### 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): March 13, 2017

# Sucampo Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

**Delaware** 

001-33609 (Commission File Number) <u>30-0520478</u> (IRS Employer Identification No.)

(State or other jurisdiction of incorporation)

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 March 13, 2017, Sucampo Pharmaceuticals, Inc. ("Company") will make a corporate update presentation at one-on-one meetings with analysts and investors in New York at the 29<sup>th</sup> Annual Roth 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. Corporate Update" dated March 13, 2017.

#### 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: March 13, 2017

### EXHIBIT INDEX

Exhibit	
Number	Exhibit Description
<u>99.1</u>	Presentation titled "Sucampo Pharmaceuticals, Inc. Corporate Update" dated March 13, 2017.



# Sucampo Pharmaceuticals, Inc. Corporate Update

29th Annual ROTH Conference

March 13, 2017



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 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 8, 2017, 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.



This presentation contains three financial metrics (Adjusted Net Income, EBITDA and Adjusted EBITDA) that are considered "non-GAAP" financial metrics under applicable Securities and Exchange Commission rules and regulations. These non-GAAP financial metrics should be considered supplemental to and not a substitute for financial information prepared in accordance with generally accepted accounting principles. The company's definition of these non-GAAP metrics may differ from similarly titled metrics used by others. Adjusted Net Income adjusts for specified items that can be highly variable or difficult to predict, and various non-cash items, which includes acquisition related expenses, amortization of intangibles, share compensation expense, restructuring costs, acquisition related acceleration of deferred revenue, legal settlements, amortization of financing costs, and the tax impact of these adjustments. EBITDA reflects net income excluding the impact of depreciation, amortization (including amortization impairment), interest expense, interest income and provision for income taxes. Adjusted EBITDA reflects EBITDA and adjusts for specified items that can be highly variable or difficult to predict, and various non-cash items, which includes acquisition related expenses, share compensation expense, acquisition related acceleration of deferred revenue, restructuring costs, and legal settlements. The company views these non-GAAP financial metrics as a means to facilitate management's financial and operational decision-making, including evaluation of the company's historical operating results and comparison to competitors' operating results. These non-GAAP financial metrics reflect an additional way of viewing aspects of the company's operations that, when viewed with GAAP results may provide a more complete understanding of factors and trends affecting the company's 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, management strongly encourages investors to review the company's consolidated financial statements and publicly-filed reports in their entirety.

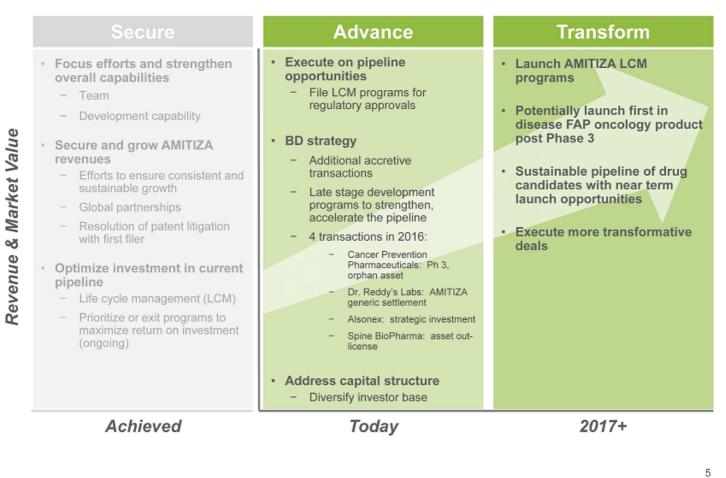


- Business model supports financial strength with significant EBITDA and cash flow to fuel continued transformation
  - Sustained revenue growth from AMITIZA<sup>®</sup> (lubiprostone): highly differentiated product with broadest label in \$5B+ constipation market
  - Transforming AMITIZA into a durable franchise that the Company will leverage to build a leading biopharmaceuticals company focused on specialty diseases
- · Business development strategy to bolster growth and diversify
  - Acquisition of R-Tech Ueno increases revenue and builds scale
  - Exclusive option to commercialize a Phase 3 program in familial adenomatous polyposis (FAP) with Cancer Prevention Pharmaceuticals
- Deep management team with proven ability to transform the Company and create value

**SUCAMPO** 

# Clear Strategy to Methodically Build a Leading Bio/Pharma Company







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

- U.S. constipation market is large and growing: ~\$5B
  - Branded and generic Rx market: \$4B / ~50M scripts/year <sup>(1)</sup>
  - OTC market: \$800M / 23M units (30-day supply) / year

### Opportunity to convert unsatisfied patients from OTC, generic options

- · Majority of prescription and OTC treated patients currently not satisfied with treatment
  - 60%+ of patients on OTCs report ineffective relief of multiple symptoms
  - OTCs not indicated for long term/chronic use
- · Only 8% of Rx patients are on novel, branded products
  - Low awareness of chronic Rx options

## Strategy: Convert from OTC and Generics to AMITIZA

1) Source: IMS and Wall Street research.

### Only product approved for all 3 constipation indications

- Chronic Idiopathic Constipation (CIC): ~14% to 16% of adults globally
- Irritable Bowel Syndrome-Constipation (IBS-C): ~15% of adults globally, 1/3 of which is IBS-C
- Opioid Induced Constipation (OIC, non-cancer): ~2-4M moderate to severe sufferers in U.S.

### · 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
  - Limited diarrhea and food effect

### · 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

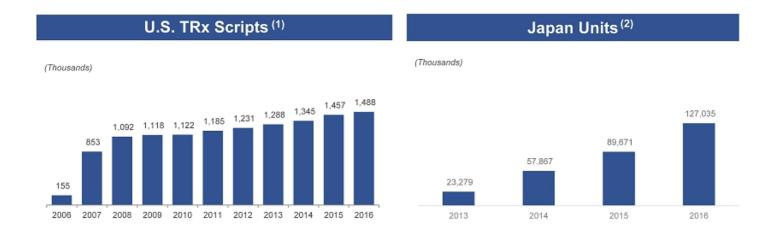






## 2016 U.S. TRx YoY growth: 1%

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



1) Source: IMS and Wall Street research.

2) Data on File



# AMITIZA is Well Positioned for Continued Growth

				Target Indication				
	Drug	Rx or OTC	Company	CIC	IBS-C	OIC	Commentary	
Branded / Patented	amitiza Iubiprostone	Rx	Sucampo (Marketed by Takeda)	✓ All adults	✓ Adult women	🖌 All aduits	<ul> <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>	
	<mark>Linzess</mark> ⊮ (linaclotide)capsules	Rx	Ironwood (Marketed by Actavis)	<b>√</b> All adults	<b>↓</b> All adults	×	<ul> <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>	
	RELISTOR methylnaltexone bromide	Rx	Injection Valeant/Progenics	×	×	<b>√</b> All aduits	Low market penetration for injection formulation	
	autoratomeus Ayerdon		Oral	×	×	✓ All aduits	Launch September 2016	
	naloxegol tablets @	Rx	AstraZeneca	×	×	🖌 All aduits	<ul> <li>Limited uptake since launch in March 2015 for OIC</li> <li>Post marketing safety commitment in place</li> </ul>	
					All Branded	/ Patented	d: 8% of market	
	MiraLAX	отс	Schering- Plough	×	×	×	<ul> <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> <li>Emerging concern re: use in children</li> </ul>	
	Bentyl (Dicylcomine)	Rx	Pantheon & Akorn (Marketed by Axcan)	×	×	×	<ul> <li>Does not relieve constipation</li> <li>Primarily used to reduce stomach and intestinal cramping that is symptom of IBS</li> </ul>	
	Other Therapies		Various	×	×	×	<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>	
					1	All Generi	c: 92% of market	

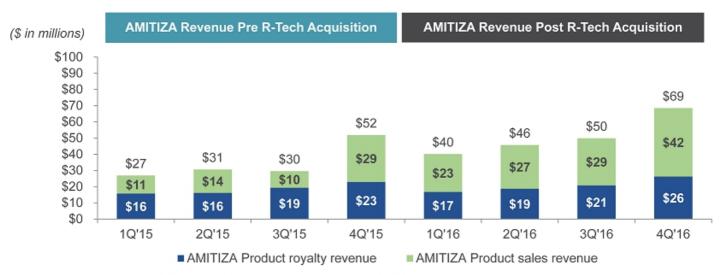
# Blue-Chip Partnerships Provide Global Growth for AMITIZA





· Revenue from product sales in ROW countries





- Sucampo's acquisition of R-Tech Ueno closed on 12/03/2015
- Secured a larger portion of the global economics of AMITIZA and greater control over the manufacturing and supply chain for the product
- Settlement agreements with Par Pharmaceutical and Dr. Reddy's Laboratories provide additional durability to AMITIZA after 2021
  - Paragraph IV certification notice letter received on March 2 regarding ANDA submitted to US FDA by Amneal Pharmaceuticals requesting approval to market, sell and use a generic version of 8 mcg and 24 mcg AMITIZA for OIC. Sucampo intends to file patent infringement lawsuit within 45 days of notice date

AMITIZA Product royalty revenue represents royalty revenue earned on the net sales of AMITIZA in North America. AMITIZA Product sales revenue represents drug product net sales of AMITIZA in North America, Japan and Europe.



## Expand AMITIZA Franchise Through New Formulation and New Indication

### 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 in children 6-17:

- · Trend to efficacy observed
- · Achieved statistical significance in key secondary endpoints: overall SBM frequency, straining, stool consistency
- · Well-tolerated
- Sufficient evidence to warrant moving forward with pediatric program and development of sprinkle formulation subject to
  discussions with FDA

#### FDA feedback

- FDA to review complement of data from AMITIZA phase 3 pediatric program (incl. long-term safety and efficacy data), confirmed
  aggregate data will be sufficient to submit sNDA for pediatric indication
- · Expect to file sNDA in 2H 2017

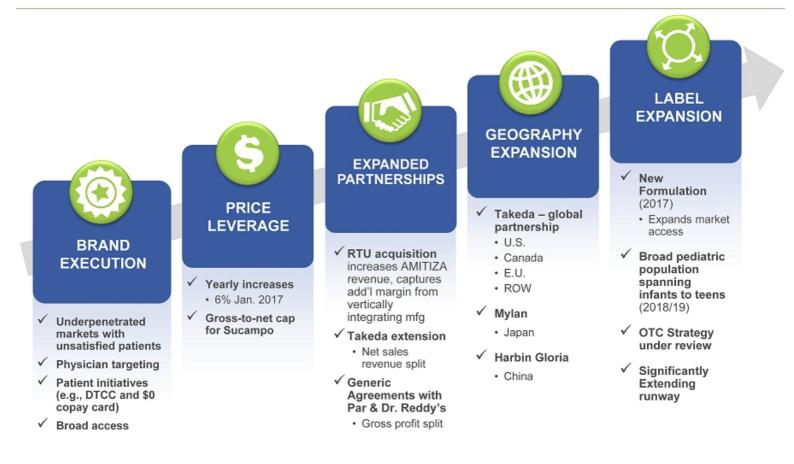
### Phase 3 program in Pediatrics (6 months-5 years)

· Based on FDA feedback, expect to initiate program in 1H 2018

#### Alternate Sprinkle Formulation

- Alternate formulation for additional adult and pediatric patients who cannot tolerate capsules, or naso-gastric tube fed patients
- ~40% of adults have difficulty swallowing pills
- · Phase 3 in adults with CIC to initiate by year-end
- · Expect to report results by mid-2017







Program	Target	First Indication	Development Stage	(s)NDA / MAA Filing	Approval
Gl/Metabolic/ Inflamation					
AMITIZA	CIC2	Pediatric functional constipation (6-17 yrs.)	Р3	2017	2018
Lubiprostone Sprinkle Formulation	CIC2	Pediatric functional constipation 6 mos- 5 yrs (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

Sucampo Program

Option

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### 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
- 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 Clinical development
  - Fully enrolled, registration eligible study
  - 150-patient, three-arm, double-blind randomized trial of the combination agent and the single agent comparators
  - Futility analysis 1H 2017
  - Expected to conclude in 2018, with potential approval in 2019

### Additional opportunity in sporadic colon adenoma therapy (CAT)





# Pipeline Progress: Upcoming Milestones



Product	Product Event			
CPP-1X/sulindac combination product	Phase 3 futility analysis	1H17		
AMITIZA	File sNDA for PFC (6–17 years)			
AMITIZA	Top-line data from Phase 3 pivotal alternate formulation in adults	2H17		
AMITIZA	AMITIZA File NDA for alternate formulation for adults in the U.S.			
AMITIZA Initiation of Phase 3 pivotal PFC, incl. extension option (6 months–5 years)		1H18		
<b>CPP-1X/sulindac</b> <b>combination product</b> Top-line data from Phase 3 pivotal; decision to opt into product licensing		2H18		



Summary of Results	Q4 2016	% Increase over Q4 2015	FY 2016	% Increase over 2015
Revenue	\$73.0M	32%	\$230.1M	50%
Net Income GAAP	\$15.3M	51%	\$18.5M	(45%)
EPS GAAP – Diluted	\$0.34	49%	\$0.42	(43%)
EBITDA	\$19.4M	(23%)	\$87.1M	44%
Adjusted Net Income*	\$30.7M	60%	\$66.2M	52%
Adjusted EPS – Diluted*	\$0.68	58%	\$1.51	58%
Adjusted EBITDA*	\$42.8M	54%	\$117.7M	68%

Balance Sheet	End 12/31/16	Change	End 12/31/15
Cash, Cash Equivalents and Restricted Cash	\$198.5M	\$35.0M	\$163.5M
Notes Payable	\$290.5M	(\$38.1M)	\$252.4M
Net Debt	\$92.0M	(\$3.1M)	\$88.9M

 At Feb. 28, 2017, cash, cash equivalents and restricted cash were \$245 million, and net debt was \$55 million

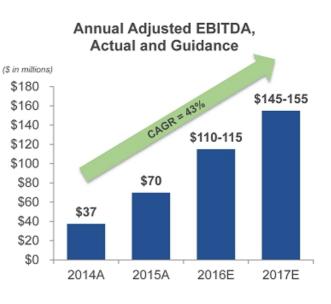
> \*A reconcilation of adjusted Net Income to GAAP Net Income and adjusted EBITDA to net income, the most directly comparable GAAP financial measure, is included in the Appendix.

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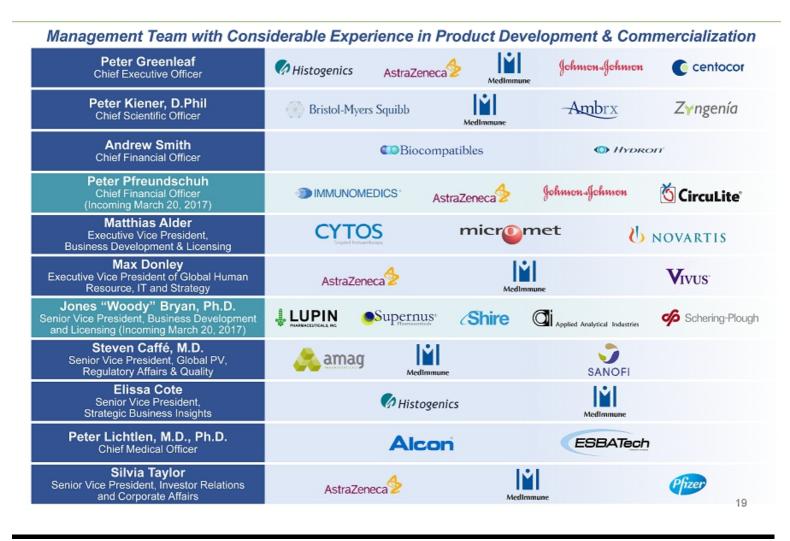


2017 Non-GAAP Guidance				
Total Revenue:	\$220M - \$230M			
Adjusted Net Income:	\$80M to \$90M			
Adjusted Diluted EPS:	\$1.35 to \$1.50			
Adjusted EBITDA:	\$145M to \$155M			





\*One-time \$10.0 million milestone in the fourth quarter of 2016 related to the achievement of sales milestone from Mylan related to sales of AMITIZA in Japan. 2014-2015 are actual numbers. 2016 and 2017 are Sucampo Management's guidance.



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	RECONCILIATION OF GAAP NET LOSS TO NON-GAAP NET INCOME					
	(in thousands, except per share amounts)					
	Three Months Ended	Three Months Ended	For the Year Ended	For the Year Ended		
	December 31, 2016	December 31, 2015	December 31, 2016	December 31 2015		
Adjusted Non-GAAP Net Income:						
GAAP Net Income	15,283	10,151	18,487	33,371		
Non-GAAP Adjustments:						
Amortization of Acquired Intangibles	6,748	3,732	25,655	3,732		
Inventory Step Up Adjustment	100 B	5,645	15,236	5,645		
R&D Intangible Asset Impairment	-	-	7,286	-		
Restructuring Costs	455	958	2,350	958		
Legal Settlement			-9,515			
Acquisition Related Expenses	-	3,914	2,173	5,135		
Amortization of Debt Financing Costs	841	870	3,526	870		
Loss on Debt Extinguishment	14,047	-	14,047	-		
R&D License Option		-	3,000			
Acceleration of Deferred Revenue	-	-4,079	-	-4,079		
Foreign Currency Translation	7,070	123	11,280	178		
Tax Effect of Adjustments	-13,762	-2,119	-27,313	-2,119		
Total Non-GAAP Adjustments	15,399	9,044	47,725	10,320		
Adjusted Non-GAAP Net Income	30,682	19,195	66,212	43,691		
Weighted Average Shares - Dilutive						
Adjusted Non-GAAP Net Income Per Share - Diluted	44,910	44,338	43,749	45,680		
GAAP Net Income per Share - Diluted	0.34	0.23	0.42	0.73		
Non-GAAP Adjustments	0.34	0.20	1.09	0.23		
Adjusted Non-GAAP Net Income per Share - Diluted	0.68	0.43	1.51	0.96		

# Reconciliation for Non-GAAP Metrics

	RECONCILIATION OF INCOME FROM OPERATIONS TO ADJUSTED						
	(	(in thousands, except per share amounts)					
	Three Months Ended	Three Months Ended	For the Year Ended	For the Year Ended			
	December 31, 2016	December 31, 2015	December 31, 2016	December 31, 2015			
GAAP Net Income	15,283	10,151	18,487	33,371			
Adjustments:							
Taxes	-8,433	-684	-4,112	10,304			
Interest expense	5,620	6,070	23,761	6,854			
Interest Income	-5	-27	-72	-181			
Depreciation	217	221	904	623			
R&D Intangible Asset Impairment		-	7,286	-			
Amortization of Acquired Intangibles	6,748	3,732	25,655	3,732			
Inventory Step Up Adjustment		5,645	15,236	5,645			
EBITDA	19,430	25,108	87,145	60,348			
Non-GAAP Adjustments:							
Share Based Compensation Expense	1,838	1,742	7,258	7,349			
Restructuring Costs	455	958	2,350	958			
Acquisition Related Expenses	-	3,914	2,173	5,135			
Loss on Debt Extinguishment	14,047		14,047	-			
R&D License Option			3,000				
Legal Settlement	1. Sec. 1.		-9,515	-			
Foreign Currency Translation	7,070	123	11,280	178			
Acceleration of Deferred Revenue	-	-4,079		-4,079			
Total Non-GAAP Adjustments	23,410	2,658	30,593	9,541			
Adjusted EBITDA	42,840	27,766	117,738	69,889			

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