, 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.

Table of Contents

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 parties await a ruling from the court on the motion to dismiss. 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 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 lead counsel in the consolidated action. On July 31, 2017, the lead counsel filed a consolidated complaint. 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 March 23, 2017, the court appointed the counsel for Gary Hirt and Precieux Art Jewelers Inc. as lead counsel and on 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. We continue 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 U.S. Food & Drug Administration ("FDA") received an Abbreviated New Drug Application ("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, 3017, we filed suit in United States District Court for the

Table of Contents

District of Delaware, in which we claim the ANDA was not sufficiently complete and allege patent infringement. We believe we have meritorious legal positions and will represent our interests vigorously in this matter.

On or about August 2, 2017, we received a Paragraph IV Notice Letter from counsel for TEVA USA related to SUBSYS®. The letter asserts that (i) the FDA received an ANDA from TEVA USA and (ii) that TEVA's formulation does not infringe SUBSYS® patents and/or that our patents for SUBSYS® are invalid. We are assessing this letter and intend to vigorously defend this matter

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. The complaint brought a cause of action for statutory and common law appraisal of Dr. Kottayil's Insys Pharma common stock. The cause of action for appraisal relates to a reverse stock split that Insys Pharma effected in June 2009, which resulted in Dr. Kottayil's ownership position becoming a fractional share of Insys Pharma common stock. Following the reverse stock split, Insys Pharma cancelled all resulting fractional shares, including the fractional share held by Dr. Kottayil, and offered a cash payment in lieu of the fractional shares. The complaint also brought causes of action for breach of fiduciary duty, fraud and negligent misrepresentation in the defendants' dealings with Dr. Kottayil on the subject of his compensation and stock ownership in Insys Pharma. In January 2010, the plaintiffs added claims seeking to rescind Dr. Kottayil's assignment to Insys Pharma of his interest in all of the fentanyl and dronabinol patent applications previously assigned to Insys Pharma and to recover the benefits of those interests. Dr. Kottayil was seeking, among other relief, the fair value of his Insys Pharma common stock as of June 2, 2009, compensatory and punitive damages, and rescission of all assignments to Insys Pharma of his interest in the patent applications, as well as attorneys' fees, costs and interest.

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.

On January 29, 2014, the plaintiffs filed a second amended complaint in the Arizona Superior Court in which Insys Therapeutics, Inc. was also named as defendant in this lawsuit. This amended complaint filed by plaintiffs re-alleged substantially the same claims set forth in the prior complaint, except that plaintiffs also alleged that they were entitled to rescissory damages, added our majority stockholder, a private trust, as a defendant to the breach of fiduciary duty claim and revised their fraud claim against the Insys Pharma director defendants.

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. Specifically, the court found (i) in favor of Insys Pharma, our majority stockholder, a private trust and four of the Insys Pharma directors who were on the board in July 2008 on plaintiffs' claim for breach of fiduciary duty arising out of transactions the board approved in July 2008, (ii) found in favor of plaintiffs and against Insys Pharma, Inc., our majority stockholder, a private trust and three of the Insys Pharma directors who were on the board in June 2009 on plaintiffs' claims under Delaware law and for breach of fiduciary duties arising out of the reverse stock split the board approved in June 2009 in the amount of $7,317,450, along with pre-judgment and post-judgment interest and court costs, (iii) found in favor of two of the Insys Pharma directors who were on the Insys Pharma board as of June 2009 and against plaintiffs on

plaintiffs' breach of fiduciary duty claims, (iv) found in favor of Insys Pharma and against plaintiff (Kottayil) on his claim for rescission of the patent application assignments that he entered in favor of Insys Pharma before and after his employment terminated, (v) found in favor of Insys Therapeutics, Inc. and against plaintiff on plaintiffs' claims of successor liability and fraudulent transfer, and (vi) found 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 entered a final judgment, awarding plaintiffs the amount of $7,317,450, along with pre-judgment interest from June 2, 2009, and post-judgment interest, from October 2, 2015, at the rate of 4.25% per annum, compounded quarterly and taxable costs in the amount of $93,163. On the same date, 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.

Table of Contents

As a result of the final ruling, we have accrued $9,567,000 at March 31, 2017, including $2,249,000 of estimated pre-judgement interest, which represents our current best estimate of this contingent liability. The final outcome of the appeal could cause this estimate to vary materially from the final award.

On October 20, 2015, plaintiffs appealed the foregoing judgment and on November 4, 2015, Insys Pharma and the other defendants against whom judgment was entered filed a notice of cross-appeal. The appeal and cross-appeal remain pending before the Court of Appeals for the State of Arizona.

On or around November 1, 2015, we received a notice from the plaintiff'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 yet. Accordingly, we are still in the process of assessing the merit of such claims as well as evaluating the basis for the costs claimed. 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.

On or about August 1, 2016, plaintiffs filed opening and reply and cross response briefs and we filed our answering and cross-appeal brief and our reply in support of our cross-appeal.

On Wednesday, April 5, 2017, the Arizona Court of Appeals conducted oral argument on the plaintiffs' appeal and on our cross-appeal. The parties now await a decision from the Arizona Court of Appeals.

Insurance Litigation. On June 23, 2017, Aetna, Inc. filed a complaint against us and a number of former employees in the Pennsylvania Court of Common Pleas, Philadelphia County. We have not been served with this complaint and have not been provided the claims nor allegations underlying the lawsuit.

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 bring 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 million 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. We intend to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter will have a material adverse effect on our business, financial position, or future results of operations.

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 federal district court in the Middle District of Florida. On September 2, 2016, we filed a motion to dismiss and are awaiting the court's ruling. We continue to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter will have a material adverse effect on our business, financial position, or future results of operations.

19

Table of Contents

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 have filed a motion to dismiss and on or about May 6, 2017, the court denied the motion to dismiss. We continue to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter will have a material adverse effect on our business, financial position, or future results of operations.

Colby. On or about January 25, 2017, Mackenzie Colby filed a complaint in the State of New Hampshire Strafford County Superior Court, Case No. 219-2017-CV-00040, against Christopher Clough, PA, Dr. O'Connell's Pain Care Centers, Inc., and Insys Therapeutics, Inc. Plaintiff's complaint states it is a personal injury action against Mr. Clough related to medical negligence, against O'Connell's Pain Care Centers, Inc. for respondeat superior claims, and against Insys Therapeutics, Inc. for negligence, all under state laws. The lawsuit seeks unspecified compensatory and punitive damages. We filed a motion to dismiss/strike on April 5, 2017 and plaintiff filed a motion to amend the complaint on April 25, 2017. On June 16, 2017, the court dismissed the complaint with leave to refile. The complaint was refiled on June 21, 2017. We continue to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter will have a material adverse effect on our business, financial position, or future results of operations.

Perusse. On or about February 21, 2017, John Perusse filed a complaint in the State of New Hampshire Strafford County Superior Court, Case No. 219-2017-CV-00067, against Christopher Clough, PA, Dr. John J Schermerhorn, Dr. O'Connell's Pain Care Centers, Inc., and Insys Therapeutics, Inc. Plaintiff's complaint states it is a personal injury action against Mr. Clough related to medical negligence, against O'Connell's Pain Care Centers, Inc. for respondeat superior claims, and against Insys Therapeutics, Inc. and Dr. Schermerhorn for negligence, all under state laws. The lawsuit seeks unspecified compensatory and punitive damages. We filed a motion to dismiss/strike on April 20, 2017 and plaintiff filed a motion to amend the complaint on April 25, 2017. On June 16, 2017, the court dismissed the complaint with leave to refile. The complaint was refiled on June 21, 2017. We continue to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter will have a material adverse effect on our business, financial position, or future results of operations.

Cassell. On or about March 8, 2017, Jerome Cassell filed a complaint in the State of New Hampshire Strafford County Superior Court, Case No. 219-2017-CV-00085, against Christopher Clough, PA, Dr. John J Schermerhorn, Dr. O'Connell's Pain Care Centers, Inc., and Insys Therapeutics, Inc. Plaintiff's complaint states it is a personal injury action against Mr. Clough related to medical negligence, against O'Connell's Pain Care Centers, Inc. for respondeat superior claims, and against Insys Therapeutics, Inc. and Dr. Schermerhorn for negligence, all under state laws. The lawsuit seeks unspecified compensatory and punitive damages. We filed a motion to dismiss/strike on April 18, 2017 and plaintiff filed a motion to amend the complaint on April 25, 2017.. On June 16, 2017, the court dismissed the complaint with leave to refile. The complaint was refiled on June 21, 2017. We continue to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter will have a material adverse effect on our business, financial position, or future results of operations.

Carver. On or about March 20, 2017, a qui tam complaint entitled United States ex rel. Lori L. Carver v. Physicians Pain Specialists of Alabama, P.C., Xiulu Ruan, M.D., John Patrick Couch, M.D., C&R Pharmacy, LLC, Castle Medical, LLC, Insys Therapeutics, Inc., Industrial Pharmacy Management, LLC and Christopher Manfuso; Case No. 13-392, that had been filed under seal with the U.S. District Court for the Southern District of Alabama Southern Division, was ordered unsealed by the court. The U.S. Department of Justice declined to intervene in this action. The complaint was originally brought by Ms. Carver, a former employee of Physician Pain Specialists of Alabama, P.C., as a private party qui tam relator on behalf of the federal government. The action alleges civil violations of the federal

False Claims Act committed by the defendants related to fraudulent claims by defendants for payment in connection with federally-funded Medicare programs, as well as other federally-funded health care programs as a result of alleged illegal activity under the Stark Law and Federal Anti-Kickback Laws. On May 1, 2017, we filed a motion to dismiss and this motion is pending. On May 10, 2017, the relator filed a Notice of Voluntary Dismissal dismissing us, without prejudice, from this action and, on May 24, 2017, the federal government consented to dismissing us.

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

Table of Contents

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 have twenty days from July 27, 2017 to file an appeal, if any, or, in the alternative, our answer is due on August 20, 2017. We continue to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter 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. Our response is due on August 18, 2017. We continue to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter will have a material adverse effect on our business, financial position, or future results of operations.

Except as it pertains to accruals of (i) $9,567,000 for the dispute with Dr. Kottayil, (ii) $500,000 for the settlement of the investigation by the State of Massachusetts and (iii) $4,450,000 for the settlement of the investigation by the State of Illinois and the potential for damages in the federal securities litigation and derivative action that we believe should be sufficiently covered by 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 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.

Responding to each of these litigation matters, 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

In April 2015, we entered into an amendment to our DPT 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 October 2015, we entered into an amended and restated supply, development and exclusive licensing agreement with 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 under our manufacturing and supply agreement with DPT and our supply, development and exclusive licensing agreement with Aptar from our parent to our

manufacturing subsidiary as part of a corporate restructuring.

In July 2016, we, through our manufacturing subsidiary, entered into a further amendment to our DPT manufacturing and supply agreement. This amendment effectively eliminates any prior minimum purchase (and batch) obligations that had been set forth in the amendment dated April 30, 2015, and replaces them with a new annual purchase commitment of $4,000,000 per calendar year commencing January 1, 2017 through December 31, 2020. As a result, the cumulative effect related to this amendment reduces our aggregated minimum purchase commitments with DPT from $49,740,000 to $16,000,000 through December 31, 2020.

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

Table of Contents

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.

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

Years ending December 31,	
Remainder of 2017	$5,500
2018	5,500
2019	6,000
2020	6,000
2021	2,000
Thereafter	—
Total	$25,000

Table of Contents

7. Stock-based Compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Research and development	$784	$1,063	$1,817	$1,924
General and administrative	3,504	3,883	6,463	7,148
Total cost of stock-based compensation	$4,288	$4,946	$8,280	$9,072

The following table summarizes stock option activity during the six months ended June 30, 2017:

	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, 2016	4,474,906	$ 9.05		
Outstanding as of December 31, 2016	7,300,873	$ 12.36		
Granted	1,656,150	$ 12.05		
Cancelled	(800,059)	$ 17.63		
Exercised	(663,690)	$ 3.51		
Outstanding as of June 30, 2017	7,493,274	$ 12.52	7.4	$ 23.5
Vested and exercisable as of June 30, 2017	4,388,397	$ 10.51	6.3	$ 22.5

As of June 30, 2017, we expected to recognize $28,659,000 of stock-based compensation for outstanding options over a weighted-average period of 2.7 years.

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, 2017:

		Weighted

	Number of Units	Average Grant-Date Fair Value Per Unit
Outstanding as of December 31, 2016	—	$ —
Granted	321,000	$ 12.40
Vested	—	$ —
Cancelled	(33,100)	$ 12.65
Outstanding as of June 30, 2017	287,900	$ 12.37

As of June 30, 2017, we expected to recognize $3,082,000 of stock-based compensation for outstanding restricted stock units over a weighted-average period of 2.5 years.

Table of Contents

Cash received from option exercises under all stock-based payment arrangements for the six months ended June 30, 2017 and 2016 was $2,331,000 and $2,123,000, respectively. For the six months ended June 30, 2016, we recorded net reductions of $934,000 of our federal and state income tax liability, with an offsetting credit to additional paid-in capital, resulting from the excess tax benefits of stock options. Effective January 1, 2017, the adoption of ASU 2016-09 eliminated the recognition of excess tax benefits of stock options in additional paid-in capital. All excess tax benefits and tax deficiencies on stock-based payment awards are recognized as income tax expense or benefit in the consolidated statement of operations and comprehensive income (loss). The tax effects of exercised or vested awards are treated as discrete items in the reporting period in which they occur. For additional information, see Note 1, Nature of Business and Basis of Presentation. For the six months ended June 30, 2017, we recorded net reductions of $108,000 of our federal and state income tax liability, with an offsetting credit recorded within income tax expense, resulting from the excess tax benefits of stock options.

8. Net Income (Loss) per Share

Basic net income (loss) per common share is computed by dividing the net income (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 income (loss) per common share (dollars in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Historical net income (loss) per share - Basic				
Numerator:				
Net income (loss)	$(8,184)	$6,027	$(14,708)	$8,317
Denominator:				
Weighted average number of common shares outstanding	72,169,361	71,543,809	72,057,552	71,567,949
Basic net income (loss) per common share	$(0.11)	$0.08	$(0.20)	$0.12
Historical net income (loss) per share - Diluted				
Numerator:				
Net income (loss)	$(8,184)	$6,027	$(14,708)	$8,317
Denominator:				
Weighted average number of common shares outstanding	72,169,361	71,543,809	72,057,552	71,567,949
Effect of dilutive stock options	—	2,509,741	—	2,713,889
Weighted average number of common shares outstanding	72,169,361	74,053,550	72,057,552	74,281,838
Diluted net income (loss) per common share	$(0.11)	$0.08	$(0.20)	$0.11

As we have incurred a net loss for the three and six months ended June 30, 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 5,559,590 and 5,067,070 outstanding stock options as of June 30, 2017 and 2016, respectively.

Table of Contents

9. 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, 2017 and 2016 we had one product line, SUBSYS®. Our chief operating decision-maker evaluates revenues based on product lines.

The following table summarizes our percentage of revenue by route to market (in thousands):

	Percent of Revenue by Route to Market							
	Three Months Ended June 30,				Six Months Ended June 30,			
	2017		2016		2017		2016	
Pharmaceutical wholesalers	59	%	69	%	62	%	71	%
Specialty pharmaceutical retailers	41	%	31	%	38	%	29	%
	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 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. Product shipments to our four largest pharmaceutical wholesalers accounted for 18%, 17%, 16% and 13% of total shipments and product shipments to one specialty pharmaceutical retailer accounted for 29% of total shipments for the six months ended June 30, 2016. Our three largest pharmaceutical wholesalers' accounts receivable balances accounted for 29%, 18% and 11% of gross accounts receivable and our two largest specialty pharmaceutical retailers' accounts receivable balances accounted for 20% and 15% of gross accounts receivable balance as of June 30, 2017. Our four largest pharmaceutical wholesalers' accounts receivable balances accounted for 36%, 23%, 21% and 13% of gross accounts receivable balance as of December 31, 2016.

Table of Contents

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, 2016, 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, 2016.

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® 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; that we may pursue strategies relating to synthetic cannabidiol; 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 status as a controlled company; that research and development and operating costs will increase; that our investments in our sales and research and development infrastructure will result in increased sales; accounting estimates and the impact of new or recently issued accounting pronouncements; that cash flows from operations will increase and/or stabilize 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," "v and similar expressions 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, 2016. 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™;

Table of Contents

- market acceptance, including by third-party payers, of our products;
- the unpredictability and regulation surrounding the reimbursement of SUBSYS® by third-party payers;
- the success of our sales and marketing strategies;
- our ability to manage growth 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;
- 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 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 adverse impacts of strategic transactions;
- our exposure to product liability claims;
- our ability to comply with environmental laws relating to our use of hazardous materials;
- security system failures;
- 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;

Table of Contents

- 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;
- control over the Company by its founder, director and principal stockholder;
- fluctuation in the price of our common stock;
- 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 our exemptions from certain Nasdaq independence rules because of our status as a “controlled company”; 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, 2017, we have one commercially marketed product and one product which received FDA approval in July 2016 and final labeling approval by the FDA in May 2017:

- 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. 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® through our U.S.-based field sales force focused on supportive care physicians. Consistent with most pharmaceutical manufacturing companies, we sell SUBSYS® primarily to pharmaceutical wholesalers and collect sales proceeds from those wholesalers. For the six months ended June 30, 2017, sales to our three largest wholesale customers accounted for 53% of gross revenue. We also sell SUBSYS® directly to certain specialty pharmaceutical retailers who distribute our product. For the six months ended June 30, 2017, direct sales to our two largest specialty pharmaceutical retailers accounted for 38% of gross revenue. We do not own or have any ownership stake in any pharmaceutical wholesaler or specialty

28

Table of Contents

pharmacy, nor do we have an option to acquire any wholesaler or specialty pharmacy. All pharmacies that fulfill SUBSYS® prescriptions are fully independent. Our relationships with every pharmacy that fulfills SUBSYS® 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, 2017, over 420 independent pharmacies have fulfilled at least one SUBSYS® prescription.

Our sales of, and revenue from, SUBSYS® 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 and consistently implement efforts to control these costs, which efforts include, but are not limited to, establishing excluded or preferred drug lists. SUBSYS® has been, and will likely continue to be, subject to these restrictions and impediments from third-party payers, particularly PBMs and private health insurers. We provide administrative reimbursement support assistance, in large part through our patient services hub, to help patients coordinate with their insurance companies.

We are also developing other product candidates, such as cannabinoid line extensions and sublingual spray product candidates.

We produce the API for SYNDROS™ at our U.S.-based, state-of-the-art dronabinol manufacturing facility. We believe that this facility has the capacity to supply sufficient commercial quantities of dronabinol API for our initial launch quantities of SYNDROS™ and support the continued development of our other dronabinol product candidates in the near-term. However, 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. On April 23, 2015, we announced that we had commenced dosing of epilepsy patients in a Phase I PK study in pediatric subjects. We intend to file an IND application with the FDA for the treatment of epilepsy.

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, and our ability to successfully develop product candidates, and complete related regulatory processes. 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, particularly as our operations and product opportunities continue to grow at a rapid pace. While each of these areas presents significant opportunities for us, they also pose significant risks and challenges that we must successfully address.

Approved Product Sales. Our operating results will depend significantly upon our, and any of our third-party distributors', sales of approved products. During the six months ended June 30, 2017, all of our net revenues were generated from the sale of our approved product, SUBSYS®. 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®. 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 89% of prescriptions as of June 30, 2017. 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 QuintilesIMS, a worldwide integrated information and technology health care service provider, the total market for TIRF products for the three months ended June 30, 2017 was approximately 11,300 prescriptions and we estimate SUBSYS® prescriptions were approximately 34% of the TIRF market, compared to a total market for TIRF products of approximately 21,000 prescriptions and approximately 44% SUBSYS® market share for the three months ended June 30, 2016.

Table of Contents

The continuing and heightened publicity surrounding the national opioid epidemic continues to result in sensitivity by some 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. Moreover, ongoing state and federal investigations into our sales, marketing and other commercial practices and developments and media reports that may arise in connection with such investigations may negatively affect our relationships with health care professionals and pharmacies and their prescribing or dispensing habits. Consequently, these current and potential future events have affected and will likely continue to affect, the manner in which, and the situations when, SUBSYS® is being prescribed, dispensed and approved for coverage. 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 2017 SUBSYS® revenue at similar levels when compared to 2016. In addition, for the same reasons, we anticipate that we will experience future declines in SUBSYS® revenue for the remainder of 2017 when compared to prior quarters in 2016.

Third Party Payer Interactions and Government Programs Associated with Reimbursement. Our interaction with 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. 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, effective January 1, 2015, in connection with its national preferred formulary. Other PBMs may take similar actions 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.

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. For example, as of June 30, 2017, we had 212 full-time sales and marketing personnel. This will lead to corresponding increases in our operating expenses, although we anticipate that these investments will result in increased product sales and net revenue. In addition, 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 will also 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 $27.0 million and $41.9 million for the six months ended June 30, 2017 and 2016, respectively. As of June 30, 2017, we had 57 full-time research and development personnel. We expect research and development expenses to increase as we continue 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.

Table of Contents

Basis of Presentation

Net Revenue

We sell SUBSYS® in packages of various sized single-dose units in dosage strengths of 100, 200, 400, 600, 800, 1,200 and 1,600 mcg 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 record revenue for SUBSYS® at the time the customer receives the shipment.

Cost of Revenue, Gross Profit and Gross Margin

Cost of revenue consists primarily of materials, third-party manufacturing costs, freight in, 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.

Sales and Marketing Expenses

Our sales and marketing expenses consist primarily of salaries, commissions, benefits, consulting fees, costs of obtaining prescription and market data, and market research studies related to SUBSYS®. As of June 30, 2017, we had 212 full-time sales and marketing personnel. We expect our sales and marketing expenses, along with our research and development expenses, to be our largest categories of operating expenses for the foreseeable future. In addition, 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 SUBSYS® net revenue. We will also incur expenses directly related to the launch of SYNDROS™.

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 and investigative sites, third-party manufacturers and consultants;
- employee-related expenses, which include salaries, benefits and stock-based compensation for the personnel involved in our preclinical and clinical drug development activities; and
- facilities, depreciation and other allocated expenses, equipment and laboratory supplies.

To date, our research and development efforts have been focused primarily on our fentanyl, dronabinol, buprenorphine and cannabidiol programs. As of June 30, 2017, we had 57 full-time research and development personnel. We expect research and development expenses to increase as we continue 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 and preclinical and clinical results of each product candidate and related regulatory action.

Table of Contents

The following table provides a breakdown of our research and development expenses during the six months ended June 30, 2017 and 2016 (in millions):

	Six Months Ended June 30,	
	2017	2016
Cannabidiol	$4.5	$8.4
Buprenorphine	2.2	7.2
Fentanyl	2.1	3.2
LEP-ETU and IL-13	0.2	2.2
Naloxone	0.6	1.8
Dronabinol	1.3	1.7
Ondansetron	0.2	0.8
Buprenorphine/Naloxone	0.5	0.6
Sildenafil	0.1	0.4
Internal research and development costs	13.8	14.8
Other	1.5	0.8
Total research and development expenses	$27.0	$41.9

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, accounting, legal, business development and internal support functions. In addition, general and administrative expenses include facility costs not otherwise included in research and development expenses and professional fees for legal, consulting and accounting services. As of June 30, 2017, we had 43 full-time general and administrative personnel. We expect general and administrative expense to modestly increase as a result of expanding our operating activities and the costs we will incur operating as a public company. We expect these increases to include salaries and related expenses, legal and consultant fees, regulatory fees as new products are commercialized, accounting fees, director fees, increased directors' and officers' insurance premiums, fees for investor relations services, and enhanced business and accounting systems.

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

There were no changes in our significant accounting policies and estimates during the six months ended June 30, 2017 from those set forth in “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Significant Accounting Policies and Estimates” in our Annual Report on Form 10-K for the year ended December 31, 2016.

Table of Contents

Results of Operations

Comparison of Three Months Ended June 30, 2017 to Three Months Ended June 30, 2016

The following table presents certain selected consolidated financial data for the three months ended June 30, 2017 and 2016, expressed as a percentage of net revenue:

	Three Months Ended June 30,	
	2017	2016
Net revenue	100.0%	100.0%
Cost of revenue	9.2	9.1
Gross profit	90.8	90.9
Operating expenses:		
Sales and marketing	31.2	28.4
Research and development	33.1	33.1
General and administrative	40.2	20.1
Charges related to litigation award and settlements	10.5	—
Total operating expenses	115.0	81.6
Operating income (loss)	(24.2)	9.3
Other income:		
Interest income	1.1	0.4
Other income (expense), net	—	—
Total other income	1.1	0.4
Income (loss) before income taxes	(23.1)	9.7
Income tax expense (benefit)	(3.9)	1.0
Net income (loss)	(19.2)%	8.7 %

Table of Contents

Net Revenue. Net revenue decreased $26.6 million, or 38.5%, to $42.6 million for the three months ended June 30, 2017, compared to $69.2 million for the three months ended June 30, 2016. The decrease in net revenue was attributable to a decrease in net revenue of SUBSYS®, which was the result of a 34.0% decrease in SUBSYS® shipments to pharmaceutical wholesalers and specialty pharmaceutical retailers for the three months ended June 30, 2017 due primarily to reduced demand for SUBSYS®, as compared to the three months ended June 30, 2016, combined with a 5.8% 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 2016, July 2016, and January 2017. Provisions for patient discounts, wholesaler discounts, rebates, and returns were $2.4 million, $4.1 million, $7.8 million, and $1.3 million, respectively, or 26.9% on a combined basis of gross revenue from the sale of SUBSYS® for the three months ended June 30, 2017, compared to $24.0 million, $9.2 million, $9.2 million, and $0.5 million, respectively, or 38.3% on a combined basis of gross revenue from the sale of SUBSYS® for the three months ended June 30, 2016. The decrease in product sales allowances was primarily attributable to lower volumes of patient assistance during the three months ended June 30, 2017 as compared to the three months ended June 30, 2016. 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, and 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 2017 when compared to 2016. In addition, for the same reasons, we anticipate that we will experience future declines in SUBSYS® revenue for the remainder of 2017 when compared to prior quarters in 2016.

Cost of Revenue, Gross Profit and Gross Margin. Cost of revenue decreased $2.4 million to $3.9 million for the three months ended June 30, 2017 compared to $6.3 million for the three months ended June 30, 2016. The decrease in cost of revenue was primarily attributable to the decrease in sales of SUBSYS® during the three months ended June 30, 2017. Gross profit decreased $24.2 million to $38.7 million for the three months ended June 30, 2017 compared to $62.9 million for the three months ended June 30, 2016 due primarily to the decrease in sales of SUBSYS®. Also contributing to the decrease in gross profit was an increase in the inventory obsolescence reserve of $0.9 million for the three months ended June 30, 2017 compared to $0.6 million for the three months ended June 30, 2016. Gross margin for the three months ended June 30, 2017 remained flat at approximately 91% compared to the three months ended June 30, 2016.

Sales and Marketing Expense. Sales and marketing expense decreased $6.4 million to $13.3 million for the three months ended June 30, 2017 compared to $19.7 million for the three months ended June 30, 2016. The decrease in sales and marketing expense was due primarily to the decrease in sales of SUBSYS®.

Research and Development Expense. Research and development expense decreased $8.8 million to $14.1 million for the three months ended June 30, 2017 compared to $22.9 million for the three months ended June 30, 2016. The decrease in research and development expense was primarily due to decreases in research and development personnel and clinical and development expenses.

General and Administrative Expense. General and administrative expense increased $3.2 million to $17.1 million for the three months ended June 30, 2017 compared to $13.9 million for the three months ended June 30, 2016. The increase in general and administrative expense was due primarily to increases in legal expense incurred in connection with various ongoing government investigation and subpoena related matters and general and administrative personnel costs.

Charges Related to Litigation Award and Settlements. 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. There was no similar charge for the three months ended June 30, 2016.

Income Tax Expense (Benefit). Provision for income taxes was $(1.7) million for the three months ended June 30, 2017, representing an effective tax benefit of 16.8%, as compared to $0.7 million for the three months ended June 30, 2016, representing an effective tax expense rate of 10.0%. The change in the effective rate for the period ended June 30, 2017, compared with the same period in the previous year was due principally to the favorable rate impact of the income tax credits and the current period loss. As of June 30, 2017, we had approximately $1.1 million of federal and $273.8 million of state net operating loss carry forwards.

We had unrecognized tax benefits of approximately $10.2 million as of June 30, 2017, primarily associated with tax positions taken in prior years. No significant penalties and approximately $1.0 million of interest are included in income taxes and accounted for on the balance sheet related to unrecognized tax positions.

Table of Contents

Comparison of Six Months Ended June 30, 2017 to Six Months Ended June 30, 2016

The following table presents certain selected consolidated financial data for the six months ended June 30, 2017 and 2016, expressed as a percentage of net revenue:

	Six Months Ended June 30,	
	2017	2016
Net revenue	100.0%	100.0%
Cost of revenue	10.9	8.4
Gross profit	89.1	91.6
Operating expenses:		
Sales and marketing	36.9	30.5
Research and development	34.3	32.3
General and administrative	41.0	22.1
Charges related to litigation award and settlements	5.7	—
Total operating expenses	117.9	84.9
Operating income (loss)	(28.8)	6.7
Other income:		
Interest income	1.1	0.4
Other income (expense), net	0.1	—
Total other income	1.2	0.4
Income (loss) before income taxes	(27.6)	7.1
Income tax expense (benefit)	(8.9)	0.7
Net income (loss)	(18.7)%	6.4 %

Net Revenue. Net revenue decreased $51.1 million, or 39.4%, to $78.5 million for the six months ended June 30, 2017, compared to $129.6 million for the six months ended June 30, 2016. The decrease in net revenue was attributable to a decrease in net revenue of SUBSYS®, which was the result of a 34.7% decrease in SUBSYS® shipments to pharmaceutical wholesalers and specialty pharmaceutical retailers for the six months ended June 30, 2017 due primarily to reduced demand for SUBSYS®, as compared to the six months ended June 30, 2016, combined with a 5.4% 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 2016, July 2016, and January 2017. Provisions for patient discounts, wholesaler discounts, rebates, and returns were $7.0 million, $7.7 million, $15.9 million, and $1.0 million, respectively, or 28.6% on a combined basis of gross revenue from the sale of SUBSYS® for the six months ended June 30, 2017, compared to $40.1 million, $15.9 million, $17.6 million, and $(0.1) million, respectively, or 36.2% on a combined basis of gross revenue from the sale of SUBSYS® for the six months ended June 30, 2016. The decrease in product sales allowances was primarily attributable to lower volumes of patient assistance during the six months ended June 30, 2017 as compared to the six months ended June 30, 2016. 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, and 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 2017 when compared to 2016. In addition, for the same reasons, we anticipate that we will experience future declines in SUBSYS® revenue for the remainder of 2017 when compared to prior quarters in 2016.

Cost of Revenue, Gross Profit and Gross Margin. Cost of revenue decreased $2.3 million to $8.6 million for the six months ended June 30, 2017 compared to $10.9 million for the six months ended June 30, 2016. The decrease in cost of revenue was primarily attributable to the decrease in sales of SUBSYS® during the six months ended June 30, 2016. Gross profit decreased $48.7 million to $70.0 million for the six months ended June 30, 2017 compared to $118.7 million for the six months ended June 30, 2016 due primarily to the decrease in sales of SUBSYS®. Also contributing to the decrease in gross profit was an increase in the inventory obsolescence reserve of $3.0 million for the six months ended June 30, 2017 compared to $0.6 million for the six months ended June 30, 2016. Gross margin for the six months ended June 30, 2017 was approximately -89% compared to approximately 92% for the six months ended June 30, 2016.

Sales and Marketing Expense. Sales and marketing expense decreased $10.5 million to $29.0 million for the six months ended June 30, 2017 compared to $39.5 million for the six months ended June 30, 2016. The decrease in sales and marketing expense was due primarily to the decrease in sales of SUBSYS®.

Table of Contents

Research and Development Expense. Research and development expense decreased $14.9 million to $27.0 million for the six months ended June 30, 2017, compared to $41.9 million for the six months ended June 30, 2016. The decrease in research and development expense was primarily due to decreases in research and development personnel and clinical and development expenses.

General and Administrative Expense. General and administrative expense increased $3.6 million to $32.2 million for the six months ended June 30, 2017 compared to $28.6 million for the six months ended June 30, 2016. The increase in general and administrative expense was due primarily to increases in legal expense incurred in connection with various ongoing government investigation and subpoena related matters and general and administrative personnel costs. The increase in legal and personnel costs were offset by a decrease in stock-based compensation costs.

Charges Related to Litigation Award and Settlements. 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. There was no similar charge for the six months ended June 30, 2016.

Income Tax Expense (Benefit). Provision for income taxes was $(7.0) million for the six months ended June 30, 2017, representing an effective tax benefit of 32.2%, as compared to $0.9 million for the six months ended June 30, 2016, representing an effective tax expense rate of 9.8%. The change in the effective rate for the period ended June 30, 2017, compared with the same period in the previous year was due principally to the favorable rate impact of the income tax credits and the current period loss. As of June 30, 2017, we had approximately $1.1 million of federal and $273.8 million of state net operating loss carry forwards.

We had unrecognized tax benefits of approximately $10.2 million as of June 30, 2017, primarily associated with tax positions taken in prior years. No significant penalties and approximately $1.0 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,	
	2017	2016
Net cash provided by (used in) operating activities	$(27.2)	$8.3
Net cash used in investing activities	(30.7)	(7.0)
Net cash provided by (used in) financing activities	3.1	(11.5)
Net decrease in cash and cash equivalents	(54.8)	(10.2)
Cash and cash equivalents, beginning of period	104.6	79.5
Cash and cash equivalents, end of period	$49.8	$69.3

Cash Flows From Operating Activities. Net cash used in operating activities was $27.2 million for the six months ended June 30, 2017, as compared to net cash provided by operating activities of $8.3 million for the six months ended June 30, 2016. The net cash used during the six months ended June 30, 2017 primarily reflects the net loss for the period driven by a reduction in SUBSYS® net sales, adjusted in part by depreciation and amortization and stock-based compensation expense, and is also impacted by changes in working capital and payments in connection with the settlement of the investigation by the State of New Hampshire.

Cash Flows From Investing Activities. Net cash used in investing activities was $30.7 million and $7.0 million for the six months ended June 30, 2017 and 2016, respectively, and consists primarily of the purchase of investments and property and equipment.

Table of Contents

Cash Flows From Financing Activities. Net cash provided by financing activities was $3.1 million for the six months ended June 30, 2017, as compared to net cash used in financing activities of $11.5 million for the six months ended June 30, 2016. During the six months ended June 30, 2017, we recorded 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. During the six months ended June 30, 2016, we expended approximately $16.1 million to repurchase shares of our common stock, partially offset by excess tax benefits on stock options and awards of $0.9 million, proceeds from the exercise of stock options of $2.1 million and proceeds from shares issued under our employee stock purchase plan of $1.6 million.

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

Our cash flows for 2017 and beyond will depend on a variety of factors, including sales of SUBSYS® and our launch of SYNDROS™, regulatory approvals, investments in manufacturing and production, capital equipment, and research and development. We expect our net cash flows from operating activities to fluctuate with the sales of SUBSYS® and SYNDROS™, partially offset by anticipated expansion in research and development, manufacturing, and general and administrative expenses.

Funding Requirements

We had cash, cash equivalents and marketable securities of $203.2 million and $237.0 million at June 30, 2017 and December 31, 2016, respectively, available to fund operations. We believe that our pre-existing cash and cash equivalents and investments, together with interest thereon, will be sufficient to fund our projected operating requirements for at least the next 12 months based upon our current operational plan, budget and spending assumptions.

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;
- 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.

In the ordinary course of business, we are involved in litigation, claims, government inquiries, investigations, charges and proceedings. Refer to Note 6 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.

37

Table of Contents

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 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 $20.8 million to $9.0 million through December 21, 2022.

Off-Balance Sheet Arrangements

During the six months ended June 30, 2017, 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, 2017, $34.8 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 $153.0 million as of June 30, 2017, and $133.1 million as of December 31, 2016. 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.

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, 2017

	Remainder of 2017	2018	2019	2020	2021	Thereafter
CD's and Available-for-sale securities	$ 54.5	$64.8	$30.4	$3.3	$ —	$ —
Weighted-average yield rate	0.39 %	0.57%	0.29%	0.04%	—	—

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.

Table of Contents

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. As disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016, we did not have effective policies and procedures, or timely and effective reviews by personnel at an appropriate level, for accounting for the rebates component of our product sales allowances and the allowance for excess and obsolete inventory in accordance with U.S. GAAP. We did not have controls designed to validate the completeness and accuracy of underlying data used in the determination of these significant estimates. Overall the management in the finance and accounting group did not display adequate tone at the top with respect to judgment and rigor required to resolve the accounting for the rebates component of our product sales allowances. As a result, our Chief Executive Officer and Chief Financial Officer identified material weaknesses in our internal control over financial reporting as of December 31, 2016, and have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were not effective. To address these material weaknesses, we have taken steps to address the underlying causes of the material weaknesses as described further below under “Remediation Efforts to Address Material Weaknesses in Internal Control over Financial Reporting.” We believe that the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q do fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented as a result of the following highly substantive validation steps taken: undertook a comprehensive review of all information available, assessed the completeness and accuracy of information utilized in the models and ensured the most current information was utilized in our analyses.

Change in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting, other than that disclosed below under “Remediation Efforts to Address Material Weaknesses in Internal Control over Financial Reporting,” that occurred during the quarterly period ended June 30, 2017, 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.

Remediation Efforts to Address Material Weaknesses in Internal Control over Financial Reporting

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the company’s annual or interim financial statements will not be prevented or detected on a timely basis. We have, and continue to, identify and implement actions to improve our internal control over financial reporting and disclosure controls and procedures. With the oversight of our audit committee, we have begun taking steps and plan to take additional measures to remediate the

underlying causes of identified the material weaknesses as set forth below:

- We have increased resources within our organization, including some key hires in the finance department to develop and implement continued improvements and enhancements to address the overall deficiencies that led to the material weaknesses. More specifically, with the oversight of the audit committee, significant personnel changes were made including the hiring of a new President and Chief Executive Officer (on April 17, 2017) and a new Chief Financial Officer (announced on July 18, 2017). In addition, a new Vice President of Managed Markets was hired with expertise around industry practices in rebates and managed care contracts. We have also hired a Director for pricing and contracting in the managed care organization. All of these executives have significant pharmaceutical industry experience and these hires resulted from a comprehensive national search process conducted by an outside recruiting firm. In addition to the above executive hires, since April 2017, we created a new position for an accounting manager within the finance department, who we

Table of Contents

hired along with two senior accountants to ensure that we have a sufficient complement of finance personnel within the accounting function responsible for the completeness and accuracy of underlying data used in the determination of significant estimates. As these employees integrate into our organization, we plan to review our policies and procedures around internal controls. We believe these personnel changes are overarching remedial measures that are assisting us with each of the material weaknesses including establishing effective policies and procedures, accomplishing timely and effective reviews by personnel at an appropriate level and ensuring that we have addressed tone at the top with respect to judgment and appropriate rigor.

- With respect to maintaining and establishing effective policies and procedures, we have also taken additional steps of engaging external accounting consultants to review and assist with the documentation of policies and procedures related to our product sales allowances and an external legal consultant to review our managed care contracts with oversight of the managed care review by our new Vice President of Managed Markets. As we integrate our new personnel, we intend to implement a cross-functional review process that includes communication with and sign-off by the finance, managed markets and legal departments to ensure proper process and accounting for rebates and other managed markets concepts.
    - We intend to hire a Plant Controller to oversee and monitor plant accounting and financial reporting activities including maintaining effective policies and procedures. Once the position is filled, we intend to implement a cross-functional review process between finance, the manufacturing department and our sales group to facilitate the timely receipt of information related to our current and future inventory levels, current business trends, projected sales and the resulting inventory allowance requirements.
- As we integrate our new personnel, we anticipate additional steps will be added to our remedial efforts as we continue to test the operating effectiveness of our processes and controls, including with respect to significant estimates related to accounting for the rebate component of our product sales allowances and the allowance for excess and obsolete inventory in accordance with U.S. GAAP throughout the rest of fiscal 2017 to assess whether such processes and controls are operatively effective, which we anticipate will include implementing additional training for our finance, managed markets and manufacturing groups and implementing cross-functional review processes with respect to rebates and other similar managed markets concepts and inventory obsolescence. We will be implementing a new standard operating procedure process on a monthly basis with finance, manufacturing, sales, managed care, and legal to review product sales allowances and the allowance for excess and obsolete inventory.

The material costs associated with the above remedial actions and planned actions include ongoing compensation expenses for newly hired personnel and engagement fees for third party consultants to assist with the design and implementation of the new processes and controls. We do not anticipate that we will incur any additional material costs, other than ongoing compensation and consultant fees, to implement these remediation efforts.

Risks and Inherent Limitations

While we believe we will remediate the material weaknesses prior to filing our Form 10-K for the period ending December 31, 2017, we can provide no assurance at this time that management will be able to report that our internal control over financial reporting is effective as of December 31, 2017. Prior to the complete remediation of these material weaknesses, there remains risk that the processes and procedures on which we currently rely, even as improved or adjusted, will fail to be sufficiently effective, which could result in material misstatement of our financial position or results of operations and require a restatement. Moreover, because of the inherent limitations in all control systems, no evaluation of controls—even where we conclude the controls operate effectively—can provide absolute assurance that all control issues, including instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will

succeed in achieving its stated goals under all potential future conditions. Over time, our control systems, as we develop them, may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and may not be detected and could be material to our financial statements.

Table of Contents

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The information contained in Note 6 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, 2016, 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

Share Repurchase Program

On November 5, 2015, we announced a stock repurchase program which authorizes up to $50 million in repurchases of common stock. This program was effective immediately and has no planned expiration date. As of June 30, 2017, we had $17.4 million remaining under this program. There were no repurchases of our common stock during the six months ended June 30, 2017.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

The Exhibit Index immediately following the Signatures to this Form 10-Q is hereby incorporated by reference into this Form 10-Q.

Table of Contents

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 4, 2017 By: /s/ Saeed Motahari
Saeed Motahari
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Darryl S. Baker
Darryl S. Baker
Chief Financial Officer
(Principal Financial and Accounting Officer)

Table of Contents

EXHIBIT INDEX

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)
10.1	Amendment to Supply, Development and Exclusive Licensing Agreement, dated as of April 6, 2017, by and between the Registrant and AptarGroup, Inc. (filed herewith)
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.