

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(d) of  
The Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): January 11, 2016**

**Sucampo Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation)

**001-33609**

(Commission File Number)

**30-0520478**

(IRS Employer  
Identification No.)

**805 King Farm Blvd, Suite 550  
Rockville, Maryland 20850**

(Address of principal executive offices, including zip code)

**(301) 961-3400**

(Registrant's telephone number, including area code)

**N/A**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 7.01. Regulation FD Disclosure.**

From January 11, 2016 through January 13, 2016, Sucampo Pharmaceuticals, Inc. (“Company”) will make a corporate update presentation at one-on-one meetings with analysts and investors in San Francisco, CA at the 34th Annual J.P. Morgan Healthcare Conference. All meetings will include written communication comprised of slides. The slides from the presentation are being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in the presentation furnished as Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and is not incorporated by reference into any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits**

<b>Exhibit Number</b>	<b>Exhibit Description</b>
99.1	Presentation titled “Sucampo Pharmaceuticals, Inc. Corporate Update” dated January 11-13, 2016.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**SUCAMPO PHARMACEUTICALS, INC.**

By: /s/ Andrew P. Smith

Name: Andrew P. Smith

Title: Chief Financial Officer

Date: January 11, 2016

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**EXHIBIT INDEX**

**Exhibit  
Number**

**Exhibit Description**

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99.1

Presentation titled "Sucampo Pharmaceuticals, Inc. Corporate Update" dated January 11-13, 2016.



# Sucampo Pharmaceuticals, Inc. Corporate Update

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January 11-13, 2016

Peter Greenleaf, Chief Executive Officer

Peter Kiener, Chief Scientific Officer

Andrew Smith, Chief Financial Officer

Silvia Taylor, Senior Vice President, Investor Relations and Corporate Affairs

This presentation contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential, future financial and operating results, and other statements that are not historical facts. The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the impact of pharmaceutical industry regulation and health care legislation; the ability of Sucampo to continue to develop the market for AMITIZA; the ability of Sucampo to develop, commercialize or license existing pipeline products or compounds or license or acquire non-prostone products or drug candidates; Sucampo's ability to accurately predict future market conditions; dependence on the effectiveness of Sucampo's patents and other protections for innovative products; the risk of new and changing regulation and health policies in the U.S. and internationally; the effects of competitive products on Sucampo's products; risks relating to Sucampo's financing for the R-Tech Ueno acquisition, including the restrictive covenants undertaken by Sucampo as part of the financing; Sucampo's ability to successfully integrate R-Tech Ueno's operations; and the exposure to litigation and/or regulatory actions.

No forward-looking statement can be guaranteed and actual results may differ materially from those projected. Sucampo undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this presentation should be evaluated together with the many uncertainties that affect Sucampo's business, particularly those mentioned in the risk factors and cautionary statements in Sucampo's most recent Form 10-K as filed with the Securities and Exchange Commission on March 9, 2015 as well as its filings with the Securities and Exchange Commission on Forms 8-K and 10-Q since the filing of the Form 10-K, all of which Sucampo incorporates by reference.

- **Fast-growing global biopharmaceutical company** with increasing revenues and focus on innovative R&D of proprietary drugs
- **Sustained revenue growth** from AMITIZA® (lubiprostone): highly differentiated product with broadest label in \$5B+ constipation market
- **Diversified pipeline** for clinical development and/or partnering:
  - Focused on gastrointestinal, ophthalmic, autoimmune/inflammatory, and oncology disorders
    - Cobiprostone: Phase 2 product with **significant market potential** for treatment of NERD/sGERD; Top-line data 1H16
    - VAP-1 inhibitor compounds for NASH, COPD
    - Exclusive option for Ph. 3 CPP-1X/sulindac combo product for FAP
    - Assets for out-licensing
- **Business development strategy** to bolster growth and diversify
  - **Acquisition of R-Tech Ueno** increases revenue and builds scale
- Demonstrated **financial performance** with strong balance sheet and cash flow to fuel continued transformation
- Deep management team with **proven ability** to create value

	Secure	Advance	Transform
<b>Revenue &amp; Market Value</b>	<ul style="list-style-type: none"> <li>• <b>Focus efforts and strengthen overall capabilities</b> <ul style="list-style-type: none"> <li>- Team</li> <li>- Development capability</li> </ul> </li> <li>• <b>Secure and grow AMITIZA revenues</b> <ul style="list-style-type: none"> <li>- Efforts to ensure consistent and sustainable growth</li> <li>- Global partnerships</li> <li>- Resolution of patent litigation with first filer</li> </ul> </li> <li>• <b>Optimize investment in current pipeline</b> <ul style="list-style-type: none"> <li>- Life cycle management (LCM)</li> <li>- Prioritize or exit programs to maximize return on investment (ongoing)</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• <b>Address capital structure</b> <ul style="list-style-type: none"> <li>- Diversify investor base</li> </ul> </li> <li>• <b>Execute on pipeline opportunities</b> <ul style="list-style-type: none"> <li>- File LCM programs for regulatory approvals</li> <li>- Progress prostones in clinical development to Phase 3</li> </ul> </li> <li>• <b>BD strategy</b> <ul style="list-style-type: none"> <li>- Additional accretive transactions</li> <li>- Acquire new development programs to strengthen and accelerate the pipeline</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• <b>Launch AMITIZA LCM programs</b></li> <li>• <b>Launch new pipeline products</b></li> <li>• <b>Sustainable pipeline of drug candidates with near term launch opportunities</b></li> <li>• <b>Execute more transformative deals</b></li> <li>• <b>Execute value creation strategy</b></li> </ul>
	<b>Achieved</b>	<b>Today</b>	<b>2017+</b>

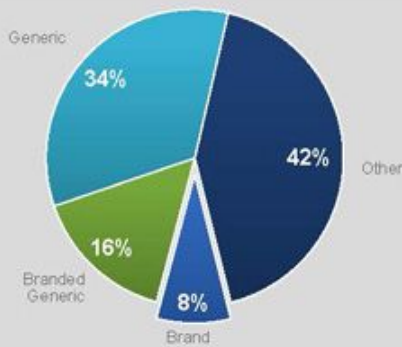


### ***Significant unmet need in efficacy, safety and patient satisfaction***

- U.S. prescription and OTC market ~\$5.2B, growing 6%+ annually (2015)
  - \$4.4B branded + generic market, ~50M annual scripts (1)
  - Additional \$800M in revenue from OTC market, 23M units (30-day supply) sold annually
- Majority of prescription and OTC treated patients currently not satisfied with treatment
  - Current OTC treatment leaves significant unmet need offering only temporary relief
    - 60%+ of patients on OTCs report ineffective symptom relief
  - Few patients aware of chronic Rx options



## Share of Prescription Constipation Products



Strategy: convert from OTC and generics to AMITIZA

> 88% of NRx are new patients

### *Chronic Idiopathic Constipation (CIC)*

- Infrequent and difficult passage of stool over 12 non-consecutive weeks within a 12-month period
- ~14% to 16% of adults globally

### *Irritable Bowel Syndrome with Constipation (IBS-C)*

- Disorder of the intestines; symptoms are severe cramping, pain, bloating and changes of bowel habits including constipation
- IBS: ~15% of adults globally, 1/3 of which is IBS-C

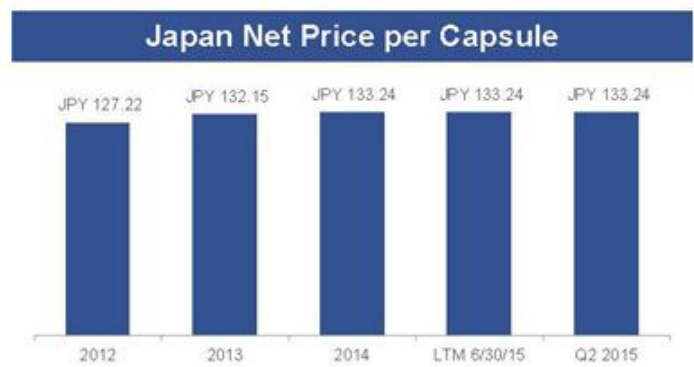
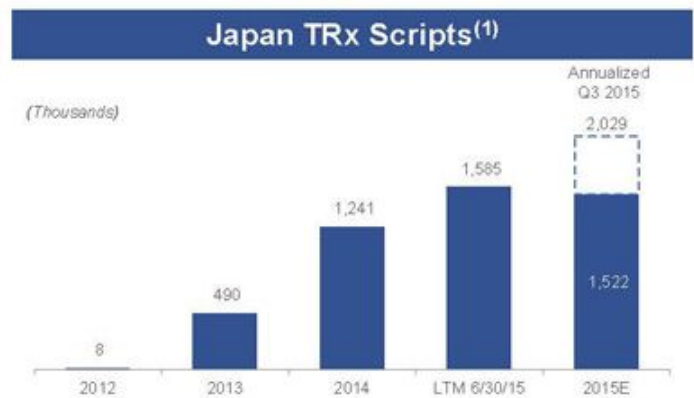
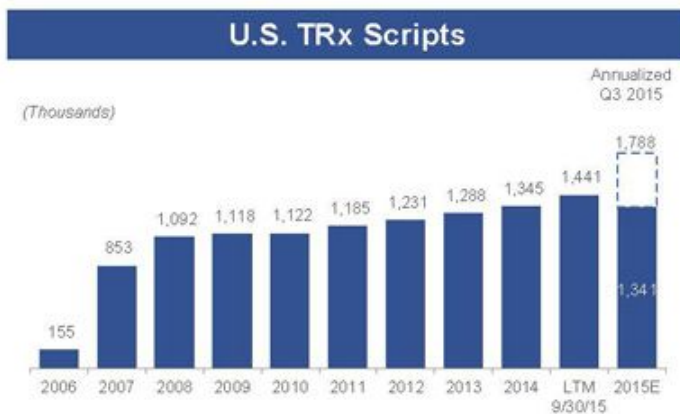
### *Opioid-Induced Constipation-Non Cancer (OIC)*

- Common adverse effect of chronic opioid use; infrequent and incomplete evacuation of stool, hard stool consistency, & straining
- ~2M-4M moderate to severe sufferers in U.S.

- **Only product approved for all 3 indications**
  - CIC
  - IBS-C
  - OIC (non-cancer)
- **Differentiated MOA: localized CIC-2 activation with dual action**
  - Increases intestinal fluid secretion
  - Stimulates recovery of mucosal barrier function
- **Key product characteristics**
  - Locally-acting
  - Rapid and predictable onset of action
- **Demonstrated efficacy and tolerability**
  - Most experienced product: 10M+ scripts over 9+ years
  - Well-tolerated product with established safety profile:
    - No black box warning
- **More than 90% of lives covered nationally across all payor channels**



## November Rx YOY growth rates: **TRx 10%; NRx 14%**



1) Based on management assumption of 46 capsules per TRx.

- **Takeda** markets AMITIZA in U.S., Canada, U.K. and Switzerland; 800 sales reps in U.S.
  - Takeda is **#1 gastroenterology company world** wide and has rights to all markets except Japan (Mylan) and China
  - Royalty arrangement in North America (18%- 26%)
  - Takeda reimburses majority of development costs for new formulations/indications
  - **50% split of annual AMITIZA net sales revenue** for North America beginning January 2021
- Agreement with **Mylan** for Japan
  - Mylan reimburses 100% of development costs
- **Harbin Gloria** developing AMITIZA in China; expected to launch in 2018
- Non-exclusive licensing agreement with **Par** beginning January 2021 with attractive economics
  - **50% gross profit split** of generic lubiprostone



**AMITIZA is well positioned for continued growth**

	Drug	Rx or OTC	Company	Target Indication			Global Market Share	Commentary
				CIC	IBS-C	OIC		
Branded / Patented	<b>amitiza</b> lubiprostone	Rx	Sucampo (Marketed by Takeda)	✓ <i>All adults</i>	✓ <i>Adult women</i>	✓ <i>All adults</i>	3%	<ul style="list-style-type: none"> <li>Long history of usage</li> <li>Well-tolerated product with an established safety profile</li> <li>No limitation on duration of use</li> </ul>
	<b>Linzess</b> (linacloctide) capsules	Rx	Ironwood (Marketed by Actavis)	✓ <i>All adults</i>	✓ <i>All adults</i>	✗	3%	<ul style="list-style-type: none"> <li>Black box warning against pediatric use</li> <li>Often used for the most severe patients</li> <li>Food restrictions</li> <li>Convenient dosing</li> </ul>
	<b>RELISTOR</b> methylntramine bromide	Rx	Salix	✗	✗	✓ <i>All adults</i>	~1%	<ul style="list-style-type: none"> <li>Very little market penetration due to method of drug delivery (via injection)</li> </ul>
	<b>movantik</b> naloxegol tablets II	Rx	AstraZeneca	✗	✗	✓ <i>All adults</i>	~1%	<ul style="list-style-type: none"> <li>Very limited uptake since launch in March 2015 for OIC</li> <li>Post marketing safety commitment in place</li> </ul>
<b>All Branded / Patented:</b>							<b>8%</b>	
Generic	<b>MiraLAX</b>	OTC	Schering-Plough	✗	✗	✗	28%	<ul style="list-style-type: none"> <li>Short-term indications no longer than 2 weeks</li> <li>Used to treat one-time symptoms but not chronic conditions</li> <li>Use of laxatives for CIC and IBS-C is not supported by long-term, well-controlled clinical trial data</li> </ul>
	<b>Bentyl</b> (Dicyclomine)	Rx	Pantheon & Akorn (Marketed by Axcan)	✗	✗	✗	11%	<ul style="list-style-type: none"> <li>Does not relieve constipation</li> <li>Primarily used to reduce stomach and intestinal cramping that is symptom of IBS</li> </ul>
	<b>Other Therapies</b>	Various		✗	✗	✗	53%	<ul style="list-style-type: none"> <li>Includes Stool softener with stim (Docusate/ Senna S), PEG preps (Osmi Prep), Irritant-stimulant (Ex-Lax, Dulcolax), Bulk Fiber, Oils and Enemas</li> </ul>
<b>All Generic:</b>							<b>92%</b>	

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## *Expand AMITIZA franchise through new formulation and new indication*

### **New Formulation**

- Alternate formulation for additional adult and pediatric patients who cannot tolerate capsules, or nasogastric tube fed patients
- ~40% of adults have difficulty swallowing pills
- Next step: **Phase 3**, commence 2H16
- Takeda to reimburse 100% of development costs

### **New Pediatric Functional Constipation Indication**

- U.S. Prevalence: 18% of pediatric population (13.5M)
- Unmet need: No FDA-approved competition for AMITIZA in pediatric population (black box warning for linaclotide; prucalopride failed in Phase 4); patients use OTC drugs off-label
- **Phase 3** program:
  - With current capsule formulation: Children 6-17 years
    - Trial ongoing; Data 2H16
  - With alternate formulation: Children 6 months-6 years
    - Trial initiates 1H17
- Takeda reimbursing 67% of development costs





# The Recent Addition of R-Tech Ueno Provides Significant Benefit



<b>Company Description</b>	<ul style="list-style-type: none"><li>• Global pharmaceutical company focused on the research and development of drugs in gastroenterology, ophthalmology and dermatology</li><li>• Exclusive manufacturer and supplier of AMITIZA and RESCULA (unoprostone isopropyl)</li></ul>
<b>Immediately and significantly accretive transaction enhancing profitability and free cash flow</b>	<ul style="list-style-type: none"><li>• ~30% pre-offer premium, ~16% 3-month VWAP premium</li><li>• Strong and stable free cash flow</li><li>• Immediate accretion from RTU's AMITIZA revenue (~1/3 of economics paid by Takeda)</li></ul>
<b>Increased manufacturing and supply chain control over AMITIZA</b>	<ul style="list-style-type: none"><li>• Improve operational efficiencies and capture additional margin from vertically integrating existing manufacturing</li></ul>
<b>Expansion and diversification of product pipeline</b>	<ul style="list-style-type: none"><li>• RTU pipeline offers development alternatives and/or partnership opportunities in ophthalmology, autoimmune and inflammatory diseases and oncology</li></ul>
<b>Significant cost synergy opportunity</b>	<ul style="list-style-type: none"><li>• \$11.4M of identified potential cost synergies expected to be achievable within 12 months</li></ul>

# Strengthened Financial Position of Combined Company



	Sucampo	RTU	Combined
Key Products Areas	Gastroenterology, Ophthalmology	Gastroenterology, Ophthalmology	Gastroenterology, Ophthalmology
Number of Marketed Products	2	2	2
LTM 6/30/15 Revenue	\$133.6M	\$63.7M	\$175.4M <sup>(1)</sup>
LTM 6/30/15 Adjusted EBITDA	\$59.1M	\$15.6M	\$86.1M <sup>(2)</sup>
Revenue by Product	<p>RESCULA and Other 1% AMITIZA 99%</p>	<p>Other 1% Rescula 17% AMITIZA 82%</p>	<p>Other 1% Rescula 6% AMITIZA 93%</p>
Revenue by Partner	<p>Other &lt;1% Mylan 41% Takeda 59%</p>	<p>Other 18% Mylan 33% Takeda 49%</p>	<p>Other 6% Mylan 31% Takeda 62%</p>

(1) Net of intercompany eliminations.  
 (2) Includes \$11.4M of cost synergies.

# Product Pipeline Overview

Program	Target	First Indication	Development Stage	NDA / MAA Filing	Approval	Comments
<b>GI/Metabolic/Inflammation</b>						
AMITIZA	CIC2	Pediatric functional constipation	P3	2016	2017	Current capsule formulation
Lubiprostone Microparticle Formulation	CIC2	Pediatric functional constipation; adult CIC	P3	2017	2018	New liquid-like formulation
Cobiprostone	CIC2	NERD/sGERD	P2	2019	2020	Mucoadhesive formulation
CPP-1X/sulindac combination product		Familial Adenomatous Polyposis	P3	2018	2019	Exclusive option from CPP
RTU-1096	Vap-1 inhibitor	NASH	P1b			Oral formulation
<b>Ophthalmology</b>						
UF-021	BK2	Retinitis Pigmentosa	P3			Financial support in Japan by AMED
RU-101		Severe dry eye	P2			Recombinant human albumin
RU-105	Substance P & IGF-1	Post-Lasik corneal epithelial defects	P1b			Topical eye drops; combination of peptides
RTU-1096	Vap-1 inhibitor	Diabetic Retinopathy, diabetic macular edema	P1a			Oral formulation
UF-021	BK2	Age-Related Macular Degeneration	P1a			Topical formulation
<b>Oncology</b>						
Cobiprostone	CIC2	Oral Mucositis	P2	2019	2020	Liquid/spray formulation
RTU-1096	Vap-1 inhibitor	Immuno-oncology	P1a			Oral formulation
<b>Other</b>						
RK-023	PG receptor	Alopecia	P2			
RTU-009	Vap-1 inhibitor	Acute cerebral infarction	Preclinical			Liquid formulation

Sucampo Program

RTU Program

Option

- **Significant opportunity**

- **Orphan indication** in U.S. for familial adenomatous polyposis (FAP)
  - 30K cases
- **No approved** treatment options
- **Dire** patient need
  - 100% risk of colon cancer
  - Progressive removal of colon/rectum
  - Poor quality of life
- Incremental opportunity of **\$200M-\$400M**



- **De-risked**

- **Exclusive Option** with Cancer Prevention Pharma
- Strong scientific rationale and **Phase 2 proof of concept** data in sporadic colon adenoma/FAP
- **Defined** regulatory pathway



- **Clinical development**

- **Phase 3** ongoing
- Futility analysis expected in 2H16
- Co-formulation efforts ongoing

- **Additional opportunities in sporadic colon adenoma therapy (CAT)**

- **Significant opportunity**

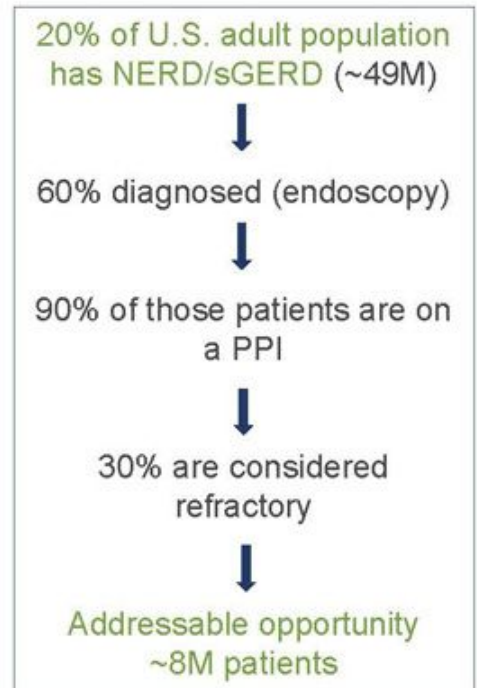
- **2–12% of total population** is Proton-Pump Inhibitor (PPI) refractory Nonerosive Reflex Disease (NERD)/ Symptomatic Gastroesophageal Reflux Disease (sGERD)
- **No effective treatment options available** for patients refractory to PPIs
  - Current PPI for refractory patients provide symptomatic relief only
  - No treatments protect membrane barrier function
- Incremental opportunity of **\$500M-\$1B**

- **Differentiated**

- **Protects epithelial barrier function** and stabilizes tight junctions in the epithelium
- **Stabilizes** epithelial mucosa and protects membrane barrier function
- Protects against both **bile and gastric acid**

- **Clinical development**

- **Phase 2** ongoing



## VAP-1 inhibitors

- VAP-1 is an enzyme and adhesion receptor
- Potential indications including NASH, COPD, diabetic macular edema and diabetic retinopathy and modulation of tumor-specific immune responses
- RTU-1096
  - MAD Phase 1b
  - Next step: generate additional preclinical data in additional formulations
- RTU-009
  - Next step: complete IND-enabling studies, initiate clinical stage development
  - IV: acute inflammatory disease
  - Oral: for chronic inflammatory disease; cancer
- Composition of matter out to 2029 and potential for future extension
- Opportunity to be best-in-class

## Sucampo's Strong Revenue Growth: Q3

- Total revenues **up 6%** to \$33.4M
- Product royalty revenue **up 15%** to \$19.3M
- Product sales revenue **up 20%** to \$11.0M (excl. 2014 milestone payment)

## Sucampo is Profitable and Cash Generating: Q3

- Net income = **\$7.2M**
- EPS = **\$0.16**
- Operating cash flow = **\$24.2M**

## Full Year Financial Guidance

### 2015

- Adjusted net income of **\$30-\$35M**:
  - Includes **\$5.3M** of interest and debt issuance expense and **\$5.7M** of one-time charges to be expensed in Q4 2015, related to the RTU acquisition
  - Excludes **\$2.9M** of non-cash amortization of intangibles and **\$3.5M** of amortization of inventory step-up costs\*, both related to the RTU acquisition
- Adjusted EPS of **\$0.65-\$0.75**
- Adjusted EBITDA\*\* of **\$55-\$60M**
- GAAP net income\*\*\* of **\$24-29M**
- GAAP EPS\*\* of **\$0.51-\$0.61**

### 2016

- Revenue of **\$195-\$205M**
- Adjusted net income of **\$45-\$50M**:
  - Excludes **\$17.6M** of amortization of acquired intangibles and **\$8.9M** of amortization of the remaining inventory step-up costs, both related to the RTU acquisition
- Adjusted EPS of **\$0.97-\$1.07**
- Adjusted EBITDA\*\* of **\$100-\$105M**

\*Amortized straight-line over seven months. In 2015, will recognize two months of amortized inventory step-up costs, with the remaining five months expensed in the 1H16.

\*\*Net income before interest, tax, depreciation, amortization and stock option expense

\*\*\*Includes non-cash amortization

## Upcoming Milestones

Product	Event	Expected Timing
Cobiprostone	Top-line data from Phase 2 NERD/sGERD	1H16
AMITIZA (lubiprostone)	Initiation of Phase 3 pivotal alternate formulation in adults	2H16
AMITIZA (lubiprostone)	Top-line data from Phase 3 pivotal alternate formulation in adults	
AMITIZA (lubiprostone)	Top-line data from Phase 3 pivotal PFC (6–17 years)	
AMITIZA (lubiprostone)	Top-line data from Phase 3 open-label PFC (6–17 years)	
AMITIZA (lubiprostone)	<b>File NDA for PFC (6-17 years)</b>	
Cobiprostone	Top-line data from Phase 2 OM	1H17
AMITIZA (lubiprostone)	Initiation of Phase 3 pivotal PFC (6 months–6 years)	

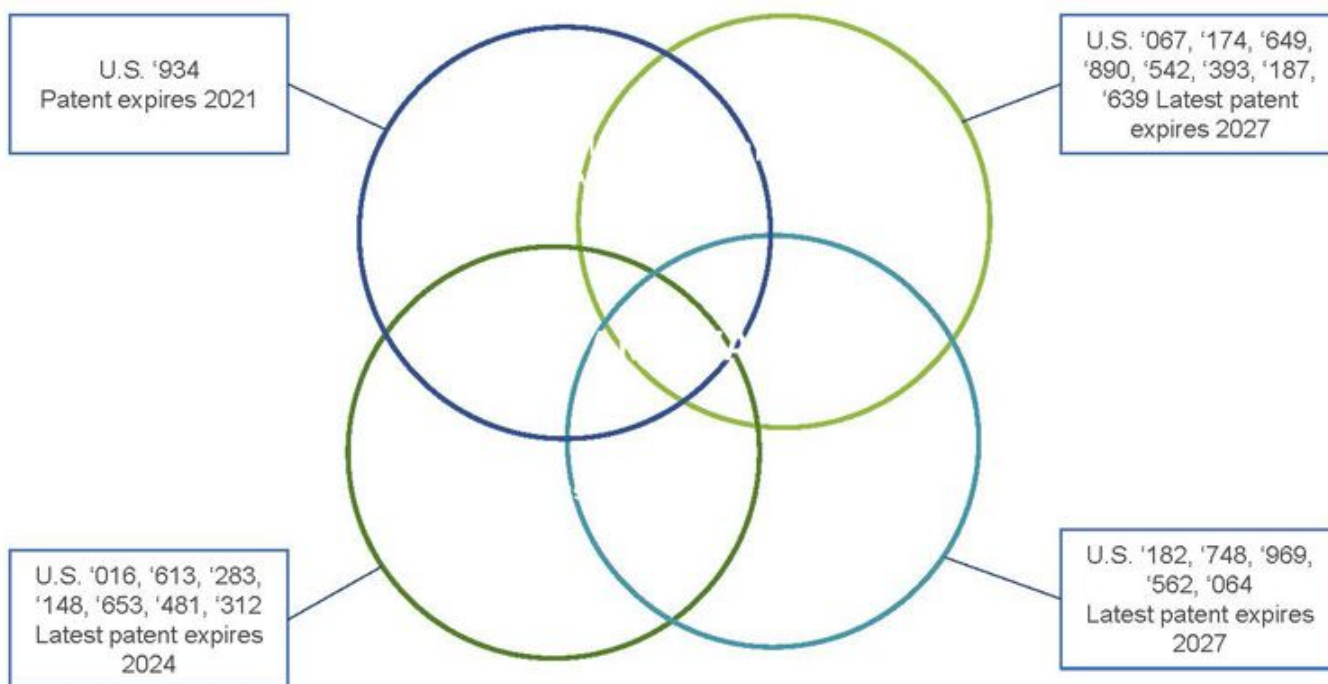


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- **Diversified pipeline** for clinical development and/or partnering:
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# Back Up Slides

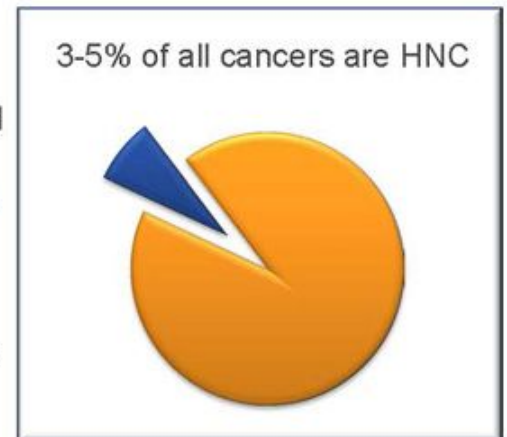


**AMITIZA well-protected by a comprehensive suite of patents through 2027**



- AMITIZA is covered by an additional 10 patents through 2028 in Japan and 6 patents in Europe through 2027

- **Significant opportunity**
  - ~60K U.S. patients develop HNC annually
  - More than half treated with radiation
  - ~550K HNC cases annually worldwide
  - Limited treatment options for OM with no approved therapies in the U.S.
  - Incremental opportunity of **\$50-\$100M in the U.S.**
- **Differentiated**
  - **Stimulates and protects** mucosal barrier function
  - Mitigates the primary damage response
- **Clinical development**
  - **FDA fast-track designation**
  - Phase 2 initiation **2H15**



**Experienced management team with considerable experience in product development and commercialization**

<b>Peter Greenleaf</b> Chief Executive Officer	
<b>Peter Kiener, D.Phil</b> Chief Scientific Officer	
<b>Peter Lichtlen, M.D., Ph.D.</b> Chief Medical Officer	
<b>Matthias Alder</b> Executive Vice President, Business Development & Licensing	
<b>Max Donley</b> Executive Vice President of Human Resources	
<b>Steven Caffé, M.D.</b> Senior Vice President, Regulatory Affairs	
<b>Stanley Miele</b> Chief Commercial Officer	
<b>Silvia Taylor</b> Senior Vice President, Investor Relations and Corporate Affairs	
<b>Andrew Smith</b> Chief Financial Officer	

# Sucampo Evolution

