# 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): July 12, 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

(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.

On July 12, 2016, Sucampo Pharmaceuticals, Inc. ("Company") will make a corporate update presentation at one-on-one meetings with analysts and investors in New York at Cantor Fitzgerald's 2<sup>nd</sup> Annual 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

Exhibit	
Number	Exhibit Description
99.1	Presentation titled "Sucampo Pharmaceuticals, Inc. Cantor Fitzgerald's 2 <sup>nd</sup> Annual Healthcare Conference" dated July 12, 2016.

### **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: <u>/s/ Andrew P. Smith</u>

Date: July 12, 2016

Name: Andrew P. Smith Title: Chief Financial Officer

### EXHIBIT INDEX

Exhibit
Number

99.1

Exhibit Description

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### Sucampo Pharmaceuticals, Inc. Cantor Fitzgerald's 2<sup>nd</sup> Annual Healthcare Conference

Tuesday, July 12th

Peter Greenleaf, Chairman and Chief Executive Officer
Silvia Taylor, Senior Vice President, Investor Relations and Corporate Affairs

### Forward Looking Statements



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, 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; Sucampo's ability to accurately predict future market conditions; dependence on the effectiveness of Sucampo's patents and other protections for innovative products; the effects of competitive products on Sucampo's products; 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 press release 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 11, 2016, as amended, 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
- Prioritized and diversified pipeline for clinical development and/or partnering:
  - Focused on gastrointestinal, ophthalmic, autoimmune/inflammatory, and oncology disorders
- Business development strategy to bolster growth and diversify
  - Acquisition of R-Tech Ueno increases revenue and builds scale
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# Clear Strategy to Methodically Build a Leading Bio/Pharma Company



# Revenue & Market Value

### Secure

- Focus efforts and strengthen overall capabilities
  - Team
  - Development capability
- Secure and grow AMITIZA revenues
  - Efforts to ensure consistent and sustainable growth
  - Global partnerships
  - Resolution of patent litigation with first filer
- Optimize investment in current pipeline
  - Life cycle management (LCM)
  - Prioritize or exit programs to maximize return on investment (ongoing)

### **Advance**

- Address capital structure
  - Diversify investor base
- Execute on pipeline opportunities
  - File LCM programs for regulatory approvals
  - Progress programs in clinical development to Phase 3
- BD strategy
  - Additional accretive transactions
  - Acquire new development programs to strengthen and accelerate the pipeline

### **Transform**

- Launch AMITIZA LCM programs
- Launch new pipeline products
- Sustainable pipeline of drug candidates with near term launch opportunities
- Execute more transformative deals
- Execute value creation strategy

Achieved Today 2017+



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

- U.S. prescription and OTC market ~\$5.2B
  - \$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

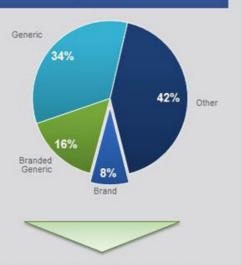


1) Source: IMS and Wall Street research. 5

### Prescription Constipation Market Is Large and Growing



# Share of Prescription Constipation Products



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.

Source: Wall Street research and Company estimates.

generics to AMITIZA

Strategy: convert from OTC and

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### AMITIZA: Broadest Label in Constipation Market



- 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: 2M patients and 11M+ exposures over 10+ years
  - Well-tolerated product with established safety profile:
    - · No black box warning



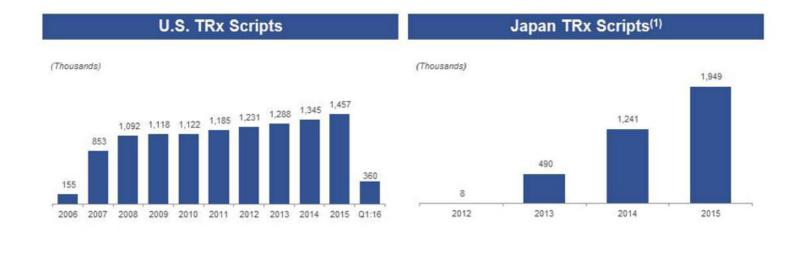


### AMITIZA Prescription Growth is Sustained



### Q1:16 TRx YoY growth: 5%

- · Growth highlights strong and enduring position in the constipation market
- · Reaffirm expectation of continued mid-to-high single digit prescription growth



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

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### Blue-Chip Partnerships Provide Global Reach for AMITIZA



- Takeda global rights to AMITIZA (except Japan, China), markets AMITIZA in U.S., 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
  - Revenue from product sales to Mylan
- Harbin Gloria developing AMITIZA in China
- Non-exclusive licensing agreement with Par beginning January 2021 with attractive economics
  - 50% gross profit split of generic lubiprostone
     January 2021+



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### AMITIZA is well positioned for continued growth

1				Target Indication		Global				
Dru		Rx or OTC	Company	CIC	IBS-C	OIC	Market Share	Commentary		
amit		Rx	Sucampo (Marketed by Takeda)	<b>✓</b> All adults	✓ Adult women	<b>✓</b> All adults	3%	Long history of usage     Well-tolerated product with an established safety profile     No limitation on duration of use		
Linze (linaclotide) d		Rx	Ironwood (Marketed by Actavis)	✓ All adults	✓ All adults	×	3%	Black box warning against pediatric use     Often used for the most severe patients     Food restrictions     Convenient dosing		
RELIST methylnatrexon		Rx	Salix	×	×	✓ All adults	~1%	Very little market penetration due to method of drug delivery (via injection)		
	vantik™ ol tablets ∉	Rx	AstraZeneca	×	×	✓ All adults	~1%	Limited uptake since launch in March 2015 for OIC     Post marketing safety commitment in place		
				All B	randed / P	atented:	8%			
MiraLA	X	отс	Schering- Plough	×	×	×	28%	Short-term indications no longer than 2 weeks     Used to treat one-time symptoms but not chronic conditions     Use of laxatives for CIC and IBS-C is not supported by long-term, well-controlled clinical trial data		
Bentyl (Dicylcomi	ne)	Rx	Pantheon & Akorn (Marketed by Axcan)	×	×	×	11%	Does not relieve constipation     Primarily used to reduce stomach and intestinal cramping that is symptom of IBS		
Other The	rapies		Various	×	×	×	53%	<ul> <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>		
					All	Generic:	92%			



### 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, initiates for adults 2H16
- File NDA for alternate formulation for adults 2H17
- Takeda to reimburse 100% of development costs

### New Pediatric Functional Constipation (PFC) Indication

- U.S. Prevalence: 18% of pediatric population (13.5M)
- Unmet need: No FDA-approved therapies for PFC (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 (pivotal and open-label)
    - File sNDA 2H16
  - With alternate formulation: Children 6 months-6 years
    - Pivotal trial initiates mid-2017 (open-label 2H17)
- Takeda reimbursing 67% of development costs





### AMITIZA Growth Strategy





 Underpenetrated markets with unsatisfied patients

BRAND

- Expanded Takeda agreement
- √ Physician Targeting
- ✓ Patient initiatives (e.g., \$0 copay card)
- ✓ OIC driving 30% of brand sales



### EXPANDED PARTNERSHIPS/ SECURING FUTURE REVENUE

- ✓ RTU acquisition increases AMITIZA revenue, captures add'I margin from vertically integrating mfg
- √ Takeda
  - Net sales revenue split (branded lubi\*, incl. LCM)
- ✓ Agreement with Par
  - Gross profit split (generic lubi\*)



### PRICE

- √ Yearly Increases
- ✓ Gross-to-net cap for Sucampo



### **GEOGRAPHY**

- Takeda global partnership
  - · U.S.
  - · Canada
  - E.U. (new reco's for approval)
  - · ROW
- √ Mylan
  - Japan
- √ Harbin Gloria
  - · China



### EXPANSION

- New Formulation (2017)
  - Expands market access
- ✓ Broad pediatric population spanning infants to teens (2017/18)
- ✓ Extends runway

\*lubiprostone

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### Prioritized and Diversified Product Pipeline



Program	Target	First Indication	Development Stage	NDA / MAA Filing	Approval
Gl/Metabolic/ Inflamation			5		
AMITIZA	CIC2	Pediatric functional constipation	P3	2016	2017
Lubiprostone Microparticle Formulation	CIC2	Pediatric functional constipation (1); adult CIC (2)	P3	2018(1); 2017 (2)	2019 (1); 2018 (2)
CPP-1X/sulindac combination product	Polyamines	Familial Adeneomatous Polyposis	P3	2018	2019
RTU-1096	Vap-1 inhibitor	Auto-immune/inflammatory	P1		
Opthalmology					
RTU-1096	Vap-1 inhibitor	Auto-immune/inflammatory	P1 Preclinical		
Oncology*					
RTU-1096	Vap-1 inhibitor	Immuno-oncology	P1		
Other					
RTU-009	Vap-1 inhibitor	Acute cerebral infarction	Preclinical		

<sup>\*</sup>P2 study for cobiprostone in oral mucositis in head and neck cancer discontinued after futility analysis; no safety concerns

Sucampo Program	RTU Program	Option	
	it i o i i o gi u i i	op.io.i	

# CPP-1X/sulindac Combo: Exclusive Option for Phase 3 Asset in FAP



### Significant opportunity

- Orphan indication in U.S. for familial adenomatous polyposis (FAP)
  - · ~30K cases currently
- 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 for N. America
- Strong scientific rationale and Phase 2 proof of concept data in sporadic colon adenoma/FAP
- Defined regulatory pathway



- Phase 3 ongoing; fully enrolled
- Futility analysis expected in 2H16
- Co-formulation efforts ongoing



 Additional opportunities in sporadic colon adenoma therapy (CAT)



- VAP-1
  - VAP-1 is an enzyme and adhesion receptor
- RTU-1096
  - MAD Phase 1 Results
    - · No significant safety issues
    - · Evidence of inhibition of systemic VAP-1 at all doses tested
    - · Provides evidence of proof of mechanism
    - · 7 day study
- Major market patent coverage into 2029 for composition of matter
  - Potential for future extension

## Pipeline Progress: Upcoming Milestones



Product	Event	Expected Timing
AMITIZA (lubiprostone)	Initiation of 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)	2H16
AMITIZA (lubiprostone)		
CPP-1X/sulindac combination product	Phase 3 futility analysis	
AMITIZA (lubiprostone)	Top-line data from Phase 3 pivotal alternate formulation in adults	1H17
AMITIZA (lubiprostone)	Initiation of Phase 3 pivotal PFC (6 months-6 years)	Mid-2017
AMITIZA (lubiprostone)	File NDA for alternate formulation for adults in the U.S.	
AMITIZA (lubiprostone)	Initiation of Phase 3 open-label PFC (6 months - 6 years)	2H17

### Strong Financial Performance



Summary of Results	Q1-16	% Increase on Q1-15
Revenue	\$47.2 M*	60%
Net Loss GAAP	(\$4.1 M)	(163%)
EPS GAAP - diluted	(\$0.10)	(168%)
EBITDA	\$14.6M	50%
Adjusted Net Income	\$9.0M	40%
Adjusted EPS - diluted	\$0.21	48%
Adjusted EBITDA	\$20.2M	87%

Balance Sheet	End 3/31/16	Change	End 12/13/15
Cash, Cash Equivalents and Restricted Cash	\$157.0M	(\$6.5M)	\$163.5M
Notes Payable	\$235.7M	\$16.7M	\$252.4M
Net Debt	\$78.7M***	(\$10.2M)	\$88.9M

### 2016 Revenue Guidance

Total revenue: \$195M-\$205M Adjusted net income: \$45M to \$50M Adjusted EPS: \$0.97 to \$1.07 \$100M to \$105M Adjusted EBITDA:

- Guidance excludes amortization of acquired intangibles of approximately \$17.6 million and amortization of the remaining inventory step-up costs of approximately \$8.9 million.

<sup>\*</sup>Includes \$12.4M as a result of the R-Tech Ueno acquisition

\*\*\* Including current portions of \$27.8 million (3/31/16) and \$39.1 million (12/13/15)

\*\*\* The change in the net debt includes the settlement of the founder notes in Q1 2016 of \$17.6 million and the collaboration with CPP, amounting to \$8.0 million, which we executed in January of 2016.

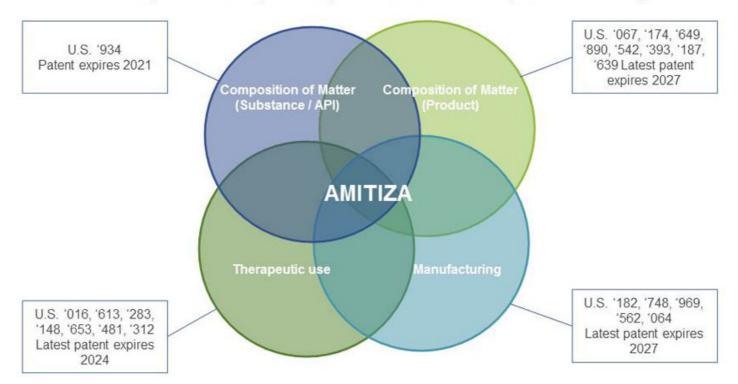


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# Back Up Slides



### 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

### Proven and Experienced Management Team



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

Peter Greenleaf Chief Executive Officer	Mistogenics	AstraZeneca 2	Medimmune	Johnson-Johnson	<b>C</b> centocor
Peter Kiener, D.Phil Chief Scientific Officer	Bristol-Myers Squil	bb Medim		Ambrx	Zγngenía
Andrew Smith Chief Financial Officer	← ALLERGAN	Biocompatibles	clearlab	O Hydron	PETROSCIEEN VIROLOGY
Matthias Alder Executive Vice President, Business Development & Licensing	CYTOS	mie	eromet		O NOVARTIS
Max Donley Executive Vice President of Human Resources	AstraZeneca 2		MedImmune		Vivus
<b>Steven Caffé, M.D.</b> Senior Vice President, Regulatory Affairs	amag	MedImmune	Baxter	SANOFI	<b>♦</b> MERCK
Elissa Cote Senior Vice President, Strategic Business Insights	<b>⊘</b> Histogeni	ics	Medin	imune	
Peter Lichtlen, M.D., Ph.D. Chief Medical Officer	Ald	con	ESE	BATech	
Silvia Taylor Senior Vice President, Investor Relations and Corporate Affairs	AstraZeneca		MedImmune		Pfizer