Sucampo Pharmaceuticals, Inc.
Form 10-Q
May 03, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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: 001-33609

SUCAMPO PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	30-0520478 (I.R.S. Employer Identification No.)
805 King Farm Boulevard, Suite 550 Rockville, MD (Address of principal executive offices)	20850 (Zip Code)

(301) 961-3400

(Registrant's telephone number,
including area code)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the 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 Smaller reporting company Emerging growth company
(Do not check if a smaller reporting company)

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of April 26, 2017, there were 46,464,934 shares of the registrant's class A common stock outstanding.

1

Sucampo Pharmaceuticals, Inc.

Form 10-Q Index

PART I — FINANCIAL INFORMATION

Item 1. ***Financial Statements***

SUCAMPO PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(In thousands, except share and per share data)

	March 31, 2017 (unaudited)	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 243,480	$ 198,308
Product royalties receivable	18,426	26,261
Accounts receivable, net	20,537	42,998
Restricted cash	213	213
Inventories, net	22,978	23,468
Prepaid expenses and other current assets	16,725	15,984
Total current assets	322,359	307,232
Investments, non-current	5,556	5,495
Property and equipment, net	6,197	6,216
Intangible assets, net	121,381	128,134
Goodwill	73,022	73,022
Other assets	688	752
Total assets	$ 529,203	$ 520,851
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 8,006	$ 9,190
Accrued expenses	17,096	12,389
Accrued interest	2,538	129
Deferred revenue, current	834	1,315
Income tax payable	3,477	7,153
Other current liabilities	2,876	2,175
Total current liabilities	34,827	32,351
Notes payable, non-current	290,979	290,516
Deferred revenue, non-current	1,572	805
Deferred tax liability, net	18,375	21,289
Other liabilities	9,142	8,791
Total liabilities	354,895	353,752
Commitments and contingencies (note 11)		

Stockholders' equity:		
Preferred stock, $0.01 par value; 5,000,000 shares authorized at March 31, 2017 and December 31, 2016; no shares issued and outstanding at March 31, 2017 and December 31, 2016	-	-
Class A common stock, $0.01 par value; 270,000,000 shares authorized at March 31, 2017 and December 31, 2016; 46,464,559 and 46,415,749 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	464	464
Class B common stock, $0.01 par value; 75,000,000 shares authorized at March 31, 2017 and December 31, 2016; no shares issued and outstanding at March 31, 2017 and December 31, 2016	-	-
Additional paid-in capital	123,984	120,251
Accumulated other comprehensive income	54,451	54,527
Treasury stock, at cost; 3,009,942 shares at March 31, 2017 and December 31, 2016	(46,269)	(46,269)
Retained earnings	41,678	38,126
Total stockholders' equity	174,308	167,099
Total liabilities and stockholders' equity	$529,203	$520,851

The accompanying Notes are an integral part of these Condensed Consolidated Financial Statements.

SUCAMPO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Income (Unaudited)

(In thousands, except per share data)

	Three Months Ended March 31,	
	2017	2016
Revenues:		
Product royalty revenue	$ 18,435	$ 16,716
Product sales revenue	34,154	26,595
Research and development revenue	3,448	3,430
Contract and collaboration revenue	246	467
Total revenues	56,283	47,208
Costs and expenses:		
Costs of goods sold	16,883	23,338
Research and development	10,333	14,671
General and administrative	17,691	8,927
Selling and marketing	516	775
Total costs and expenses	45,423	47,711
Income (loss) from operations	10,860	(503)
Non-operating income (expense):		
Interest income	28	25
Interest expense	(2,890)	(6,270)
Other income (expense), net	211	(347)
Total non-operating expense, net	(2,651)	(6,592)
Income (loss) before income taxes	8,209	(7,095)
Income tax (provision) benefit	(3,585)	3,038
Net income (loss)	$ 4,624	$ (4,057)
Net income (loss) per share:		
Basic	$ 0.11	$ (0.10)
Diluted	$ 0.10	$ (0.10)
Weighted average common shares outstanding:		
Basic	43,442	42,539
Diluted	62,107	42,539
Comprehensive income		
Net income (loss)	$ 4,624	$ (4,057)
Other comprehensive income (expense):		
Unrealized gain (loss) on pension benefit obligation	1	(8)
Foreign currency translation gain (loss)	(77)	15,555
Comprehensive income	$ 4,548	$ 11,490

The accompanying Notes are an integral part of these Condensed Consolidated Financial Statements.

SUCAMPO PHARMACEUTICALS, INC.

Condensed Consolidated Statement of Changes in Stockholders' Equity (Unaudited)

(In thousands, except share data)

	Class A Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Treasury Stock	
	Shares	Amount	Capital	Income	Shares	Amou
Balance at December 31, 2016	46,415,749	$464	$120,251	$54,527	3,009,942	$(46,2
Stock-based compensation expense	-	-	3,425	-	-	-
Stock issued upon exercise of stock options	41,472	-	240	-	-	-
Stock issued under employee stock purchase plan	7,338	-	68	-	-	-
Unrealized gain on pension benefit obligation	-	-	-	1	-	-
Foreign currency translation	-	-	-	(77)	-	-
Cumulative-effect adjustment from adoption of ASU 2016-09			-	-		
Net income	-	-	-	-	-	-
Balance at March 31, 2017	46,464,559	$464	$123,984	$54,451	3,009,942	$(46,2

The accompanying Notes are an integral part of these Condensed Consolidated Financial Statements.

SUCAMPO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows (Unaudited)

(In thousands)

	Three Months Ended March 31,	
	2017	2016
Cash flows from operating activities:		
Net income (loss)	$ 4,624	$ (4,057)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	7,422	15,573
Deferred tax provision	(2,915)	2,347
Stock-based compensation	2,352	1,971
Unrealized currency translations	151	4,226
Changes in operating assets and liabilities:		
Product royalties receivable	7,835	6,292
Accounts receivable	22,461	7,291
Inventory	490	1,774
Prepaid and income taxes receivable and payable, net	(3,677)	(3,177)
Accounts payable	(1,184)	(6,266)
Accrued expenses	4,707	(2,067)
Accrued interest payable	2,410	4,743
Deferred revenue	286	58
Collaboration obligation	-	(425)
Other assets and liabilities, net	318	(4,546)
Net cash provided by operating activities	45,280	23,737
Cash flows from investing activities:		
Convertible note receivable	-	(5,000)
Changes in restricted cash	-	10,598
Payment of squeeze-out liability for non-tendering R-Tech shareholders	-	(8,213)
Purchases of property and equipment	(350)	(735)
Net cash used in investing activities	(350)	(3,350)
Cash flows from financing activities:		
Payments of notes payable	-	(17,574)
Changes in restricted cash	-	17,676
Proceeds from exercise of stock options	240	757
Proceeds from employee stock purchase plan	68	58
Net cash provided by financing activities	308	917
Effect of exchange rates on cash and cash equivalents	(66)	489
Net increase in cash and cash equivalents	45,172	21,793
Cash and cash equivalents at beginning of period	198,308	108,284
Cash and cash equivalents at end of period	$ 243,480	$ 130,077

The accompanying Notes are an integral part of these Condensed Consolidated Financial Statements.

6

1. Business Organization and Basis of Presentation

Description of the Business

Sucampo Pharmaceuticals, Inc., (Company) is a global biopharmaceutical company focused on developing, identifying, acquiring and bringing to market innovative medicines that meet unmet medical needs. Our primary focus areas are medicines that treat gastrointestinal, ophthalmic, neurological, and oncology disorders.

The Company currently generates revenue mainly from product royalties, upfront and milestone payments, product sales and reimbursements for development activities. The Company expects to continue to incur significant expenses for the next several years as the Company continues its research and development activities, seeks additional regulatory approvals and additional indications for approved products and other compounds, seeks strategic opportunities for acquiring new products and product candidates.

AMITIZA® (lubiprostone) is being marketed for three gastrointestinal indications under the collaboration and license agreement (as amended in October 2014, the North America Takeda Agreement) with Takeda Pharmaceutical Company Limited (Takeda). These indications are chronic idiopathic constipation (CIC) in adults, irritable bowel syndrome with constipation (IBS-C) in adult women and opioid-induced constipation (OIC) in adults suffering from chronic non-cancer related pain. Under the North America Takeda Agreement, the Company is primarily responsible for clinical development activities, while Takeda is responsible for commercialization of AMITIZA in the United States (U.S.) and Canada. The Company and Takeda initiated commercial sales of AMITIZA in the U.S. for the treatment of CIC in April 2006, for the treatment of IBS-C in May 2008 and for the treatment of OIC in May 2013. Takeda is required to provide a minimum annual commercial investment during the current term of the North America Takeda Agreement and may reduce the minimum annual commercial investment when a generic equivalent enters the market. In October 2015, Health Canada approved AMITIZA for CIC in adults. In October 2014, the Company and Takeda executed amendments to the North America Takeda Agreement which, among other things, extended the term of the North America Takeda Agreement beyond December 2020. During the extended term beginning in January 2021, Takeda and the Company will split the annual net sales revenue of the branded AMITIZA products.

We have also partnered with Par Pharmaceuticals, Inc., or Par, and Dr. Reddy's Laboratories, Ltd., or Dr. Reddy's, in connection with the settlement of patent litigation in the United States related to our AMITIZA 8 mcg and 24 mcg soft gelatin capsule products. Under our agreement with Par, we granted Par a non-exclusive license to market Par's generic version of lubiprostone 8 mcg and 24 mcg soft gelatin capsules in the United States for the indications approved for AMITIZA beginning January 1, 2021, or earlier under certain circumstances. Beginning on January 1, 2021, Par will split with us the gross profits of the licensed products sold during the term of the agreement, which continues until each of our related patents has expired. Under our agreement with Dr. Reddy's, we granted Dr. Reddy's a non-exclusive license to market Dr. Reddy's generic version of lubiprostone 8 mcg and 24 mcg soft gelatin capsules in the United States for the indications approved for AMITIZA. This license does not begin until more than six years

from November 9, 2016, or earlier under certain circumstances. Dr. Reddy's will pay to us a share of net profits of generic lubiprostone products sold during the term of the agreement, which decreases over time and ends when all of our related patents have expired. In the event that either Par or Dr. Reddy's elect to launch an authorized generic form of lubiprostone, we have agreed to supply such product under the terms of a manufacturing and supply agreement at a negotiated price.

In Japan, AMITIZA is marketed under a license, commercialization and supply agreement (the Japan Mylan Agreement) that was transferred to Mylan, Inc. (Mylan) from Abbott Laboratories, Inc. (Abbott), as of February 2015, as part of Mylan's acquisition of a product portfolio from Abbott. The Company received approval of its new drug application (NDA) for AMITIZA for the treatment of chronic constipation (CC), excluding constipation caused by organic diseases, from Japan's Ministry of Health, Labour and Welfare in June 2012 and pricing approval in November 2012. AMITIZA is Japan's only prescription medicine for CC. The Company did not experience any significant changes in the commercialization of AMITIZA in Japan as a result of the transfer of the Japan Mylan Agreement from Abbott to Mylan.

In May 2015, the Company entered into an exclusive license, development, commercialization and supply agreement (the China Gloria Agreement) with Harbin Gloria Pharmaceuticals Co., Ltd. (Gloria), for AMITIZA in the People's Republic of China. Under the China Gloria Agreement, Gloria is responsible for all development activities and costs, as well as commercialization and regulatory activities, for AMITIZA in the People's Republic of China. The Company will be the exclusive supplier of AMITIZA to Gloria at an agreed upon supply price. Upon entering into the China Gloria Agreement, the Company received an upfront payment of $1.0 million. In June 2015, the China Food and Drug Administration accepted an Investigational New Drug (IND) application for a pivotal trial of AMITIZA in patients with CIC; as a result, the Company received an additional payment of $500,000 from Gloria. In addition to the $1.5 million in payments received and recognized as revenue through June 2015, the Company is eligible to receive an additional payment in the amount of $1.5 million upon the occurrence of a specified regulatory or commercial milestone event.

In October 2014, the Company entered into an exclusive license, development, commercialization and supply agreement (the Global Takeda Agreement) for lubiprostone with Takeda, through which Takeda has the exclusive rights to further develop and commercialize AMITIZA in all global markets, except the U.S., Canada, Japan and the People's Republic of China. Takeda became the marketing authorization holder in Switzerland in April 2015, in the United Kingdom, Austria, Belgium, Germany, Netherlands, Ireland, Italy, Luxembourg and Spain during 2016.

Before the execution of the Global Takeda Agreement, the Company retained full rights to develop and commercialize AMITIZA for the rest of the world's markets outside of the U.S., Canada and Japan. In the U.K., the Company received approval in September 2012 from the Medicines and Healthcare Products Regulatory Agency (MHRA) for the use of AMITIZA to treat CIC. The Company made AMITIZA available in the U.K. in the fourth quarter of 2013. In July 2014, National Institute of Health and Care Excellence (NICE) published the technology appraisal guidance recommending the use of AMITIZA in the treatment of CIC and associated symptoms in adults who have failed laxatives. In January 2015, the Company successfully completed the European mutual recognition procedure (MRP) for AMITIZA for the treatment of CIC in select European countries, resulting in marketing authorizations in these countries.

In Switzerland, AMITIZA was approved to treat CIC in 2009. In 2012, the Company reached an agreement with the Bundesamt fur Gesundheit, (BAG), the Federal Office of Public Health in Switzerland, on a reimbursement price for AMITIZA in Switzerland, and began active marketing in the first quarter of 2013. In February 2014, the Company announced that the BAG revised several reimbursement limitations with which AMITIZA was first approved for reimbursement and inclusion in the Spezialitätenliste (SL) to allow all Swiss physicians to prescribe AMITIZA to patients who have failed previous treatments with at least two laxatives over a nine-month period. In July 2014, AMITIZA was approved for the treatment of OIC in chronic, non-cancer adult patients by the Swissmedic, the Swiss Agency for Therapeutic Products, and in October 2015, the BAG added this indication to the SL.

In October 2015, Takeda obtained approval of the clinical trial application (CTA) for AMITIZA for the treatment of CIC and IBS-C in Russia that was submitted in June 2015. In December 2015, a CTA was filed for AMITIZA for the treatment of CIC, IBS-C and OIC in Mexico and South Korea. Takeda initiated Phase 3 registration trials in Russia in March 2016 and in South Korea and Mexico in May 2016. An NDA for the treatment of CIC, IBS-C, and OIC was submitted in Israel in June 2015, and approved in July 2016, and in Kazakhstan in December 2015. Additional NDA submissions have been made by Takeda in Singapore in May 2016, and South Africa and Indonesia in June 2016, and are planned in various other markets for 2017 and beyond.

In the U.S., the Company ceased marketing RESCULA in the fourth quarter of 2014 and no product was made available after the March 2015 expiration date. In May 2015, the Company returned all licenses for unoprostone isopropyl to R-Tech. As part of the acquisition of R-Tech in October 2015, the Company acquired all rights to RESCULA. RESCULA is being commercialized by Santen Pharmaceutical Co., Ltd in Japan, and Zuellig Pharma Inc. in Taiwan.

The Company's other clinical development programs include the following:

Lubiprostone Alternate Formulation

The Company has been developing an alternate formulation of lubiprostone for both adult and pediatric patients who are unable to take or do not tolerate capsules and for naso-gastric tube fed patients. Takeda has agreed to fund 100% of the costs, up to a cap, of this alternate formulation work. We initiated the Phase 3 program of the alternate formulation of lubiprostone in adults in the second half of 2016 and, if the program is successful, we intend to file an NDA in the United States for the alternate formulation for adults in the second half of 2017.

Lubiprostone for Pediatric Functional Constipation

The Phase 3 program required to support an application for marketing authorization of lubiprostone for pediatric functional constipation comprises four clinical trials. The first two trials, one of which was recently completed, test the soft gelatin capsule formulation of lubiprostone in patients 6 to 17 years of age. The first of these trials was a pivotal 12-week, randomized, placebo-controlled trial which was initiated in December 2013 and completed enrollment in April 2016. The second trial is a follow-on, long-term safety extension trial that was initiated in March 2014. In November 2016, we announced that the Phase 3 trial of AMITIZA in pediatric functional constipation in children 6 to 17 years of age failed to achieve its primary endpoint of overall spontaneous bowel movement, or SBM, response. The trial achieved statistical significance for some secondary endpoints, notably overall SBM frequency, straining, and stool consistency. In addition, in this study lubiprostone was well tolerated. We have entered into a process with the U.S. Food and Drug Administration, or FDA, and other constituencies, and as a result of initial discussion with the FDA expect to submit a supplemental NDA in the second half of 2017. Additionally, after further consultations with the FDA to better determine the doses and endpoints that should be studied, the Phase 3 program for the alternate formulation of lubiprostone described above will be followed in mid-2018 with a Phase 3 program in patients 6 months to 6 years of age using the alternate formulation. Takeda has agreed to fund 70% of the costs, up to a cap, of this pediatric functional constipation program.

CPP 1-X/Sulindac Combination Product

In January 2016, the Company entered into an option and collaboration agreement under which Cancer Prevention Pharmaceuticals, Inc. (CPP) granted the Company the sole option to acquire an exclusive license to commercialize CPP-1X/sulindac combination product in North America. This product is currently in a Phase 3 clinical trial, which is being conducted by CPP for the treatment of familial adenomatous polyposis (FAP). Under the agreement with CPP, the Company has the exclusive option to license this product in North America. There are currently no approved treatments for FAP. The ongoing Phase 3 study is a 150-patient, three-arm, double-blind, randomized trial of the combination agent and the single agent comparators. Enrollment in the study has completed and the results from a Phase 3 futility analysis are expected to be available mid-2017. Results from the clinical trial are expected at the end of 2018.

VTS-270 for Niemann-Pick Disease Type C1 (NPC-1)

On March 31, 2017, the Company entered into an Agreement and Plan of Merger with Vtesse Inc. ("Vtesse") a privately-held rare disease company. Following the closing of this acquisition on April 3, 2017, the Company gained Vtesse's lead product candidate, known as VTS-270. VTS-270 is a well-characterized mixture of 2-hydroxypropyl-ß-cyclodextrins (HPßCD) with a specific compositional fingerprint that distinguishes it from other HPßCD mixtures. It is administered by an intrathecal infusion to directly address the neurological manifestations of disease. Preclinical and early clinical studies suggest that the administration of VTS-270 may slow or stop certain indicators of NPC-1, an ultra-orphan, progressive and fatal disease caused by a defect in lipid transport within the cell. VTS-270, which is currently in a fully-enrolled pivotal Phase 2b/3 trial, has been granted breakthrough therapy designation in the United States and orphan designation in both the United States and EU. Effective treatment of NPC-1 remains a high unmet need, with no approved products for patients in the United States. Results from the pivotal trial are expected in mid-2018.

The Company expects to account for the transaction as an asset acquisition and expects to incur an acquired in-process research and development charge of $180.0 million to $200.0 million (and no related current tax benefit) in the second quarter of 2017.

Basis of Presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP) and the rules and regulations of the U.S. Securities and Exchange Commission (SEC) for interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company's Consolidated Financial Statements as of and for the year ended December 31, 2016

included in the Company's Annual Report on Form 10-K, which was filed with the SEC on March 8, 2017. The financial information as of March 31, 2017 and for the three months ended March 31, 2017 and 2016 is unaudited. The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by GAAP. In the opinion of the Company's management, all adjustments, consisting only of normal recurring adjustments or accruals, considered necessary for a fair statement of the results of these interim periods have been included. The results of the Company's operations for any interim period are not necessarily indicative of the results that may be expected for any other interim period or for a full fiscal year.

The Condensed Consolidated Financial Statements include the accounts of the Company and its wholly-owned subsidiaries: Sucampo AG (SAG) based in Zug, Switzerland, through which the Company conducts certain of its worldwide and European operations; Sucampo Pharma, LLC (SPL) based in Osaka, Japan, through which the Company conducts its Asian operations, manufacturing and certain development operations; and Sucampo Pharma Americas LLC (SPA), based in Rockville, Maryland, through which the Company conducts its North American operations. All inter-company balances and transactions have been eliminated.

The preparation of financial statements in conformity with GAAP requires management to make estimates that affect the reported amounts of assets and liabilities at the date of the financial statements, disclosure of contingent assets and liabilities, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

2. Summary of Significant Accounting Policies

Certain Risks, Concentrations and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist of cash and cash equivalents, restricted cash and receivables. The Company places its cash, cash equivalents and restricted cash with highly rated financial institutions. As of March 31, 2017 and December 31, 2016, approximately $1.1 million or less than 1%, and $1.2 million or less than 1%, respectively, of the Company's cash, cash equivalents, and restricted cash were issued or insured by the United States government or other government agencies. The Company has not experienced any losses on these accounts related to amounts in excess of insured limits.

Revenues from Takeda, an unrelated party, accounted for 59.1% and 61.5% of the Company's total revenues for the three months ended March 31, 2017 and 2016, respectively. Accounts receivable and product royalties receivable from Takeda accounted for 77.7% and 69.6% of the Company's total accounts receivable and product royalties receivable at March 31, 2017 and December 31, 2016, respectively.

Revenues from another unrelated party, Mylan, accounted for 35.6% and 30.6% of the Company's total revenues for the three months ended March 31, 2017 and 2016, respectively. Accounts receivable from Mylan accounted for 17.5% and 30.1% of the Company's total accounts receivable and product royalties receivable at March 31, 2017 and December 31, 2016, respectively.

The Company depends significantly upon collaborations with Takeda and Mylan, and its activities may be impacted if these relationships are disrupted.

Fair Value of Financial Instruments

The carrying values of the Company's financial instruments approximate their fair values due to their short maturities, independent valuations or internal assessments. The Company's financial instruments include cash and cash

equivalents, restricted cash, receivables, accounts payable and other accrued liabilities. The Company's investment in CPP is measured at fair value on a recurring basis, and the Company estimates the fair value of its long-term debt based on similar types of borrowings.

Variable Interest Entities

The Company performs initial and on-going evaluations of the entities with which it has variable interests, such as equity ownership, in order to identify entities (i) that do not have sufficient equity investment at risk to permit the entity to finance its activities without additional subordinated financial support or (ii) in which the equity investors lack an essential characteristic of a controlling financial interest. Such entities are classified as variable interest entities (VIE's). If an entity is identified as a VIE, the Company performs an assessment to determine whether the Company has both (i) the power to direct activities that most significantly impact the VIE's economic performance and (ii) have the obligation to absorb losses from or the right to receive benefits of the VIE that could potentially be significant to the VIE. If both of these criteria are satisfied, the Company is identified as the primary beneficiary of the VIE. As of March 31, 2017 and December 31, 2016, Cancer Prevention Pharmaceuticals, Inc. ("CPP"), in which the Company held a variable interest, was determined to be a VIE; however, the Company does not have the power to direct CPP's economic performance.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, "Revenue from Contracts with Customers", which will replace numerous requirements in U.S. GAAP, including industry-specific requirements. This guidance provides a five-step model to be applied to all contracts with customers, with an underlying principle that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. ASU No. 2014-09 requires extensive quantitative and qualitative disclosures covering the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including disclosures on significant judgments made when applying the guidance. This guidance is effective for annual reporting periods beginning after December 15, 2017 and interim periods therein. Early adoption is permitted for reporting periods and interim periods therein, beginning after December 15, 2016. An entity can elect to apply the guidance under one of the following two methods: (i) retrospectively to each prior reporting period presented – referred to as the full retrospective method or (ii) retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earning – referred to as the modified retrospective method. While the Company has not yet completed its final review of the impact of the new standard, the adoption of ASU No. 2014-09 could potentially have the following impacts to our contracts:

(i) Variable consideration including milestone payments, escalating royalty payments based on volume, and product sales price adjustments may be recognized at an earlier point in time under the new guidance, when it is probable that the variable consideration will be achieved without a significant future reversal of cumulative revenue expected.

(ii) Expense reimbursement revenue of certain R&D projects may result in a change in presentation.

The Company continues to evaluate the impact of adoption, the implementation approach to be used and the applicable disclosure requirements, which will be significant and quite comprehensive. The Company plans to adopt the new standard effective January 1, 2018, and will continue to monitor additional changes, modifications, clarifications or interpretations by the FASB, which may impact the Company's current conclusions.

In July 2015, the FASB issued ASU No. 2015-11, "Inventory (Topic 330): Simplifying the Measurement of Inventory." ASU No. 2015-11 applies only to inventory for which cost is determined by methods other than last in, first-out and the retail inventory method, which includes inventory that is measured using first-in, first-out or average cost. Inventory within the scope of this standard is required to be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The new standard is effective for the Company's calendar year beginning January 1, 2017. The adoption of this standard had no impact on the Company's consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, "Improvements to Employee Share-Based Payment Accounting," which changes the accounting for certain aspects of share-based payments to employees. The new guidance requires excess tax benefits and tax deficiencies to be recorded in the statement of operations when the awards vest or are settled. In addition, cash flows related to excess tax benefits will no longer be separately classified as a financing activity apart from other income tax cash flows. The standard also clarifies that all cash payments made on an employee's behalf for withheld shares should be presented as a financing activity on the statement of cash flows, and provides an accounting policy election to account for forfeitures as they occur. The new standard is effective for the Company's calendar year beginning January 1, 2017. On January 1, 2017, as a result of adopting ASU No. 2016-09, the Company recorded a cumulative-effect adjustment of $1.1 million between retained earnings and additional paid in capital. Additionally, a retrospective adjustment to the Company's statement of cash flows for the three months ended March 31, 2016 resulted in an increase of $180,000 to net cash provided by operating activities and a decrease of $180,000 to net cash provided by financing activities.

In January 2017, the FASB issued ASU No. 2017-01, "Clarifying the Definition of a Business," This definition is used in determining whether acquisitions are accounted for as business combinations or as the acquisition of assets. This standard modifies the definition of a business, including providing a screen to determine when an acquired set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. The standard also makes other modifications to clarify what must be included in an acquired set for it to be a business and how to evaluate the set to determine whether it is a business. Our acquisitions subsequent to December

31, 2016, are subject to the application of the modified definition.

In January 2017, the FASB issued ASU No. 2017-04, “Intangibles - Goodwill and Other (Topic 350): Simplifying the test for goodwill impairment.” ASU No. 2017-04 simplifies the subsequent measurement of goodwill by eliminating Step 2 in the step quantitative test and record an impairment charge based on the excess of a reporting unit’s carrying amount over its fair value. ASU 2017-04 will be applied prospectively and is effective for annual and interim goodwill impairment tests conducted in fiscal years beginning after December 15, 2019. The new standard is effective for the Company for its fiscal 2021 fourth quarter goodwill impairment test. Early adoption is permitted for annual and interim goodwill impairment testing dates after January 1, 2017. The Company elected to early adopt ASU No. 2017-04 on January 1, 2017. The adoption had no impact on the Company’s consolidated financial statements.

3. Net Income (loss) per Share

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average common shares outstanding. Diluted net income per share is computed by dividing net income by the sum of the weighted average common shares and potential dilutive common shares outstanding. Diluted net loss per share is computed by dividing net loss by the weighted average common shares outstanding without the impact of potential dilutive common shares outstanding because they would have an anti-dilutive impact on diluted net loss per share. The treasury-stock method is used to determine the dilutive effect of the Company's stock option grants, and the if-converted method is used to determine the dilutive effect of the Company's Convertible Notes.

The computation of net income (loss) per share for the three months ended March 31, 2017 and 2016 is shown below.

	Three Months Ended March 31,	
(In thousands, except per share data)	2017	2016
Basic net income (loss) per share:		
Net income (loss)	$ 4,624	$ (4,057)
Weighted-average number of common shares-basic	43,442	42,539
Basic net income (loss) per share	$ 0.11	$ (0.10)
Diluted net income (loss) per share:		
Net income (loss)	$ 4,624	$ (4,057)
Interest expense applicable to convertible debt, net of tax	1,438	-
Amortization of debt issuance costs, net of tax	282	-
Net income for calculation of diluted net income (loss) per share	$ 6,344	$ (4,057)
Weighted-average number of common shares-basic	43,442	42,539
Assumed exercise of stock options under the treasury-stock method	586	-
Assumed shares under if-converted method	18,079	-
Weighted-average number of common shares-diluted	62,107	42,539
Diluted net income (loss) per share	$ 0.10	$ (0.10)

The following securities were excluded from the computation of diluted net income (loss) per share as their effect would have been anti-dilutive for the three months ended March 31, 2017 and 2016:

Three Months Ended March 31,

(In thousands)	2017	2016
Employee stock options	4,126	5,537

4. Segment Information

The Company has one operating segment which is the development and commercialization of pharmaceutical products. Summarized product category and geographic information is shown in the tables below.

Product Category Information

Revenues for product categories are attributed based on the following categories.

Product royalty revenue represents royalty revenue earned on the net sales of AMITIZA in North America. Product sales revenue represents drug product net sales of AMITIZA in North America, Japan and Europe and drug product net sales of RESCULA in Japan. Research and development revenue represents funded development work primarily related to AMITIZA. Contract and collaboration revenue represents the amortization of up-front payments under the North America Takeda Agreement and release of the collaboration obligation under the Global Takeda agreement.

Company revenues by product category for the three months ended March 31, 2017 and 2016 were as follows:

	Three Months Ended March 31,	
(In thousands)	2017	2016
Product royalty revenue	$ 18,435	$ 16,716
Product sales revenue - AMITIZA	31,340	23,434
Product sales revenue - RESCULA	2,814	3,161
Research and development revenue	3,448	3,430
Contract and collaboration revenue	246	467
Total	$ 56,283	$ 47,208

Geographical Information

Revenues are attributable to countries based on the location of the customer. The Company operates a manufacturing facility in Japan that supplies products to customers as well as the Company's subsidiaries in other countries. The sales from the manufacturing operations to other countries are included in the net sales of the country in which the manufacturing location is based. All intercompany sales are excluded to derive consolidated revenues. The Company's country of domicile is the United States.

Company revenues by geographic location for the three months ended March 31, 2017 and 2016 were as follows:

	Three Months Ended March 31,	
(In thousands)	2017	2016
United States	$ 33,199	$ 28,939
Japan	22,885	17,848
Rest of the world	199	421
Total	$ 56,283	$ 47,208

The Company's long-lived assets by geographic location where located on March 31, 2017 and December 31, 2016 were as follows:

(In thousands)	March 31, 2017	December 31, 2016
United States	$ 2,933	$ 3,065
Japan	3,235	3,119
Rest of the world	29	32

Total	$ 6,197	$ 6,216

5. Fair Value measurements

The Company performs fair value measurements in accordance with the FASB's guidance for fair value measurements and disclosures, which defines fair value as the exchange price that would be received for selling an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. A fair value hierarchy is established which requires the Company to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The Company classifies its assets and liabilities into the following categories based on the three levels of inputs used to measure fair value:

Level 1: Observable inputs, such as quoted prices in active markets for identical assets or liabilities;

Level 2: Inputs, other than the quoted price in active markets, that are observable, either directly or indirectly, such as quoted prices in active markets for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; or

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The carrying values of cash and cash equivalents, restricted cash, accounts receivable, product royalties receivable, accounts payable and other accrued liabilities, approximate their fair values due to their short maturities.

The Company has elected the fair value option on its investment in CPP; as such, it is measured at fair value on a recurring basis. At March 31, 2017, the estimated fair value of the investment in CPP was $5.3 million. For the three months ended March 31, 2017, the Company recorded $0.1 million in other income due to the increase in fair value of the investment in CPP.

The estimated fair value of long term debt at March 31, 2017 was $297.0 million, and was based on similar types of borrowings.

The estimated fair values may not represent actual values of the financial instruments that could be realized as of the balance sheet date or that will be realized in the future. As of March 31, 2017 and December 31, 2016, there were no financial instruments measured at fair value on a non-recurring basis.

6. Inventory

Inventories are valued under a standard costing method and are stated at the lower of cost or net realizable value. Inventories consist of raw materials, work-in-process and finished goods. The Company’s inventories include the direct purchase cost of materials and supplies and manufacturing overhead costs.

Inventory consisted of the following at March 31, 2017 and December 31, 2016:

(In thousands)	March 31, 2017	December 31, 2016
Raw materials	$ 3,316	$ 1,414
Work in process	18,134	18,045
Finished goods	1,528	4,009
Total	$ 22,978	$ 23,468

7. Investments, non-current

Investment in CPP

In 2016, the Company entered into a Securities Purchase Agreement ("CPP Securities Agreement") and an Option and Collaboration Agreement ("CPP Agreement") with CPP for the development and commercialization of CPP-1X/sulindac combination.

Under the terms of the CPP Securities Agreement, the Company provided $5.0 million to CPP in exchange for a convertible note. The convertible note bears interest at the rate of 5% per annum and matures on January 31, 2019 unless earlier converted or prepaid. Under the terms of the CPP Agreement, CPP granted the Company the sole option to acquire an exclusive license to commercialize CPP-1X/sulindac combination product in North America.

CPP is considered to be a VIE with respect to the Company. It has been determined that the power to direct the activities that most significantly impact CPP's economic performance is held by the board of directors of CPP. The Company does not have a representative on CPP's board and does not have the right to appoint or elect such a representative. Therefore, the Company is not the primary beneficiary of CPP, and the entity is not consolidated with the financial statements of the Company.

The Company's maximum exposure to loss as a result of its involvement with CPP was $5.3 million and $5.2 million as of March 31, 2017, and December 31, 2016, respectively.

The Company has elected the fair value option on the convertible note received from CPP due to the nature of the financial characteristics of the investment. As of March 31, 2017 and December 31, 2016, the fair value of the convertible note was $5.3 million and $5.2 million, respectively.

8. Intangible Assets and Goodwill

Intangible assets by major class consisted of the following as of March 31, 2017 and December 31, 2016:

(In thousands)	March 31, 2017 Weighted average life (in months)	Carrying amount	December 31, 2016 Weighted average life (in months)	Carrying amount
Amortized intangible assets				
Patent and license rights	57	$10,513	60	$ 10,513
Manufacturing know-how	62	134,600	65	134,600
Accumulated amortization		(40,895)		(34,142)
Impairment losses		(5,651)		(5,651)
Foreign currency translation adjustments		22,814		22,814
Total amortized intangible assets		$121,381		$ 128,134
Unamortized intangible assets				
Goodwill		$73,022		$ 73,022
Total unamortized intangible assets		$73,022		$ 73,022
Total intangible assets		$194,403		$ 201,156

The changes in intangible assets for the three months ended March 31, 2017 are as follows:

(In thousands)	Intangibles	Goodwill
Balance at December 31, 2016	$128,134	$73,022
Amortization	(6,753)	-
Balance at March 31, 2017	$121,381	$73,022

9. Accrued Expenses and Other Current Liabilities

Accrued expenses consisted of the following at March 31, 2017 and December 31, 2016:

(In thousands)	March 31, 2017	December 31, 2016
Research and development costs	$ 5,224	$ 3,030
Employee compensation	3,647	7,513
Legal and accounting fees	1,756	622
Consulting fees	6,148	-
Restructuring	-	163
Other accrued expenses	321	1,061
Total	$ 17,096	$ 12,389

Other current liabilities consisted of the following at March 31, 2017 and December 31, 2016:

(In thousands)	March 31, 2017	December 31, 2016
Indirect taxes payable	$ 2,425	$ 1,756
Squeeze out liability for non-tendering R-Tech shareholders	154	155
Other current liabilities	297	264
Total	$ 2,876	$ 2,175

10. Restructuring

In December 2015, the Company adopted a plan to restructure certain of its operations and to consolidate certain functions in the Company's corporate headquarters located in Rockville, Maryland and in the Company's Japanese subsidiaries. The restructuring plan primarily included headcount reductions due to the ongoing integration of R-Tech. In connection with these restructuring activities, the Company recorded restructuring charges of $365,000 and $183,000 for the three months ended March 31, 2017 and 2016, respectively. These costs are reflected within general and administrative expenses and consisted primarily of termination benefits.

The changes in accrued restructuring costs for the three months ended March 31, 2017 are as follows:

(In thousands)	Accrued Restructuring
Balance at December 31, 2016	$ 163
Expenses incurred	365
Amounts paid	(528)
Balance at March 31, 2017	$ -

The Company does not expect to record any additional restructuring charges under this plan. The Company has incurred total restructuring charges under this plan of $3.7 million through March 31, 2017.

11. Other Liabilities

Other liabilities consisted of the following at March 31, 2017 and December 31, 2016:

(In thousands)	March 31, 2017	December 31, 2016
Deferred grants	$ 750	$ 750
Unrecognized tax benefits	4,182	4,060
Deferred leasehold incentive	1,582	1,582
Defined benefit obligation	832	818
Lease liability	1,388	1,183
Other	408	398
Total	$ 9,142	$ 8,791

12. Convertible Notes Payable

On December 27, 2016, the Company issued $300.0 million aggregate principal amount of its 3.25% Convertible Senior Notes due 2021 (the “Convertible Notes”). Interest is payable semi-annually in cash in arrears on June 15 and December 15 of each year, beginning on June 15, 2017, at a rate of 3.25% per year. The Convertible Notes mature on December 15, 2021 unless earlier converted or repurchased, are not redeemable prior to the maturity date and no sinking fund is provided for the Convertible Notes.

As of March 31, 2017, the Company was compliant with all covenants and conditions under the Convertible Notes.

The Convertible Notes are subject to the fair value disclosure requirements as discussed in note 5 and are classified as a Level 2 instrument. The estimated fair value of the Convertible Notes at March 31, 2017 and December 31, 2016 was $297.0 million and $319.5 million, respectively.

13. Commitments and Contingencies

Operating Leases

The Company leases office space in the United States, Switzerland and Japan under operating leases through 2027. Total future minimum, non-cancelable lease payments under operating leases are as follows:

(In thousands)	March 31, 2017
2017	$ 1,518
2018	1,765
2019	1,518
2020	1,104
2021	997
Total minimum lease payments	$ 6,902

Rent expense for all operating leases was approximately $430,000 and $645,000 for the three months ended March 31, 2017 and March 31, 2016, respectively.

CPP

Under the terms of the CPP Securities Agreement, the Company provided $5.0 million to CPP in exchange for a convertible note. The convertible note is automatically convertible into securities of CPP, subject to certain limitations, in the event CPP consummates a future financing with aggregate proceeds of at least $10.0 million, exclusive of any investment by the Company, whether through a public offering or a private offering (a “Qualified Financing”). The Company has agreed to purchase up to $5.0 million of CPP’s securities in any such Qualified Financing.

14. Stock Option Plans

A summary of employee stock option activity for the three months ended March 31, 2017 under the Company's Amended and Restated 2006 Stock Incentive Plan is presented below:

2006 Stock Incentive Plan	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2016	4,648,549	$ 10.86		
Options granted	-	-		
Options exercised	(41,472)	$ 5.80		
Options forfeited	(83,775)	$ 14.10		
Options expired	(12,599)	$ 9.60		
Options outstanding, March 31, 2017	4,510,703	$ 10.85	7.8	$ 8,353,703
Options exercisable, March 31, 2017	2,310,152	$ 9.88	7.3	$ 5,687,067
Options vested and expected to vest, March 31, 2017	4,510,703	$ 10.85	7.8	$ 8,353,703

17

A summary of employee stock option activity for the three months ended March 31, 2017 under the Company's 2016 Equity Incentive Plan (the "2016 Plan") is presented below:

2016 Equity Incentive Plan	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2016	74,750	$ 12.66		
Options granted	1,244,419	$ 11.78		
Options exercised	-	-		
Options expired	(36,700)	$ 13.97		
Options outstanding, March 31, 2017	1,282,469	$ 11.77	9.4	$ 30,080
Options exercisable, March 31, 2017	78,750	$ 14.34	0.6	$ 0
Options vested and expected to vest, March 31, 2017	1,282,469	$ 11.77	9.4	$ 30,080

The weighted average grant date fair value of options granted during the three months ended March 31, 2017 was $6.09.

A summary of employee restricted stock units activity for the three months ended March 31, 2017 under the Company's 2016 Plan is presented below:

2016 Equity Incentive Plan	Shares	Weighted Average Grant Date Fair Value
Outstanding Restricted Stock Units, December 31, 2016	63,700	$ 12.29
Restricted Stock Units granted	461,804	$ 11.85
Restricted Stock Units vested	-	-
Restricted Stock Units forfeited	-	-
Outstanding Restricted Stock Units, March 31, 2017	525,504	$ 11.90

Employee Stock Purchase Plan

The following table summarizes the Company's 2006 Employee Stock Purchase Plan activity for the three months ended March 31, 2017 and 2016:

	Three Months Ended March 31,	
(In thousands, except share amounts)	2017	2016
Shares issued under the ESPP	7,338	6,285
Cash received under the ESPP	$ 68,610	$ 58,391

Accumulated Other Comprehensive Income

The following table details the accumulated other comprehensive income (loss) activity for the three months ended March 31, 2017 and 2016:

(In thousands)	Foreign currency translation adjustments	Unrealized income on investments, net of tax effect	Unrealized gain (loss) on pension benefit obligation	Accumulated other comprehensive income
Balance January 1, 2016	$ 14,243	$ 42	$ (873)	$ 13,412
Other comprehensive income (loss) before reclassifications	15,555	-	(8)	15,547
Amounts reclassified from accumulated other comprehensive loss	-	-	-	-
Balance March 31, 2016	$ 29,798	$ 42	$ (881)	$ 28,959
Balance January 1, 2017	$ 55,119	$ 42	$ (634)	$ 54,527
Other comprehensive income (loss) before reclassifications	(77)	-	1	(76)
Amounts reclassified from accumulated other comprehensive loss	-	-	-	-
Balance March 31, 2017	$ 55,042	$ 42	$ (633)	$ 54,451

15. Income Taxes

The provision for income taxes is based upon the estimated annual effective tax rates for the year applied to the current period income before tax plus the tax effect of any significant unusual items, discrete events or changes in tax law. Our operating subsidiaries are exposed to effective tax rates ranging from zero to approximately 40%. Fluctuations in the distribution of pre-tax income among our operating subsidiaries can lead to fluctuations of the effective tax rate in the condensed consolidated financial statements. In the three-month periods ended March 31, 2017 and 2016, the actual effective tax rates were 43.7% and 42.8%, respectively.

We assess uncertain tax positions in accordance with ASC 740 (ASC 740-10 Accounting for Uncertainties in Tax). As of March 31, 2017, our net unrecognized tax benefits totaled $3.2 million. Of this balance $1.7 million would favorably impact our effective tax rate in the periods if they are recognized. Management has not identified any material uncertain tax positions that are reasonably likely to be released during the next 12 months due to lapse of statutes of limitations or settlements with tax authorities.

We conduct business globally and, as a result, file numerous consolidated and separate income tax returns in the U.S., Switzerland and Japan, as well as in various other state and foreign jurisdictions. In the normal course of business, we are subject to examination by taxing authorities throughout the world. Currently tax years 2012 to 2016 remain open and subject to examination in the major tax jurisdictions in which tax returns are filed. The tax years 2009-2011 were examined by the U.S. tax authorities and resulted in no tax adjustments.

16. Subsequent Event

On March 31, 2017, the Company entered into a merger agreement with Vtesse Inc., and on April 3, 2017, acquired Vtesse Inc. for upfront consideration of $200.0 million. The acquisition was funded through the issuance of 2,782,676 shares of Sucampo Class A common stock and $170.0 million of cash on hand. Substantially all of the fair value of Vtesse Inc. is related to VTS-270, its only significant asset. VTS-270 is an investigational drug in a pivotal Phase 2b/3 study for the treatment of NPC-1, an ultra-orphan, progressive and fatal disease. The Company expects to account for the transaction as an asset acquisition and expects to incur an acquired in-process research and development charge of $180.0 million to $200.0 million (and no related current tax benefit) in the second quarter of 2017.

Item 2. ***Management's Discussion and Analysis of Financial Condition and Results of Operations.***

This Quarterly Report on Form 10-Q contains forward-looking statements regarding Sucampo Pharmaceuticals, Inc. and our business, financial condition, results of operations and prospects within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These forward-looking statements are based on our current expectations and projections about future events and they are subject to risks and uncertainties, known and unknown, that could cause actual results and developments to differ materially from those expressed or implied in such statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included in our other filings with the Securities and Exchange Commission (SEC) including our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, which we filed with the SEC on March 8, 2017. Statements made herein are as of the date of the filing of this Form 10-Q with the SEC and should not be relied upon as of any subsequent date. Unless otherwise required by applicable law, we do not undertake, and we specifically disclaim any obligation to update any forward-looking statements to reflect occurrences, developments, unanticipated events or circumstances after the date of such statement.

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 that appear in Item 1 of this Form 10-Q and with our consolidated financial statements and related notes for the year ended December 31, 2016 which are included in our Annual Report on Form 10-K.

Overview

We are a global biopharmaceutical company focused on innovative research and development of proprietary drugs to treat gastrointestinal, ophthalmic, autoimmune, inflammatory, neurological and oncology disorders.

We currently generate revenue mainly from product royalties, development milestone payments, product sales and reimbursements for clinical development activities. We expect to continue to incur significant expenses for the next several years as we continue our research and development activities, seek additional regulatory approvals and additional indications for our approved products and other compounds and seek strategic opportunities for acquiring new products and product candidates.

Our operations are conducted through subsidiaries based in the United States (U.S.), Japan and Switzerland. We operate as one segment, which focuses on the development and commercialization of pharmaceutical products.

AMITIZA (lubiprostone)

United States and Canada

AMITIZA is marketed in the U.S. for three gastrointestinal indications under a collaboration and license agreement (North America Takeda Agreement) with Takeda Pharmaceutical Company Limited (Takeda). These indications are chronic idiopathic constipation (CIC) in adults, irritable bowel syndrome with constipation (IBS-C) in adult women and opioid-induced constipation (OIC) in adults suffering from chronic non-cancer related pain. Under the North America Takeda Agreement, we are primarily responsible for clinical development activities, while Takeda is responsible for commercialization of AMITIZA in the U.S. and Canada. Takeda is required to provide a minimum annual commercial investment during the current term of the North America Takeda Agreement and may reduce the minimum annual commercial investment when a generic equivalent enters the market. In October 2015, Health Canada approved AMITIZA for CIC in adults. In October 2014, we signed an amendment (Takeda Amendment) to the North America Takeda Agreement which, among other things, extended the term of the North American Takeda Agreement beyond December 2020. During the extended term beginning in January 2021, we will share with Takeda the net sales revenue on branded AMITIZA sales.

We have also partnered with Par Pharmaceuticals, Inc., or Par, and Dr. Reddy's Laboratories, Ltd., or Dr. Reddy's, in connection with the settlement of patent litigation in the United States related to our AMITIZA 8 mcg and 24 mcg soft gelatin capsule products. Under our agreement with Par, we granted Par a non-exclusive license to market Par's generic version of lubiprostone 8 mcg and 24 mcg soft gelatin capsules in the United States for the indications approved for AMITIZA beginning January 1, 2021, or earlier under certain circumstances. Beginning on January 1, 2021, Par will split with us the gross profits of the licensed products sold during the term of the agreement, which continues until each of our related patents has expired. Under our agreement with Dr. Reddy's, we granted Dr. Reddy's a non-exclusive license to market Dr. Reddy's generic version of lubiprostone 8 mcg and 24 mcg soft gelatin capsules in the United States for the indications approved for AMITIZA. This license does not begin until more than six years from November 9, 2016, or earlier under certain circumstances. Dr. Reddy's will pay to us a share of net profits of generic lubiprostone products sold during the term of the agreement, which decreases over time and ends when all of our related patents have expired. In the event that either Par or Dr. Reddy's elect to launch an authorized generic form of lubiprostone, we have agreed to supply such product under the terms of a manufacturing and supply agreement at a negotiated price.

Japan

In Japan, AMITIZA is the only prescription medicine for chronic constipation, excluding constipation caused by organic diseases, and is marketed under a license, commercialization and supply agreement (Japan Mylan Agreement) originally entered into with Abbott Laboratories, Inc. (Abbott). In February 2015, Mylan purchased Abbott's non-U.S. developed markets specialty and branded generics business, as a result of which Mylan acquired the rights to commercialize AMITIZA in Japan. We did not experience any significant changes in the commercialization of AMITIZA in Japan as a result of the transfer of the Japan Mylan Agreement from Abbott to Mylan.

People's Republic of China

In May 2015, we entered into an exclusive license, development, commercialization and supply agreement (China Gloria Agreement) with Harbin Gloria Pharmaceuticals Co., Ltd. (Gloria) for AMITIZA in the People's Republic of China. We will be the exclusive supplier of AMITIZA to Gloria at an agreed upon supply price. Under the China Gloria Agreement, Gloria is responsible for all development activities and costs, as well as commercialization and regulatory activities, for AMITIZA in the People's Republic of China. Upon entering into the China Gloria Agreement, we received an upfront payment of $1.0 million. In June 2015, the China Food and Drug Administration accepted an Investigational New Drug (IND) application for a pivotal trial of AMITIZA in patients with CIC, as a result of which we received an additional payment of $500,000 from Gloria. In addition to the $1.5 million in payments received and recognized as revenue through June 2015, we are eligible to receive an additional payment in the amount of $1.5 million upon the occurrence of a specified regulatory or commercial milestone event.

Other Global Markets

In October 2014, we entered into an exclusive license, development, commercialization and supply agreement (Global Takeda Agreement) for lubiprostone with Takeda. Under the Global Takeda Agreement, Takeda develops and markets AMITIZA globally except in the U.S., Canada, Japan and the People's Republic of China. We supply Takeda with the clinical and commercial product at a negotiated price. Takeda currently markets AMITIZA for CIC and OIC in Switzerland, and for CIC in the U.K.

In January 2016, we received notification from the Medicines and Healthcare Products Regulatory Agency of the United Kingdom (U.K.) that our appeal for the OIC indication was not approved. In January 2015, we successfully completed the European mutual recognition procedure for AMITIZA for the treatment of CIC in Austria, Belgium, Germany, Italy, Ireland, Luxembourg, Netherlands and Spain, resulting marketing authorizations in these markets. Takeda became the marketing authorization holder in Switzerland in April 2015, in the United Kingdom, Austria, Belgium, Germany, Netherlands, Ireland, Italy, Luxembourg and Spain during 2016.

In October 2015, Takeda obtained approval of the clinical trial application (CTA) for AMITIZA for the treatment of CIC and IBS-C in Russia that was submitted in June 2015. In December 2015, a CTA was filed for AMITIZA for the treatment of CIC, IBS-C and OIC in Mexico and South Korea. Takeda initiated Phase 3 registration trials in Russia in March 2016 and in South Korea and Mexico in May 2016. A new drug application (NDA) for the treatment of CIC, IBS-C, and OIC was submitted in Israel in June 2015, and approved in July 2016, and in Kazakhstan in December 2015. Additional NDA submissions have been made by Takeda in Singapore in May 2016, and South Africa and Indonesia in June 2016, and are planned in various other markets for 2017 and beyond.

RESCULA (unoprostone isopropyl)

As part of the acquisition of R-Tech Ueno, Ltd. (R-Tech) in October 2015, we acquired global rights to RESCULA, an ophthalmology product used to lower intraocular pressure (IOP).

In the fourth quarter of 2014 we ceased marketing RESCULA in the United States and no product was made available after the March 2015 expiration date. In May 2015, we returned all licenses for unoprostone isopropyl to R-Tech. In June 2016, we completed the withdrawal of the marketing authorization for RESCULA in the U.S.

In Japan, RESCULA was approved by the MHLW in 1994 for the treatment of glaucoma and ocular hypertension. In Japan, RESCULA is no longer protected by regulatory or intellectual property exclusivity. In March 2012, R-Tech signed a distribution agreement (Japan Santen Agreement) with Santen Pharmaceutical Co., Ltd. (Santen) to commercialize RESCULA in Japan. As part of the acquisition of R-Tech in 2015, we acquired R-Tech's rights and obligations under the Japan Santen Agreement.

In Taiwan, R-Tech signed a manufacturing and supply agreement with Sinphar Pharmaceutical, Co., Ltd. and also executed the distribution agreement with Zuellig Pharma, Inc. in April 2013.

In February 2017, the import license for RESCULA in South Korea was withdrawn by Dong-A ST Co., Ltd., our local distributor.

Product Pipeline

The table below summarizes the development status of our marketed products and key product candidates. The commercialization rights to lubiprostone have been licensed to Takeda on a global basis other than Japan and the People's Republic of China, to Mylan for Japan, and to Gloria for the People's Republic of China. Commercialization of each product candidate may occur after successful completion of clinical trials and approval from competent regulatory agencies. For CPP-1X/sulindac, we have an option to acquire an exclusive license to commercialize in North America.

Country	Program Type	Target Indication	Development Phase	Next Milestone
Lubiprostone (AMITIZA ®)				
U.S.	Commercial	Chronic idiopathic constipation (CIC) adults of all ages	Marketed	____
U.S.	Commercial	Irritable bowel syndrome with constipation (adult women) (IBS-C)	Marketed	Initiate Phase 4 study on higher dosage and with additional male subjects
U.S.	Commercial	Opioid-induced constipation (OIC) in patients with chronic non-cancer pain	Marketed	____
U.S.	Clinical	Alternate (Sprinkle) formulation - adults of all ages	In development	Complete Phase 3 trial
U.S.	Clinical	Pediatric functional constipation (6 months - 6 years)	Alternate (Sprinkle) formulation in development	Initiate Phase 3 program
U.S.	Clinical	Pediatric IBS-C (6 years - 17 years)	Alternate (Sprinkle) formulation in development	Initiate Phase 3 program
U.S. & European Union	Clinical	Pediatric functional constipation (6 years - 17 years)	Open label Phase 3 trials ongoing	Complete open label Phase 3 trial and submit sNDA
Japan	Commercial	Chronic constipation	Marketed	____
Japan	Clinical	CIC adults, 2x12mcg capsule	CTN submitted	Submit sNDA
Switzerland	Commercial	CIC-adults of all ages	Marketed	____
Switzerland	Commercial	OIC in patients with chronic non-cancer pain	Marketed	____
U.K.	Commercial	CIC-adults of all ages	Marketed	____
Canada	Clinical	CIC-adults of all ages	Received approval from Health Canada	Market in Canada
China	Clinical	CIC-adults of all ages	IND accepted	Initiate CIC study
European Union	Clinical	CIC-adults of all ages	Received national marketing approvals in Ireland, Germany, Austria, Belgium, the Netherlands, Luxembourg, Italy and Spain (where product is not yet launched)	Launch feasibility and planning under evaluation
Israel	Commercial	CIC-adults of all ages	Approved	Develop pricing and reimbursement assessments and, based on outcome, determine launch feasibility and plans
Mexico	Clinical	CIC-adults of all ages	CTA Approved	Complete Phase 3 trial
Mexico	Clinical	IBS-C - adult women	CTA Approved	Complete Phase 3 trial
Mexico	Clinical	OIC in patients with chronic non-cancer pain	CTA Approved	Complete Phase 3 trial

Russia	Clinical	CIC-adults of all ages	Phase 3 completed	MAA submission
Russia	Clinical	IBS-C - adult women	Phase 3 completed	MAA submission
South Korea	Clinical	CIC-adults of all ages	CTA Approved	Complete Phase 3 trial
South Korea	Clinical	IBS-C - adult women	CTA Approved	Complete Phase 3 trial
South Korea	Clinical	OIC in patients with chronic non-cancer pain	CTA Approved	Complete Phase 3 trial

Country	Program Type	Target Indication	Development Phase	Next Milestone
Unoprostone isopropyl (RESCULA®)				
Japan Taiwan	Commercial	Glaucoma and ocular hypertension	Marketed	____
CPP-1X/sulindac combination product				
U.S.	Option	Familial adenomatous polyposis (FAP) - adults of all ages	Phase 3	Complete Phase 3 trial
VTS-270 for Niemann-Pick disease type C1 product				
U.S.	Clinical	Niemann-Pick disease type C1	Phase 2b/3	Complete Phase 2b/3 trial

Our Clinical Development Programs

Lubiprostone

Alternate Formulation

We are developing an alternate formulation of lubiprostone for both adult and pediatric patients who are unable to take or do not tolerate capsules and for naso-gastric tube fed patients. Takeda has agreed to fund 100% of the costs, up to a cap, of this alternate formulation work. We initiated the Phase 3 program of the alternate formulation of lubiprostone in adults in the second half of 2016 and, if the program is successful, we intend to file an NDA in the United States for the alternate formulation for adults in the second half of 2017.

Pediatric Functional Constipation

The Phase 3 program required to support an application for marketing authorization of lubiprostone for pediatric functional constipation comprises four clinical trials. The first two trials, one of which was recently completed, test the soft gelatin capsule formulation of lubiprostone in patients 6 to 17 years of age. The first of these trials was a pivotal 12-week, randomized, placebo-controlled trial which was initiated in December 2013 and completed enrollment in April 2016. The second trial is a follow-on, long-term safety extension trial that was initiated in March 2014. In November 2016, we announced that the Phase 3 trial of AMITIZA in pediatric functional constipation in children 6 to 17 years of age failed to achieve its primary endpoint of overall spontaneous bowel movement, or SBM, response. The trial achieved statistical significance for some secondary endpoints, notably overall SBM frequency, straining, and stool consistency. In addition, in this study lubiprostone was well tolerated. We have entered into a process with the U.S. Food and Drug Administration, or FDA, and other constituencies, and as a result of initial discussion with the FDA plan to submit an sNDA in the second half of 2017. Additionally, after further consultations with the FDA to better determine the doses and endpoints that should be studied, following the Phase 3 program for the alternate formulation of lubiprostone described above, we plan to initiate in mid-2018 a Phase 3 program in

patients 6 months to 6 years of age using the alternate formulation. Takeda has agreed to fund 70% of the costs, up to a cap, of this pediatric functional constipation program.

CPP 1-X/Sulindac Combination Product

In January 2016, we entered into an option and collaboration agreement under which Cancer Prevention Pharmaceuticals, Inc. (CPP) has granted us the sole option to acquire an exclusive license to commercialize CPP-1X/sulindac combination product in North America. This product is currently in a Phase 3 clinical trial, conducted by CPP for the treatment of familial adenomatous polyposis (FAP). Under our agreement with CPP, we have the exclusive option to license this product for North America. There are currently no approved treatments for FAP. The ongoing Phase 3 study is a 150-patient, three-arm, double-blind, randomized trial of the combination agent and the single agent comparators. Enrollment in the study has completed and the results from a Phase 3 futility analysis are expected to be available mid-2017. Results from the clinical trial are expected at the end of 2018.

VTS-270 for Niemann-Pick Disease Type C1 (NPC-1)

On March 31, 2017, we entered into an Agreement and Plan of Merger with Vtesse Inc. ("Vtesse") a privately-held rare disease company. Following the closing of this acquisition on April 3, 2017, we gained Vtesse's lead product candidate, known as VTS-270. VTS-270 is a well-characterized mixture of 2-hydroxypropyl-ß-cyclodextrins (HPßCD) with a specific compositional fingerprint that distinguishes it from other HPßCD mixtures. It is administered by an intrathecal infusion to directly address the neurological manifestations of disease. Preclinical and early clinical studies suggest that the administration of VTS-270 may slow or stop certain indicators of NPC-1, an ultra-orphan, progressive and fatal disease caused by a defect in lipid transport within the cell. VTS-270, which is currently in a fully-enrolled pivotal Phase 2b/3 trial, has been granted breakthrough therapy designation in the United States and orphan designation in both the United States and EU. Effective treatment of NPC-1 remains a high unmet need, with no approved products for patients in the United States. Results from the pivotal trial are expected in mid-2018.

Non-GAAP Financial Metrics

In addition to disclosing financial results that are determined in accordance with GAAP, we also use the following non-GAAP financial metrics to understand and evaluate our operating performance:

- Adjusted net income, which is GAAP net income (loss) adjusted to exclude the tax-effected impact of (i) amortization of acquired intangibles and patents, (ii) inventory step-up adjustment, (iii) impairment of in-process research and development, (iv) restructuring costs, (v) legal settlement, (vi) acquisition related expenses, (vii) amortization of debt financing costs, (viii) loss on debt extinguishment, (ix) research and development license option expense, (x) acceleration of deferred revenue, (xi) foreign currency translation, and (xii) one-time severance payments;
- Adjusted EPS-diluted, which is adjusted net income as defined above expressed on a diluted per share basis;
- EBITDA, which is GAAP net income adjusted to exclude (i) taxes, (ii) interest expense, (iii) interest income, (iv) depreciation, (v) impairment of in-process research and development, (vi) amortization of acquired intangibles, and (vii) inventory step-up adjustment;
- Adjusted EBITDA, which is EBITDA as defined above further adjusted to exclude (i) share-based compensation expense, (ii) restructuring costs, (iii) acquisition-related expenses, (iv) loss on debt extinguishment, (v) research and development license option expense, (vi) legal settlement, (vii) foreign currency translation, (viii) acceleration of deferred revenue, and (ix) one-time severance payments.

We believe that providing this additional information is useful to the reader to better assess and understand our operating performance, primarily because management typically monitors the business adjusted for these items in addition to GAAP results. These non-GAAP financial metrics should be considered supplemental to and not a substitute for financial information prepared in accordance with GAAP. Our definition of these non-GAAP metrics may differ from similarly titled metrics used by others. We view these non-GAAP financial metrics as a means to facilitate our financial and operational decision-making, including evaluation of our historical operating results and comparison to competitors' operating results. These non-GAAP financial metrics reflect an additional way of viewing

aspects of our operations that, when viewed with GAAP results may provide a more complete understanding of factors and trends affecting our business. The determination of the amounts that are excluded from these non-GAAP financial metrics is a matter of management judgment and depends upon, among other factors, the nature of the underlying expense or income amounts. Because non-GAAP financial metrics exclude the effect of items that will increase or decrease the company's reported results of operations, we strongly encourage investors to review our consolidated financial statements and periodic reports in their entirety.

The following tables present reconciliations of these non-GAAP financial metrics to the most directly comparable GAAP financial measure for the three months ended March 31, 2017 and 2016.

	Three Months Ended March 31,	
(In thousands, except per share amounts)	2017	2016
Non-GAAP adjusted net income		
GAAP net income (loss)	$ 4,624	$ (4,057)
Amortization of acquired intangibles	6,748	5,906
Amortization of patents	5	5
Amortization of inventory step-up adjustment	-	8,932
Research and development license expense	-	3,000
Restructuring costs	365	183
One-time severance payments	476	-
Acquisition related expenses	7,010	527
Amortization of debt financing costs	472	922
Foreign currency translation	(194)	351
Tax effect of adjustments	(6,528)	(6,019)
Non-GAAP adjusted net income	$ 12,978	$ 9,750
Non-GAAP adjusted EPS - diluted	$ 0.23	$ 0.23
(In thousands)		
Non-GAAP EBITDA		
GAAP net income (loss)	$ 4,624	$ (4,057)
Taxes	3,585	(3,038)
Interest expense	2,890	6,270
Interest income	(28)	(25)
Depreciation and amortization	198	259
Impairment of in-process research and development		
Amortization of acquired intangibles	6,753	5,911
Amortization of inventory step-up adjustment	-	8,932
EBITDA	$ 18,022	$ 14,252
(In thousands)		
Non-GAAP adjusted EBITDA		
EBITDA	$ 18,022	$ 14,252
Share-based compensation expense	2,275	1,915
Research and development license expense	-	3,000
Restructuring costs	365	183
One-time severance payments	476	-
Acquisition related expenses	7,010	527
Foreign currency translation	(194)	351
Adjusted EBITDA	$ 27,954	$ 20,228

Results of Operations

Revenues

The following table summarizes our revenues for the three months ended March 31, 2017 and 2016:

	Three Months Ended March 31,	
(In thousands)	2017	2016
Product royalty revenue	$ 18,435	$ 16,716
Product sales revenue - AMITIZA	31,340	23,434
Product sales revenue - RESCULA	2,814	3,161
Research and development revenue	3,448	3,430
Contract and collaboration revenue	246	467
Total	$ 56,283	$ 47,208

Total revenues were $56.3 million for the three months ended March 31, 2017, compared to $47.2 million for the three months ended March 31, 2016, an increase of $9.1 million or 19.2%.

Product royalty revenue

Product royalty revenue primarily represents royalty revenue earned on Takeda net sales of AMITIZA in North America and was $18.4 million for the three months ended March 31, 2017 compared to $16.7 million for the three months ended March 31, 2016, an increase of $1.7 or 10.3%. The increase was primarily due to higher Takeda reported AMITIZA net sales which were driven by a mix of price and volume increases.

Product sales revenue

Product sales revenue represents drug product sales of AMITIZA in North America, Japan and Europe, and drug product sales of RESCULA in Japan. AMITIZA product sales revenue was $31.3 million for the three months ended March 31, 2017 compared to $23.4 million for the three months ended March 31, 2015, an increase of $7.9 million or 33.7%. The increase was primarily attributable to increased AMITIZA sales in Japan under the Japan Mylan Agreement. RESCULA product sales revenue was $2.8 million for the three months ended March 31, 2017 compared to $3.2 million for the three months ended March 31, 2016, a decrease of $347,000.

Research and development revenue

Research and development revenue was $3.4 million for the three months ended March 31, 2017 compared to $3.4 million for the three months ended March 31, 2016. The amounts remain reasonably consistent year over year due to the advancement of the pediatric and alternative formulation studies.

Contract and collaboration revenue

Contract and collaboration revenue was $246,000 for the three months ended March 31, 2017 compared to $467,000 for the three months ended March 31, 2016, a decrease of $221,000 or 47.3%. The decrease was primarily due to the higher release of the collaboration obligation under the Global Takeda Agreement in the first quarter 2016.

Costs of Goods Sold

Costs of goods sold were $16.9 million for the three months ended March 31, 2017 compared to $23.3 million for the three months ended March 31, 2016, a decrease of $6.5 million or 27.7%. The decrease was primarily due to an $8.9 million decrease in amortization of R-Tech inventory step up, partially offset by increased costs of goods sold related to increased AMITIZA product sales.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2017 and 2016:

	Three Months Ended March 31,	
(In thousands)	2017	2016
Direct costs:		
Lubiprostone	$ 7,965	$ 5,626
Cobiprostone	-	2,109
CPP-1X	-	2,989
RTU-1096	-	920
VAP-1	-	29
Other	1,056	1,390
	9,021	13,063
Indirect costs	1,312	1,608
Total	$ 10,333	$ 14,671

Total research and development expenses for the three months ended March 31, 2017 were $10.3 million compared to $14.7 million for the three months ended March 31, 2016, a decrease of $4.3 million or 29.6%. The decrease was primarily due to the discontinuance of cobiprostone development and non-recurring CPP option costs in 2016.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended March 31, 2017 and 2016:

	Three Months Ended March 31,	
(In thousands)	2017	2016
Salaries, benefits and related costs	$ 3,694	$ 2,847
Legal, consulting and other professional expenses	9,746	2,070
Stock-based compensation	1,608	1,278
Pharmacovigilance	160	428
Other expenses	2,483	2,304
Total	$ 17,691	$ 8,927

General and administrative expenses were $17.7 million for the three months ended March 31, 2017, compared to $8.9 million for the three months ended March 31, 2016, an increase of $8.8 million or 98.2%. The increase was primarily due to a $7.7 million increase in legal, consulting and other professional expenses related to acquisition activities. The Company recorded restructuring charges of $365,000 and $183,000 for the three months ended March 31, 2017 and 2016, respectively. These costs are reflected within other expenses and consisted primarily of termination benefits.

Selling and Marketing Expenses

The following table summarizes our selling and marketing expenses for the three months ended March 31, 2017 and 2016:

	Three Months Ended March 31,	
(In thousands)	2017	2016
Salaries, benefits and related costs	$ 239	$ 227
Consulting and other professional expenses	70	35
Data purchases	40	46
Promotional materials & programs	67	1
Other expenses	100	466
Total	$ 516	$ 775

Non-Operating Income and Expense

The following table summarizes our non-operating income and expense for the three months ended March 31, 2017 and 2016:

	Three Months Ended March 31,	
(In thousands)	2017	2016
Interest income	$ 28	$ 25
Interest expense	(2,890)	(6,270)
Other income (expense), net	211	(347)
Total	$ (2,651)	$ (6,592)

Interest expense was $2.9 million for the three months ended March 31, 2017, compared to $6.3 million for the three months ended March 31, 2016, a decrease of $3.4 million or 53.9%. This decrease resulted from interest rates on notes payable decreasing from 8.4% to 3.3% as a result of refinancing our debt with Convertible Notes. The benefit from the lower interest rates was partially offset by higher principal balances.

Other income (expense), net was income of $211,000 for the three months ended March 31, 2017, compared to expense of $347,000 for the three months ended March 31, 2016, a change of $558,000, substantially all of which was attributable to increased foreign currency exchange gains.

Income Taxes

We recorded an income tax expense of $3.6 million and benefit of $3.0 million for the three months ended March 31, 2017 and 2016, respectively. The increase in the tax provision for the three months ended March 31, 2017 primarily pertained to increased pretax earnings in 2017 as compared to 2016 as well as foreign taxes paid on foreign exchange gains. The tax provision for the three months ended March 31, 2016 primarily pertained to pre-tax profits and losses generated by our Japanese and Swiss subsidiaries.

The effective tax rate (ETR) for the first quarter of 2017 was 43.7%, compared to 42.8% in the same period of 2016. The ETR for the quarter was based on a projection of the full year rate. The increase in the ETR was primarily due to foreign taxes paid on foreign exchange gains.

Reportable Operating Segments

We have one operating segment which is the development and commercialization of pharmaceutical products.

Financial Condition, Liquidity and Capital Resources

Financial Condition

Sources of Liquidity

We finance our operations principally from cash generated from revenues, cash and cash equivalents on hand, debt and to a lesser extent, from cash generated from the issuance and sale of our class A common stock and through the exercise of employee stock options. Revenues generated from operations principally consist of a combination of royalty payments, product sales, upfront and milestone payments, and research and development expense reimbursements received from Takeda, Mylan and other parties.

Our cash, cash equivalents and restricted cash consist of the following as of March 31, 2017 and December 31, 2016:

(In thousands)	March 31, 2017	December 31, 2016
Cash and cash equivalents	$243,480	$ 198,308
Restricted cash, current	213	213
Total	$243,693	$ 198,521

Our cash and cash equivalents are deposited in operating accounts and highly liquid investments with an original maturity at time of purchase of 90 days or less. As of March 31, 2017, and December 31, 2016, our restricted cash consisted of a certificate of deposit pledged to support an operating lease for our former office facility in Bethesda, Maryland.

On March 31, 2017, we entered into a merger agreement with Vtesse Inc., and on April 3, 2017, acquired Vtesse Inc. for upfront consideration of $200.0 million. The acquisition was funded through the issuance of 2,782,676 shares of Sucampo Class A common stock and $170.0 million of cash on hand. Substantially all of the fair value of Vtesse Inc. is related to VTS-270, its only significant asset. VTS-270 is an investigational drug in a pivotal Phase 2b/3 study for the treatment of NPC-1, an ultra-orphan, progressive and fatal disease.

Cash Flows

The following table summarizes our cash flows for the three months ended March 31, 2017 and 2016:

	Three Months Ended March 31,	
(In thousands)	2017	2016
Cash provided by (used in):		
Operating activities	$ 45,280	$ 23,737
Investing activities	(350)	(3,350)
Financing activities	308	917
Effect of exchange rates	(66)	489
Net increase in cash and cash equivalents	$ 45,172	$ 21,793

Three months ended March 31, 2017

Net cash provided by operating activities was $45.3 million for the three months ended March 31, 2017. This was primarily due to net income of $4.6 million plus adjustments to reconcile net income to net cash provided by operating activities consisting of depreciation and amortization of $7.4 million, stock-based compensation expense of $2.4 million, less deferred tax provision of $2.9 million, as well as changes in operating assets and liabilities consisting of a decrease in receivables of $30.3 million, and an increase in payables and accrued expenses of $5.9 million, partially offset by a change in prepaid and income taxes payable and receivable, net of $3.7 million.

Net cash used in investing activities was $0.4 million for the three months ended March 31, 2017 due to purchases of property and equipment.

Net cash provided by financing activities was $0.3 million for the three months ended March 31, 2017. This was realized through the issuance of Class A common stock upon the exercise of options and purchases through the employee stock purchase plan.

The effect of exchange rates on the cash balances of currencies held in foreign denominations for three months ended March 31, 2017 was a decrease of $66,000.

Three months ended March 31, 2016

Net cash provided by operating activities was $23.7 million for the three months ended March 31, 2016. This was primarily due to depreciation and amortization of $15.6 million, a decrease in receivables of $13.6 million, an increase in payables and accrued expenses of $3.6 million, offset by a net loss of $4.1 million and a net change in other assets and liabilities of $4.4 million.

Net cash used in investing activities was $3.4 million for the three months ended March 31, 2016. This was primarily due to the payment of the squeeze-out liability for non-tendering R-Tech shareholders of $8.2 million and investment in a convertible note receivable of $5.0 million, offset by a decrease in restricted cash of $10.6 million.

Net cash provided by financing activities was $0.9 million for the three months ended March 31, 2016. This was primarily realized through the issuance of Class A common stock upon the exercise of options.

The effect of exchange rates on the cash balances of currencies held in foreign denominations for three months ended March 31, 2016 was an increase of $489,000.

Off-Balance Sheet Arrangements

As of March 31, 2017, we did not have any off-balance sheet arrangements, as such term is defined in Item 303(a)(4) of Regulation S-K under the Securities Act of 1933, as amended.

Funding Requirements and Capital Resources

We may need substantial amounts of capital to continue growing our business. We may require this capital, among other things, to fund:

- our share of the on-going development program of AMITIZA;
- research, development, manufacturing, regulatory and marketing efforts for VTS-270 and other potential product candidates;
- the costs involved in obtaining and maintaining proprietary protection for our products, technology and know-how, including litigation costs and the results of such litigation;
- activities to resolve our on-going and potential legal matters;
- any option and milestone payments under general option and licensing ventures, including our exclusive option and collaboration agreement with CPP;
- other business development activities, including partnerships, alliances and investments in or acquisitions of other businesses, products and technologies;
- the expansion of our commercialization activities including the purchase of inventory; and
- the payment of principal and interest under our Convertible Notes.

The timing of these funding requirements is difficult to predict due to many factors, including the outcomes of our preclinical and clinical research and development programs and when those outcomes are determined, the timing of obtaining regulatory approvals and the presence and status of competing products. Our capital needs may exceed the capital available from our future operations, collaborative and licensing arrangements and existing liquid assets. Our future capital requirements and liquidity will depend on many factors, including, but not limited to:

- the cost and time involved to pursue our research and development programs;
- our ability to establish collaborative arrangements and to enter into licensing agreements and contractual arrangements with others; and
- any future change in our business strategy.

To the extent that our capital resources may be insufficient to meet our future capital requirements, we may need to finance our future cash needs through at-the-market sales, public or private equity offerings, further debt financings or corporate collaboration and licensing arrangements.

At March 31, 2017, based upon our current business plan, we believe our future cash flows from operating activities and our existing capital resources will be sufficient to meet our cash requirements for at least the next 12 months.

Effects of Foreign Currency

We currently receive a portion of our revenue, incur a portion of our operating expenses, and have assets and liabilities denominated in currencies other than the U.S. Dollar, the reporting currency for our consolidated financial statements. As such, the results of our operations could be adversely affected by changes in exchange rates either due to transaction losses, which are recognized in the statement of operations, or translation losses, which are recognized in comprehensive income. We currently do not hedge foreign exchange rate exposure via derivative instruments.

Item 3. ***Quantitative and Qualitative Disclosures About Market Risk.***

Our market risks during the three months ended March 31, 2017 have not materially changed from those discussed in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2016, which was filed with the SEC on March 8, 2017.

Foreign Currency Exchange Rate Risk

We are subject to foreign exchange risk for revenues and expenses denominated in foreign currencies. Foreign currency risk arises from the fluctuation of foreign exchange rates and the degree of volatility of these rates relative to the U.S. Dollar. We do not currently hedge our foreign currency transactions via derivative instruments.

Interest Rate Risk

Our exposure to market risks associated with changes in interest rates relates to both (i) the amount of interest income earned on our investment portfolio, and (ii) the amount of interest payable by us on the Convertible Notes. As our

investment portfolio is immaterial at this time and the interest rate on our Convertible Notes is fixed at 3.25% through 2021, we believe that our exposure to market risks associated with changes in interest rates is nominal.

Credit Risk

Our exposure to cr edit risk generally consists of cash and cash equivalents, restricted cash, investments and receivables. We place our cash, cash equivalents and restricted cash with what we believe to be highly rated financial institutions and invest the excess cash in highly rated investments. Our investment policy limits investments to certain types of debt and money market instruments issued by institutions primarily with investment grade credit ratings and places restrictions on maturities and concentrations by asset class and issuer.

Our exposure to credit risk also extends to strategic investments made as part of our ongoing business development activities, such as the $5.0 million investment in CPP made in January 2016.

As of March 31, 2017 and December 31, 2016, less than 1.0% of our cash, cash equivalents, restricted cash and investments are issued or insured by the federal government or government agencies. We have not experienced any losses on these accounts related to amounts in excess of insured limits.

Item 4. ***Controls and Procedures.***

a) Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), as of March 31, 2017. In designing and evaluating such controls, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Based upon the evaluation we carried out, our Chief Executive Officer and Chief Financial Officer have concluded that, as of March 31, 2017, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified under the applicable rules and forms of the SEC, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

32

b) Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II — OTHER INFORMATION

Item 1. ***Legal Proceedings.***

On December 28, 2015, in connection with our acquisition of R-Tech, three non-tendering stockholders of R-Tech submitted complaints to the Tokyo District Court alleging that the purchase price of R-Tech's shares was unfair, and demanding an appraisal of the fair value of the shares. The number of shares subject to these proceedings is minimal. On November 11, 2016, the Court (i) dismissed the petitions with respect to all shares purchased by the complainants after the public notice of the acquisition and (ii) with respect to shares purchase prior to such public notice, determined that the tender offer price was fair. One of the petitioners appealed this ruling; however, the appellate proceeding was dismissed on February 15, 2017. The petitioner has appealed to the Supreme Court of Japan; this final appeal remains ongoing as of the date of this filing.

On March 2, 2017, the Company received a Paragraph IV certification notice letter ("Notice Letter") regarding an Abbreviated New Drug Application ("ANDA") submitted to the FDA by Amneal Pharmaceuticals, LLC ("Amneal") requesting approval to market, sell and use a generic version of the 8 mcg and 24 mcg AMITIZA® (lubiprostone) soft gelatin capsule products. In its Notice Letter, Amneal alleges that certain patents covering compositions, formulations and methods of using AMITIZA, are invalid, unenforceable and/or will not be infringed by Amneal's manufacture, use or sale of the product described in its ANDA.

On April 13, 2017, the Company, Takeda, and certain affiliates of Takeda filed a patent infringement lawsuit in the U.S. District Court for the District of New Jersey against Amneal related to the ANDA filed by Amneal. The lawsuit claims infringement of five patents that are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book), with the latest expiring in 2027. Under the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, as a result of the patent infringement lawsuit, final FDA approval of Amneal's ANDA will be stayed up to 30 months from the date of receipt of the notice letter.

Item 1A. ***Risk Factors.***

Our business is subject to certain risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our common stock. For a discussion of these risks, please refer to the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, filed by us with the SEC on March 8, 2017. There have not been any material changes from the risk factors as previously disclosed in our Form 10-K for the fiscal year ended December 31, 2016.

Item 6. ***Exhibits***

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date
2.1**	Agreement and Plan of Merger, dated March 31, 2017, among the Company, Saber Merger Sub, Inc., Vtesse Inc. and Fortis Advisors, LLC solely in its capacity as Vtesse Inc. equityholder representative	Included herewith			
3.1	Certificate of Incorporation	8-K	001-33609	3.1	12/29/2008
3.2	Certificate of Amendment	8-K	001-33609	3.2	12/29/2008
3.3	Amended and Restated Bylaws	8-K	001-33609	3.3	8/2/2013
4.1	Specimen Stock Certificate evidencing the shares of class A common stock	S-1/A	333-135133	4.1	2/1/2007
10.1^	Employment Agreement, dated as of March 20, 2017, between the Company and Peter Pfreundschuh	Included herewith			
12.1	Ratio of earnings to fixed charges	Included herewith			
31.1	Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002	Included herewith			
31.2	Certification of the Principal Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002	Included herewith			
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Included herewith			
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Included herewith			
101.[INS]	XBRL Instance Document	Included herewith			
101.[SCH]	XBRL Taxonomy Extension Schema Document	Included herewith			
101.[DEF]	XBRL Taxonomy Extension Definition Linkbase Document	Included herewith			
101.[CAL]	XBRL Taxonomy Extension Calculation Linkbase Document	Included herewith			
101.[LAB]	XBRL Taxonomy Extension Label Linkbase Document	Included herewith			
101.[PRE]	XBRL Taxonomy Extension Presentation Linkbase Document	Included herewith			

** Confidential treatment has been requested for certain portions of this exhibit. The confidential portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission.
^ Compensatory plan, contract or arrangement.
The exhibits filed as part of this Form 10-Q are set forth on the Exhibit Index immediately preceding such exhibits, and are incorporated herein by reference.

34

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.

Sucampo Pharmaceuticals, Inc.

May 3, 2017 By: /s/ PETER GREENLEAF
Peter Greenleaf
Chief Executive Officer
(Principal Executive Officer)

May 3, 2017 By: /s/ PETER PFREUNDSCHUH
Peter Pfreundschuh
Chief Financial Officer
(Principal Financial Officer)

Sucampo Pharmaceuticals, Inc.

Exhibit Index

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date
2.1**	Agreement and Plan of Merger, dated March 31, 2017, among the Company, Saber Merger Sub, Inc., Vtesse Inc. and Fortis Advisors, LLC solely in its capacity as Vtesse Inc. equityholder representative	Included herewith			
3.1	Certificate of Incorporation	8-K	001-33609	3.1	12/29/2008
3.2	Certificate of Amendment	8-K	001-33609	3.2	12/29/2008
3.3	Amended and Restated Bylaws	8-K	001-33609	3.3	8/2/2013
4.1	Specimen Stock Certificate evidencing the shares of class A common stock	S-1/A	333-135133	4.1	2/1/2007
10.1^	Employment Agreement, dated as of March 20, 2017, between the Company and Peter Pfreundschuh	Included herewith			
12.1	Ratio of earnings to fixed charges	Included herewith			
31.1	Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002	Included herewith			
31.2	Certification of the Principal Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002	Included herewith			
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Included herewith			
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Included herewith			
101.[INS]	XBRL Instance Document	Included herewith			
101.[SCH]	XBRL Taxonomy Extension Schema Document	Included herewith			
101.[CAL]	XBRL Taxonomy Extension Calculation Linkbase Document	Included herewith			
101.[DEF]	XBRL Taxonomy Extension Definition Linkbase Document	Included herewith			
101.[LAB]	XBRL Taxonomy Extension Label Linkbase Document	Included herewith			
101.[PRE]	XBRL Taxonomy Extension Presentation Linkbase Document	Included herewith			

** Confidential treatment has been requested for certain portions of this exhibit. The confidential portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission.
^ Compensatory plan, contract or arrangement.

36