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# Marketing Plan 2007

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# **Table of Contents**

- Executive Summary
- Market Situation Analysis
  - Disease Overview
  - Opioid Market
  - Competitive Analysis
  - Environmental Trends
- Product Situation Analysis
  - Profile & Position
  - Actiq Performance
  - FENTORA Performance
- SWOT Analysis & Key Issues

- Marketing Strategy
  - Mission & Strategic Vision
  - Objectives, CSFs & Strategies
  - LCM / Clinical Plan
  - Targeting
- Tactical Plan
  - Key Milestones
  - Overview Tactics by CSF
  - Campaign Evolution
  - Budget
  - Tactical Detail Grids
- Appendix
  - A: Publication Plan
  - B: Public Relations Plan
  - C: Medical Education Plan



Major Milestones	sNDA Target Submissions: Non-CA – 4Q07	PDUFA dates: 300 mcg – 3/3/07 Label modifications: 4/07 Patent Expiration – 2019 (Method of Use – #6,200,604							
	Source: IMS NPA & NSP		4	2005	Value 2005	04-05	2005	Volume 2005	04-05
		Opioi Catego		(\$ - mil)	(%)	Δ	(TRx - mil)	(%)	Δ
Market Overview		Pure SAOs		\$663	11%	22%	8	4%	20%
overview		Combi SA	Os	\$1,221	21%	3%	156	84%	6%
		LAOs Total Opioids		\$3,965	68%	-6%	22	12%	7%
				\$5,848	100%	-2%	186	100%	7%
	Growth Drivers				G	rowth I	nhibitors		
<ul> <li>Aging baby boomers and growing US population will increase the size of the chronic pain patient population</li> <li>Increase in treatment of chronic pain with opioids</li> <li>Pain Specialists are more aggressive in treating chronic pain</li> <li>More sophisticated usage of opioids by PCPs who continue to drive the majority of opioid TRx volume</li> <li>Increasing understanding about the proper identification, diagnosis and treatment of BTP</li> <li>New competitive entries</li> </ul>			•	Scrutiny from r stakeholders fr diversion of op Due to the wid managed care branded opioid Chronic pain p evolving Physicians bel LAOs can ade effects of over	uels conc bioids lespread a has place ds practice st lieve that quately co	ern abou availabilit ed signifi andards increasin over a BT	t the abuse, a y of generics cant restriction (especially for g the dose or "P episode wh	ddiction, a in the opio ns on the BTP) are dosing fre nile ignorir	and bid market, use of still equency of ng the
			•	Perception by option for BTP	some phy	sicians t	hat SAOs are	a preferre	dtreatmen

			Com	petito	or Analysis	
	Company	2005 Pain Sales (US)	Primary Focus Pain Products		Pain Products	Potential to Lead in Future
	Purdue	\$1.4B	Pain Care	Pain Care OxyContin (\$1.36B), MS Contin (\$32M), Palladone (\$20M)*, OxyIR		Reputation suffers due to OxyContin issues and Palladone withdrawal
	J&J	\$1.4B	Primary Care	Primary Care Duragesic (\$687M), Ultracet (\$145M), Ultram (\$37M), Ultram ER*		Part of corporate strategy is to re-focus efforts in pain, developing new business unit
	Endo	\$1.2B	Pain Care	Pain Care Lidoderm (\$573M), Percocet (\$122M), Depodur, Opana, Opana ER, Additional generic opioids (\$370M)		Potential to lead in the future due to single focus in Pain Category
	King/Ligand	\$179M	Oncology, Pain Care			Strong presence in LAO market with a focus on TR (Remoxy)
	Alpharma	\$140M	Pain Care	Kadian (\$140M)		Limited product portfolio
Product Description Fentanyl incorporated into OraVescent® drug delivery platform			/	Efficacy	oduct Features	
Strengtl	ns: 100, 200, 40	0, 600, 800 mc	g tablets		point measured)	ration up to 120 minutes (last t
Pack Si	Pack Size: 28 tabs (7 blisters with 4 tabs each)			Advantages over Actiq		
<ul> <li>Indication</li> </ul>	Indication: BTP in pts w/cancer			<ul> <li>Greater absolute bioavailability (65% vs. 47%)</li> </ul>		
<ul> <li>Safety:</li> </ul>	Similar to other	opioids			Greater absorption through oral mucosa (48% vs. 22%)	
<ul> <li>RiskMA</li> </ul>	P: Secure Prog	ram			Simpler initial titration scheme	
	4			🕂 More discreet, easier	to administer, & sugar free	

#### **Position Statement** FENTORA is the first and only fentanyl buccal tablet that utilizes an effervescence reaction to provide the most rapid onset of analgesia of any oral opioid resulting in improved patient functioning and activities of daily living

	Clinical Studies					
NDA:	NDA:		pand indication to non-CA			
99-14	Efficacy: CA BTP	3040	Safety: all non-CA BTP (open label)			
99-15	Safety: CA BTP (open label)	3041	Efficacy: neuropathic BTP			
1026-29	PK: 4 main studies	3042	Efficacy: lower back BTP			
-			Pain anxiety symptoms			
		3052	Pivotal efficacy: non-CA			
Labeling	Supplement: Label 🛆					
PK TBD	New doses: 300 mcg, high dose (mcg TBD)	-				
		Other PK Studies				
		1043	Buccal vs. sublingual			
		TBD	Relative potency (IV morphine)			
H-2-H Stu	H-2-H Studies		Relative potency (SAO)			
3055	vs. OxyIR ST efficacy & safety					
3056	vs. OxyIR LT efficacy & safety					

#### Key Issues

- 1. Reimbursement challenges
- 2. Need to expand prescribing audience
- 3. FENTORA is not well differentiated
- 4. Limited BTP awareness/knowledge
- 5. Dosing & administration challenges
- 6. Risk for abuse & diversion
- 7. Limited KOL & society relationships

#### **Critical Success Factors**

- → Maximize access
- $\rightarrow$  Gain acceptance among Actiq users & beyond
- → Physicians understand FENTORA is superior treatment option for BTP
- → Improve awareness & understanding of BTP
- → Clear & consistent messaging on dosing & administration
- → Clear & consistent communication of FENTORA risks
- → KOLs & professional societies support FENTORA

#### **Objectives**

Total Revenue: \$139.5 M TRXs: 81,207

#### Assumptions

- TRx Share @ month 12 = 28% of ROO (fentanyl) market
- FENTORA will grow from Actiq loyalist conversion & incremental market growth
- WAC/TRx = \$1,357 (2.5% annual price increase)

#### Budget 2007

Category	Spend	Share of Total Spend
Market Research	\$1,750,000	6%
Consultants	\$400,000	1%
Journal Reprints	\$200,000	1%
Conventions	\$1,600,000	6%
Advertising/Promotional Materials	\$8,900,000	32%
Sample Coupons	\$6,000,000	21%
Public Relations	\$600,000	2%
Field Driven Speaker Programs (CSPs)	\$6,000,000	21%
Medical Education	\$2,500,000	9%
Corporate Contributions	\$50,000	0%
TOTAL SPEND	\$28,000,000	100%

#### **Tactical Timeline**



#### **Contribution Margin**

Category	2007F (mil)
FENTORA Net Rev	\$139.5
Marketing Expense	28
Sales Expense	23
Contribution Margin	\$88.5

Note:

Contribution includes Marketing Budget expenditures and Sales Force personnel estimate only. Sales expense for 2007F factored on \$205K/person & includes 100% of 100 Reps, 12 DMs, & 2 RSDs (ONS, NAMS & MDMs not included)



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### **Market Situation**

### **Disease Overview**



### **Chronic Pain: Prevalence**

 Chronic pain prevalence, diagnosed & treated by underlying conditions



Source: Analysis of secondary data reports by Cephalon Market Research Department



# **Chronic Pain: Components**

#### **Baseline or Persistent Pain**

Pain that is continuous throughout the day (≥12 hours/day) and is managed with around-the-clock medication.

#### **Breakthrough Pain**

Transitory exacerbation, or flare, of moderate-to-severe pain that occurs in patients on chronic opioid therapy with otherwise stable persistent pain.



Portenoy RK, Hagen NA. *Pain*. 1990;41:273-281. Bennett D, et al. *Pharm Ther*. 2005;30:354-361.



### **BTP Prevalence** & Characteristics

	Cancer BTP (N =63) <sup>1</sup>	Noncancer BTP (N=228) <sup>4</sup>
Prevalence	64% to 89% <sup>1,2</sup>	74%
Median Episodes/Day	4 to 7 <sup>1-3</sup>	2
Time to Peak Intensity	43% in 3 min	50% in 5 min
Median Duration	30 min	60 min
Incident Related	55%	92%
	<ul> <li>somatic (33%)</li> </ul>	<ul> <li>somatic (38%)</li> </ul>
	<ul> <li>visceral (20%)</li> </ul>	<ul> <li>visceral (4%)</li> </ul>
Pathophysiology	<ul> <li>neuropathic (27%)</li> </ul>	<ul> <li>neuropathic (18%)</li> </ul>
	<ul> <li>mixed (20%)</li> </ul>	<ul> <li>mixed (40%)</li> </ul>

<sup>1</sup>Portenoy, Hagen. *Pain*. 1990;41:273-281
<sup>2</sup>Zeppetella. *J Pain Symptom Manage*. 2000;20:87-92
<sup>3</sup>Portenoy et al. *Pain*. 1999;81:129-134
<sup>4</sup>Portenoy, et al. APS. 2005



### BTP Pain: Current Treatment





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### **BTP Treatment Patterns**

	# of BTP Episodes	
Typical Course of Action	≤ 3	≥ 4
Increase dose of LAO	34%	64%
Increase frequency of LAO	7%	12%
Increase frequency of SAO	21%	10%
Switch the LAO	2%	7%
Increase dose of SAO	28%	4%
Switch the SAO	3%	2%

- The most common treatment choice is to increase the dose of LAOs regardless of # of episodes
- The next most common approach is to either increase the frequency or dose of the SAO
- Switching to an alternative SAO is typically the last course of action



# **BTP Pain: Treatment Evolution**





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### **Market Situation**

### **Opioid Market**



### Market Overview Opioid Market 2005



#### Size & Growth

- Opioid market is large
- Value is relatively flat over '04 due to generic LAO entry
- Volume up 7%

#### Share

- LAOs make up the largest share in terms of value
- SAOs make up the largest share in terms of volume



Source: IMS - NPA & NSP 2005

### Pure SAO 2005



#### Size & Growth

- Pure SAO market is moderate
- Value & Volume have strong growth (>20%)

#### Share

- Actiq (fentanyl) made up largest share in terms of value
  - Only branded Pure SAO in 2005
- Oxycodone dominates in terms of volume
  - Fentanyl is often perceived as more potent analgesic & held in reserve



# ROO Market



#### Prior to Oct 2006

- Actiq was sole ROO
- Consistent Value growth (more recently due to price increases)
- Strong Volume growth up to 2004 (reached plateau)

#### As of Oct 2006

- Generic OTFC introduced
  - Captured 21% of volume
- FENTORA introduced
  - Captured 13% of volume



# **Customer Analysis**\*



#### Pure SAO Sub-Class

- PCPs generate largest volume
- Pain/Anesth only account for 18% of volume

#### ROO Sub-Class (Actiq)

- Pain/Anesth generate largest volume
  - Typically early adopters of emerging therapies
- The other major contributors are PCPs & Other



\*Pain Medicine, Anesthesiology & Physical Medicine and Rehab \*\*Source: IMS Prescribers - NPA TRx – Class of Trade – NSP Units

21

### **Trade Class**

#### Pure SAO Distribution Channels



\*Pain Medicine, Anesthesiology & Physical Medicine and Rehab \*\*Source: IMS Prescribers - NPA TRx – Class of Trade – NSP Units

22

- Vast majority of product moves through Retail Pharmacy
- Modest penetration of Pure SAO in non-retail segment
  - Non-Retail often provides spillover effect
- Less penetration by ROO (Actiq) sub-class in non-retail segment
  - Non-retail segment is price sensitive



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### **Market Situation**

### **Competitive Analysis**





# **Major Chronic Pain Players**

	2005 Pain Sales (US)	Primary Focus	Pain Products	Potential to Lead in Future
Purdue	\$1.4B	Pain Care	OxyContin (\$1.36B), MS Contin (\$32M), Palladone (\$20M)*, OxyIR	Reputation suffers due to OxyContin issues and Palladone withdrawal
J&J	\$1.4B	Primary Care	Duragesic (\$687M), Ultracet (\$145M), Ultram (\$37M), Ultram ER*	Part of corporate strategy is to re-focus efforts in pain, developing new business unit
Endo	\$1.2B	Pain Care	Lidoderm (\$573M), Percocet (\$122M), Depodur, Opana, Opana ER, Additional generic opioids (\$370M)	Potential to lead in the future due to single focus in Pain Category
King/Ligand	\$179M	Oncology, Pain Care	Avinza (\$179M)	Strong presence in LAO market with a focus on TR (Remoxy)
Alpharma	\$140M	Pain Care	Kadian (\$140M)	Limited product portfolio



# **Product Pipeline**

Company	Phase I-II	Phase III	Reg. – Approval
J&J ▪ Alza ▪ OMP PriCara		Oros Hydromorphone Tapentadol	Ionsys (Fentanyl Iontophoretic Transdermal System) – Approved May 2006
Endo	Lidoderm (chronic LBP) LidoPAIN (acute LBP) Chronogesic(Chronic moderate to severe pain) Ketoprofen patch Hydrocodone/paracetamol/dextromethorphan Oxycodone/dextromethorphan Oxycodone/paracetamol/dextromethorphan Sufentanil – DURECT Morphine/dextromethorphan	Rapinyl (BTP in cancer patients)	
Forest	Memantine Neramexane RGH-896	Milnacipran	
Purdue			Tramadol XR
BioDelivery Sciences		BEMA Fentanyl	



# **ROOs in Development**



### **Share of Voice**

27

Rank	Pain	PCP
Depodur	1 <sup>st</sup>	8 <sup>th</sup>
Actiq	2 <sup>nd</sup>	5 <sup>th</sup>
Kadian	3rd	4 <sup>th</sup>
📕 Avinza	4 <sup>th</sup>	1 <sup>st</sup>
Duragesic	5 <sup>th</sup>	6 <sup>th</sup>
OxyContin	6 <sup>th</sup>	3rd
Other	7 <sup>th</sup>	7 <sup>th</sup>
Combunox	8 <sup>th</sup>	2 <sup>nd</sup>

#### **Opioid Sales Calls (Q1 06)**

- Actiq has a significant SOV in the Pain specialty (ranked 2nd vs. LA Depodur) market segment
  - The branded LAOs represent the greatest SOV in the PCP segment (approximately 63%) while Actiq SOV was limited to 9%



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Source: IMS IPS Q1 06

### **Market Situation**

### **Market Environment**



### **Key Environmental Trends**

<b>Key Factors</b>	Current Dynamics
Economic	<ul> <li>Unfavorable reimbursement environment</li> <li>Payers are increasing restrictions to drive usage to less costly drugs</li> <li>Payers don't understand BTP</li> </ul>
Social / Cultural	<ul> <li>Abuse and diversion are top-of-mind topics for physicians and other stakeholders</li> <li>Society (including many physicians) are critical of their patients' inability to cope with their pain</li> <li>Pain patients feel misunderstood by physicians, friends, and family and often become frustrated and depressed</li> <li>Patients are often looking for an easy short-term solution to their pain and are not focused on long-term wellness</li> </ul>
Political / Governmental	<ul> <li>Opioid abuse is a hot political issue and physicians are under significant scrutiny about proper use of opioids</li> <li>FDA is hypersensitive about safety issues in a post-Cox II and OxyContin world</li> </ul>
Legal	<ul> <li>DEA guidelines for writing opioids are unclear</li> <li>Ongoing issues between the DEA and various pain societies</li> <li>Perception that more physicians getting sued/licenses taken away</li> </ul>
Clinical / Technological	<ul> <li>Lack of significant practical advancements in pain medicine</li> <li>New drugs, routes of administration, and improved control of side effects</li> <li>New insights into the anatomy and physiology of pain perception</li> <li>Greater understanding of how to integrate pharmacotherapeutic, psychological, and behavioral pain management approaches</li> <li>New tracking technology for packaging to avoid diversion</li> </ul>



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## Economic

#### Pure SAO (w/o Actiq) Reimbursement



### Reimbursement

- Opioid market is highly genericized
- Vast majority of Pure SAOs & ROOs covered by TPP
- FENTORA more apt to have TPP reimbursement barriers due to its premium price
  - Tiered co-pays, co-insurance, PAs, step-edits, qty limits, dose limits
- Overall Pure SAO class has slightly greater share of Medicaid reimbursement compare to ROO sub-class



\*Source: NDC Claims - 2005

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### **Social: BTP Awareness**

### Prescribers

- BTP is a relatively new disease state, only generally recognized by top tier opioid prescribers
  - First in print in 1990 (Portenoy survey)
  - Actiq first product indicated for BTP, launched 1998

### **Patients**

Do not recognize term "Breakthrough Pain"



# **BTP Communication**

Торіс	Physician*	Patient**
BTP Terminology	If BTP discussed, use "BTP" and "pain flares" interchangeably	Don't use "BTP", describe pain as "uncontrolled" or use descriptive terminology (e.g., flares, burning)
Quality of Life	Treatment success reported by patient in terms of function or activity	<ul> <li>Focus on holistic impact on life</li> <li>E.g. emotion, personality, social, &amp; function</li> </ul>
Fear	<ul> <li>Patient abuse, addiction, &amp; diversion of opioids</li> <li>Regulatory scrutiny</li> </ul>	<ul> <li>Addiction (loss of independence)</li> <li>Over medication (sedated / confused)</li> <li>Running out of opioids (rationing)</li> <li>Anxiety over severity and timing of next BTP episode (unpredictability)</li> <li>Physicians will stop prescribing opioids</li> </ul>
Communication of Pain	Distance themselves from chronic pain patients	Hold back communicating full impact of pain



### Market Drivers – BTP Market

#### **Growth Drivers**

- <u>Aging baby boomers</u> and growing US population will increase the size of the chronic pain patient population
- <u>Increase in treatment</u> of chronic pain with opioids
- <u>Pain Specialists</u> are <u>more aggressive</u> in treating chronic pain
- <u>More sophisticated</u> usage of opioids by <u>PCPs</u> who continue to drive the majority of opioid TRx volume
- <u>Increasing understanding</u> about the proper identification, diagnosis and treatment of <u>BTP</u>
- New <u>competitive entries</u>

#### **Growth Inhibitors**

- Scrutiny from regulators and general confusion on the part of key stakeholders fuels <u>concern about the abuse, addiction,</u> <u>and diversion of opioids</u>
- Due to the widespread availability of generics in the opioid market, <u>managed</u> <u>care</u> has placed significant <u>restrictions</u> on the use of branded opioids
- Chronic pain <u>practice standards</u> (especially for BTP) are still evolving
- Physicians believe that <u>increasing the</u> <u>dose or dosing frequency of LAOs</u> can adequately cover a BTP episode while ignoring the effects of overmedication [influenced by Purdue and Janssen]
- Perception by some physicians that <u>SAOs are a preferred treatment option</u> for BTP based on familiarity, ease-of-use, and cost



# Summary

- The chronic pain opioid market remains attractive because of its substantial size and growth
  - Pure SAOs highest growth rate (TRx +21%, \$ +23%)
  - Combination SAOs dominate volume (83% TRx market share)
  - LAOs dominate market value (68% \$ market share)
- Generic expirations of blockbuster brands (ie, Duragesic) has resulted in a promotional void in the pain market
- Purdue to regain the patent on OxyContin; renewed promotion is expected
- Innovative drug delivery technology is the foundation of recent successful brands and drugs in the later stage of development



### Summary

- BTP remains an untapped market
  - Physicians rely heavily on LAOs when addressing patients' BTP
  - Physicians also utilize generic SAOs due to familiarity, ease of use and cost
  - Even among high-users of Actiq, SAOs remain the treatment standard for BTP
- For the treatment of BTP, a communication gap exists between physicians and patients
- Concerns over opioid misuse and reimbursement hurdles continue to be key barriers to utilization
- The pain specialist continues to be the key market segment for new brand adoption
- Several new formulations of ROOs are in development and should come to market over the next 1-5 years helping to solidify this emerging sub-class of opioids



### **Product Situation**

### **Profile & Position**


# **FENTORA** Description & Indication





#### Description

FENTORA, which employs the OraVescent<sup>®</sup> drug delivery technology, is a potent opioid analgesic, intended for buccal administration. FENTORA is formulated as a flat-faced, round, beveled-edge tablet.

#### Indication

FENTORA is indicated for the management of <u>breakthrough pain in</u> <u>patients with cancer</u> who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain



## FENTORA Product Profile Comparison

Indication		Launch: BTP in patients w/ Ca	
		2008: BTP in non-Ca patients	BTCP
	Onset	15 min (99-14) 10 min + "meaningful relief" (3039)	15 min
Efficacy	Duration	60 min (99-14) 120 min (3039)	60 min
	Absolute Bioavailability	65%	47%
FN	Transmucosal Absorption	48%	22%
and the second	Cmax (mean ng/mL)	1.02	1.26
	Tmax (median, min)	46.8	90.8
	Convenience	Discreet tablet	Lozenge on a stick
	Ease of Use	Passive administration	Active administration
Administration	Dosage	Launch: 100, 200, 400, 600, 800 mcg sNDA: 300 mcg In development: higher dose	200, 400, 600, 800, 1200, 1600 mcg
	Titration	Multiple 100 & 200 mcg tablets	1 higher strength at a time

fentanyl buccal tablet @

## FENTORA Product Profile Comparison

Attributes		FENTORA Actiq	
Safety	AE Profile	Comparable to other opioids (except for application site abnormalities)	Comparable to other opioids (except for application site abnormalities)
	Abuse Potential	Comparable to other opioids	Comparable to other opioids
	Accidental Exposure	Comparable to other opioids	Lozenge on stick presents potential concerns: – Pediatric exposure – Partially used unit exposure
Formulation		Sugar-free	Sugar



## FENTORA Product Profile Comparison

Features/Benefits	FENTORA	Actiq	SAOs
Efficacy – Onset	+++	++	-
Efficacy – Duration	++	++	+
Convenience	++	+	++
Ease of Use	+		++
Ease of Titration	+		++
Side Effect Profile	+	-	++
Abuse Potential	-	-	-



## FENTORA Product Profile: Physician Reactions

#### **Physician Perception of FENTORA**

Drivers	Barriers
Faster onset of pain relief	Anticipated high cost (reimb. hassle)
Overall efficacy	Potential for abuse
<ul> <li>Convenient administration</li> </ul>	<ul> <li>Potent opioid (held in reserve)</li> </ul>
<ul> <li>Ease of use (vs IV administration)</li> </ul>	<ul> <li>No handle administration*</li> </ul>
Sugar-free	<ul> <li>Actiq saves \$ with partial dosing</li> </ul>
<ul> <li>Unique delivery system</li> </ul>	<ul> <li>Perception Actiq can be removed if</li> </ul>
<ul> <li>Utilizes less fentanyl</li> </ul>	S/Es
Discreet (ie, no handle vs Actiq)	

41

 Overwhelmingly, the majority of physicians expressed an interest in this product and felt it had a place in their practice



## **Position & RTB**

### **Position Statement**

*FENTORA* is the first and only fentanyl buccal tablet which utilizes an effervescent reaction to provide the most *rapid onset of analgesia* of any oral opioid, resulting in improved patient functioning and activities of daily living.

### **Reason to Believe**

*FENTORA* employs the *OraVescent*<sup>®</sup> *drug delivery technology*, which generates a reaction that releases carbon dioxide when the tablet comes in contact with saliva<sup>1,2</sup>

 It is believed that transient pH changes accompanying this reaction may optimize dissolution (at a lower pH) and membrane permeation (at a higher pH)



## Messaging (Vanilla at Launch)

- Onset of pain relief within 15 min in some patients (1<sup>st</sup> time pt measured)
- Duration of pain relief up to 60 min (last time pt measured)
- OraVescent drug delivery technology may optimize delivery of fentanyl across the buccal mucosa
- Fentanyl is readily absorbed, achieving an absolute bioavailability of 65%
- AEs comparable to other opioids, except for application site abnormalities (8%)
- Convenient, discreet, and sugar-free tablet

Note:

• 99-14 data only included in label at launch



## **Product Situation**

### **Actiq Performance**



#### Franchise Assessment

## **Actiq Gross Sales**

Actiq continues growth in Sales



\*Actuals through 10/06, 11,12/06: per 9+3 forecast

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fentanyl buccal tablet @

# **Actiq Pricing**



## **Actiq TRxs**

- Actiq has performed beyond expectations despite limited data
- Field Force has been able to maintain TRx volume



\* Actuals through 10/06,

11,12/06: per 9+3 forecast

fentanyl buccal tablet @

### **PDEs\* & TRxs**



### Actiq Monthly Prescriber Count by Specialty\*

PCPs continue to outnumber Pain Specialists





### Actiq Monthly TRx by Specialty\*

Pain Specialists continue to write majority of prescriptions



Cephalon defined Specialty Group \* Anesthesiology, PM&R and Pain Source: IMS NPA



# **Conditions Treated with Actiq**

Despite promotion in BTCP, Actiq use mirrors that of all opioids

51

#### Underlying Conditions Treated with Actiq

N=774 Patients

Chronic Pain Patients Treated with Opioids Estimate – 2.8 M Patients

Arthritis



Cancer 12% Headache 5% Neuropathic 30%

> FENTORA fentanyl buccal tablet @

Source: ACTIQ - Gfk V2 Chart Audit, 2006 \* Chronic pain – Cephalon market research 2nd reports

## **Product Situation**

### **FENTORA** Performance



# **Product Availability**

- Initial supply chain hiccups (resolved quickly)
- Currently stocked in ~1,400 pharmacies
  - ~13% of the number of pharmacies stocking Actiq (11K)
  - Initial stocking more in independent pharmacies



### **FENTORA** Shipments Forecast vs Actual

FENTORA Shipments (\$20M YTD 11/16)



Source: SPS Shipments

### ROO Weekly TRxs As of 12/1/06



Source: IMS Health Weekly Report 12/1/06

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fentanyl buccal tablet @

### ROO Weekly TRxs As of 12/1/06





## FENTORA vs. Actiq\* Weekly TRxs



57

\*Actiq weeklies are from Cephalon re-launch (April 2001)

fentanyl buccal tablet @

### **FENTORA TRxs** Forecast vs Actual

#### **FENTORA TRxs**



TRxs

### FENTORA TRx Origin Sum of weeks 10/06 – 11/10





## Specialty Count & Productivity

Pain Specialists are early adopters driving TRxs •



fentanyl buccal tablet @

# **TRx by Targets**



# **Field Activity**

- Cephalon Speaker Programs (CSP)
  - 284 Speakers Trained (148 E & 136 W)
  - FENTORA YTD (2 mos) 781 completed, 271 pending
    - Reach YTD: 5,570 attendees (non-Cephalon)
    - Reach Pending: 1,700
  - Actiq YTD ~ 400/qtr
- October vouchers
  - 942 redeemed
  - 20% of TRxs



### Vouchers by Strength October

Total vouchers redeemed: 942





Source: NDC October 2006

## **SWOT & Key Issues**



# **FENTORA SWOT Analysis**

#### Strengths

- Onset of analgesia 10 min
- Duration of analgesia 120 min
- Discreet and convenient dosing formulation
- Predictable bioavailability vs. Actiq
- Efficient drug delivery (65% absolute bioavailability)
- Easier dose titration scheme than Actiq
- Data on Actiq to FENTORA switch
- Clinical program to expand label
- Patent on FENTORA through 2019
- Published data in non-cancer BTP

#### Weaknesses

- <u>C-II abuse and diversion potential</u>
- <u>Cost vs. other SAOs (branded and generic</u> <u>alternative therapeutic options)</u>
- Reimbursement restrictions
- Limited label (BTP in cancer patients) at launch and potentially up to 3 years post-launch due to carcinogenicity study
- Perceived safety concerns of fentanyl due to misunderstanding of potency and equianalgesic conversion (mg vs. mcg)
- Cephalon not a lead player in pain market
- Current sales force size limits ability to expand into new market segments, e.g., broader audience, hospitals, etc.



# **FENTORA SWOT Analysis**

#### **Opportunities**

- KOL eagerness to evaluate and establish standards for treatment guidelines for BTP
- Increased focus on pain management from JCAHO (5<sup>th</sup> vital sign) and NIH (Decade of pain Control and Research)
- <u>Though limited, there is some increasing</u> <u>awareness and understanding of BTP</u>
- Concentrated Actiq prescriber base enables for focused targeting
- Limited number of promoted products within the market segment (SOV)
- Aging population
- Opportunity to develop outcomes data for BTP (burden of illness)

#### Threats

- Limited understanding of BTP and its appropriate management outside a small community of pain specialists
- Fear of abuse and diversion with opioids
- Increasing government restrictions on C-II opioids
- <u>Generic SAOs</u>
- <u>Generic OTFC</u>
- Published data for Actiq vs. IV morphine documenting median time for pain relief 4.2 minutes
- <u>Managed care and other third-party payers</u> (including Medicare Part D and Medicaid) increasing their efforts to restrict high-cost drug use
- Competitive pricing pressure
- Treatment guidelines include competitive products, e.g. Actiq, SAOs
- Emerging ROO pain formulations (e.g., Rapinyl)



# **Key Issues**

- Third Party Payers manage costs by placing reimbursement limitations/restrictions on premium priced therapies
- Limited number of health care providers prescribe a ROO for BTP
- FENTORA is not clearly differentiated from other BTP and non-BTP treatment options
- Physicians and patients have limited understanding about the appropriate diagnosis and treatment of BTP; a contributing factor is the communication disconnect between physicians and patients in regards to pain
- Anticipated dosing and administration challenges for both physicians and patients
- Risk for abuse, addiction, and diversion
- Limited KOL and professional society relationships impact peer-to-peer knowledge and uptake of FENTORA



# Marketing Strategy

### **Mission & Strategic Vision**



## **Mission**

### **Franchise Mission**

Establish Cephalon as a major player in pain management

### **FENTORA Mission**

Establish FENTORA as the gold standard for BTP



# **Three Year Strategy**



# **Three Year Strategy**



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# **Three Year Strategy**


## **Three Year Strategy**



## **Three Year Strategy**



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# **Three Year Strategy**



#### **FENTORA** Positioning

FENTORA is the first and only fentanyl buccal tablet that utilizes an effervescence reaction to provide the most **rapid onset** of analgesia of any oral opioid resulting in improved patient functioning and activities of daily living



## Marketing Strategy

## 2007 Objectives, CSFs, Strategies



**76** 

## Objectives 2007

## \$139.5M Total Revenue 81,207 TRxs

#### **Assumptions**

- TRx Share @ month 12 = 28% of ROO (fentanyl) Market
- FENTORA will grow from Actiq conversion & incremental market growth
- WAC/TRx = \$1,357 (2.5% annual price increase)



# TRx Objectives 2006 - 2007



Source: FENTORA Forecast

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fentanyl buccal tablet @

## **Critical Success Factors**

Issues	CSFs
Reimbursement challenges	Maximize access
Need to expand prescribing audience	Gain acceptance among Actiq users & beyond
FENTORA not well differentiated	Physicians understand <i>FENTORA</i> is a superior treatment option for BTP
Limited BTP awareness/knowledge	Improve awareness & understanding of BTP
Dosing & administration challenges	Clear & consistent messaging on dosing & administration
Risk for abuse & diversion	Clear & consistent communication of <i>FENTORA</i> risks
Limited KOL & professional society relationships	KOLs and professional societies support <i>FENTORA</i>







Issue	Physicians and patients have limited understanding about the appropriate diagnosis and treatment of BTP; a contributing factor is the communication disconnect between physicians and patients in regards to pain
Critical Success Factor	BTP awareness and understanding of treatment options among physicians and patients
Strategies	<ul> <li>Continue to establish BTP as a distinct clinical problem among opioid prescribing physicians</li> <li>Facilitate dialogue between physicians and patients to improve the proper diagnosis and treatment of BTP</li> <li>Support BTP educational initiatives</li> </ul>







Maximize SECURE outreach program initiatives

# **LCM** Plan



# **Clinical Plan Highlights**

Study #	Study	Status				
PK Studies						
TBD	PK/Efficacy Modeling	Phase 1 complete, awaiting 3039				
1043	Buccal Sublingual	Start 1Q07, complete 1Q07				
TBD	Relative Potency (IV morphine)	Start Jan 07, complete 2Q07				
TBD	PK Higher Dose	Start 2Q07?, complete 3Q07?				
TBD	Relative Potency (SAO)	Start 3Q07, complete 4Q07				
Cancer Studies						
9915	OL LT Safety-Cancer BTP	LPLV Nov 06, DB lock Feb 07				
3039	Efficacy-Cancer BTP (Onset)	Complete, data available				
Non-Cancer Studies						
3040	OL LT Safety-Non-Cancer BTP	LPLV Jan 08, data Jan 08				
3041	Efficacy-Neuropathic BTP	Complete, data available				
3042	Efficacy-Back BTP	Complete, data available				
3052	Non-Cancer Pivotal Efficacy	89 enrolled, LPLV May 07, DB lock Jul 07				
3054	Pain Anxiety Symptoms	Study start Nov, complete 3Q07				
3055	OxyIR H2H ST Efficacy/Safety	Study start 2Q07, LPLV 4Q07				
3056	OxyIR H2H LT Efficacy/Safety	Study start 3Q07, LPLV 3Q08				





## Targeting



## **Rxers Reaction to Messages**





\* To what degree does this new information motivate you to prescribe FENTORA over other short-acting opioid (SAO) medications for breakthrough pain (1-7 scale)?

Source: Gfk V2 Q2 06 N = 77 (users) N = 52 (non-users) 91

## Targeting



## **Tactical Plan**

# FENTORA fentanyl buccal tablet @

93

## **Tactical Plan**

Overview Tactics by CSF



## FENTORA Key Milestones

Campaigns:	Vanilla		Mocha	
Milestone	1Q	2Q	3Q	4Q
Submit sNDA – Efficacy 3039	1			
Publication 1029 (Multi-dose PK)	Jan/Feb			
AAPM – 3040, 3041 1st public presentation, 3042 abstracts	Feb 7-10			
NSM	Feb			
Final Data of 99-15 (OL Safety - CA)	Feb			
FDA Type B meeting – Non-cancer sNDA requirements	Feb/Mar			
PDUFA – 300 mcg sNDA	Mar 3			
3039 BTP CA efficacy – target pub date	Mar/Apr			
Publication 1028 (Absolute bioavailability)		√?	√?	
PDUFA - label changes		Apr 26		
PDUFA - Efficacy 3039 (Onset)		√?		
AAN - 3041 (NP – Secondary efficacy)		Apr 28-May 5		
APS - 3040, 3041, 3042 (LT Safety, NP, LB)		May 2-5		
Publication 99-11 + 99/18 (Dose proportionality)				√?
Publication 3041 (NP)				√?
sNDA Non-CA				√?

# CSF #1: Physicians & patients have access to reasonable/favorable reimbursement for FENTORA

#### STRATEGY

- Selectively contract with MCOs
- Educate MCOs regarding:
  - FENTORA value to health system
  - BTP:
    - Optimal assessment and treatment of BTP
    - Establish the Burden of Illness of BTP
    - Further develop ROO sub-class as an optimal treatment for BTP
  - Minimize risk of Abuse, Addiction, and Diversion
- Provide physician/patient assistance access programs

- AMCP Dossier
- NAM Slide Kit
- Formulary Kit
- CSPs (MCO Speaker Training)
- Reprints
- BTP Collateral Material
  - Direct Mail, Journal Ads, targeted media
- ESP Tool Kit & Collateral
- AMCP Convention Presence
- Reimbursement Kit / Hotline
- Debit Card Pilot Program
- In-Office Reimbursement Training

#### CSF #2: Expand FENTORA prescribing audience beyond Actiq users

#### STRATEGY

- Maximize core prescribers to set the stage for expanded use
- Expand use with high opioid prescribers and low Actiq users
- Explore non-retail segments opportunities, as well as other potential channels

- NSM Workshops
- Field driven promotional programs
  - CSPs \$6M
  - Vouchers 75/rep 1st half, 50/rep 2nd half
  - Sales collateral materials (w/ 3039)
    - Actiq users material
    - Animation, case study series
  - Hospital program grand rounds
  - Case Studies
  - Reprints
- Marketing driven promotional programs
  - Direct mail, targeted media, journal ads
  - E-detail
  - Website
  - Convention presence

# CSF #3: Physicians understand *FENTORA* is a superior treatment option for BTP

#### STRATEGY

- Create high level of awareness among target segments
- Educate physicians on the potential limitations of prescribing LAOs and SAOs to treat BTP
- Leverage new clinical data when available and appropriate
- Further develop ROO sub-class as an optimal treatment for BTP

- Appropriate dissemination of clinical data
- Branded collateral material
- CSPs
- Case Studies Program
- FENTORA animation
- PR outreach to KOLs, societies, advocacy groups, & pain centers of excellence
- Government affairs outreach to USP
- SECURE educational initiatives

# CSF #4: BTP awareness and understanding of treatment options among physicians and patients

#### STRATEGY

- Continue to establish BTP as a distinct clinical problem among opioid prescribing physicians
- Facilitate dialogue between physicians and patients to improve the proper diagnosis and treatment of BTP
- Support BTP educational initiatives

- BTP campaign
  - Journal ad & targeted media
  - DA Convention Booth
  - BTP website
  - Direct Mail
  - PR initiatives (outreach, etc)
- ISS Support (e.g. Knox Todd, MD)
- Appropriate support of 3rd party educators
- In-office patient material

# CSF #5: Physicians and patients understand the proper dosing and administration of *FENTORA*

#### STRATEGY

- Educate physicians and patients on
  - How the delivery system is different from traditional oral administration
  - Dosing and titration
  - Package Handling & Administration

- Administration poster
- Wallet card
- Administration script for Prof Services
- Pain diary
- Flip chart
- Patient starter kit
- Catalina newsletter
- E-detail
- Pod cast
- Blackberry download (in booth promotion)
- Case Studies

# CSF #6: FENTORA risks are understood by health care professionals

#### STRATEGY

- Educate HCPs on appropriate patient selection
- Educate patients about safe use of *FENTORA* and allay fears of opioids
- Continue to implement risk minimization tools
- Maximize SECURE outreach program initiatives

- Branded collateral materials
- Lunch & Learns
- AAD CSPs
- SECURE educational initiatives
- ESP initiatives
- Media outreach training (issues mgt)

#### CSF #7: KOLs and societies support *FENTORA* as an effective treatment option for BTP

#### STRATEGY

- Improve and expand select KOL and society relationships
- Continue to consult KOLs to develop clinical & commercial plans

- Implement KOL Plan, e.g. roundtables, congress interaction, one-on-ones, HOVs
- Speaker Training / CSPs
- Media outreach training
- Society outreach initiatives, e.g. educational programs
- Implement Pain Centers of Excellence Program
- Ad Boards
- Consultant Meetings

## **Tactical Plan**

### **FENTORA** Campaign Evolution



103

# Campaign



# **Campaign Evolution**



## **Current Campaign**



# **Campaign Evolution**



# **Campaign Evolution**




Bennett D et al. *Pharm Ther*. 2005;30:354-361. Simon S. *MedGenMed*. 2005;7(4):54.



Bennett D et al. Pharm Ther. 2005;30:354-361.

## **Ideal BTP Treatment**



#### **Tactical Plan**

#### **BTP Campaign Evolution**



**112** 

#### Expanded BTP Disease Awareness Campaign

- Goal: To continue to establish BTP as a distinct clinical problem & to facilitate dialogue between physicians and patients to improve the proper diagnosis and treatment of BTP
- Phase I (completed)
  - Understand how others in the industry have built disease states (Bipolar, HPV, Depression Pain, RLS)
  - Understand physician and patient interactions around BTP
  - Create a 'portrait' of our target audience
  - Understand how to leverage the internet
- Phase II (Nov 06 Jan 07)
  - Create BTP messaging & concepts based on Ph I learnings
  - Start enhancing BTP.com / Start to maximize internet search

Cephalon

Phase III (April 2007) – Execution



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# **2007 Promotional Budget**

Category	Spend	Share of Total Spend
Market Research	\$1,750,000	6%
Consultants	\$400,000	1%
Journal Reprints	\$200,000	1%
Conventions	\$1,600,000	6%
Advertising/Promotional Materials	\$8,900,000	32%
Sample Coupons	\$6,000,000	21%
Public Relations	\$600,000	2%
Field Driven Speaker Programs (CSPs)	\$6,000,000	21%
Medical Education	\$2,500,000	9%
Corporate Contributions	\$50,000	0%
TOTAL SPEND	\$28,000,000	100%



# **CSP** Allocation

	Total		PCS		NAMS	OAS
CSP Budget Total	\$ 7,000,000					
CSP Budget (Minus Mgmt Fees)	\$ 5,250,000	\$	4,750,000	\$	300,000	\$ 200,000
Avg Cost per CSP	\$ 1,400	\$	1,400	\$	1,400	\$ 1,400
Total # of Programs per Year	3751		3,393		214	143
# of Programs per Field Rep	0		34		11	5



### **FENTORA 2007 Tactical Plan**



**116** 

## **Tactics**

The remainder of this deck describes the tactics planned to address the 2007 FENTORA CSFs and strategies. The tactics are organized within the following categories:

- FENTORA
- Dosing and Administration
- Managed Care
- Market Development
- Disease Awareness
- Conventions
- Advisory Boards
- Publications
- Education
- Public Relations
- Special Programs: SECURE (RiskMAP), Reimbursement Hotline, PAP)



# **CSF and Strategy Coding**

CSF	Strategy	CSF Number	Strategy letter
Majority of lives covered by	Selectively contract with MCOs	1	A
Majority of lives covered by Third Party Payers have access to reasonable/favorable reimbursement for FENTORA       • Selectively contract with MCOs         • Educate MCOs regarding:       • Educate MCOs regarding:         • FENTORA value to health system       • BTP: • Optimal assessment and treatment of BTP • Establish the Burden of Illness of BTP • Further develop ROO sub-class as an optimal treatment for BTP         • Minimize risk of Abuse, Addiction, and Diversion       • Further explore and maximize retail segment expansion opportunitie: • Explore non-retail segments opportunities, as well as other potential channels         • Target segments and audiences with focused messages and programs/materials       • Create high level of awareness among target segments • Leverage new clinical data when available and appropriate • Further develop ROO sub-class as an optimal treatment for BTP         • Continue to establish BTP as a distinct clinical problem among opioid prescribing physicians	Educate MCOs regarding:	1	В
	1	С	
FENTORA	<ul> <li>Optimal assessment and treatment of BTP</li> </ul>	1	D
	<ul> <li>Minimize risk of Abuse, Addiction, and Diversion</li> </ul>	1	E
Expand FENTORA	Further explore and maximize retail segment expansion opportunities	2	F
prescribing audience beyond ACTIQ users		2	G
		2	н
Physicians understand FENTORA is a superior treatment option for BTP	Leverage new clinical data when available and appropriate	3	l J K
Measurable improvement of BTP awareness and	<ul> <li>Continue to establish BTP as a distinct clinical problem among opioid prescribing physicians</li> </ul>	4	L
understanding of treatment options among physicians and patients	<ul> <li>Facilitate dialogue between physicians and patients to improve the proper diagnosis and treatment of BTP</li> </ul>	4	М
	Support BTP educational initiatives	4	N



# Coding (cont.)

CSF	Strategy	CSF Number	Strategy letter
Physicians and patients understand the proper dosing and administration of FENTORA	Educate physicians and patients on - How the delivery system is different from traditional oral administration - Dosing and titration - Administration	5	0
FENTORA risks are	sicians and patients       Educate physicians and patients on         erstand the proper       - How the delivery system is different from traditional oral administration         iTORA       - Dosing and titration         ITORA risks are       • Educate HCPs on appropriate patient selection         • Educate patients about safe use of FENTORA and allay fears of opi         • Continue to implement risk minimization tools         • Maximize SECURE outreach program initiatives         • Partner with KOLs and key professional/advocacy societies to advart the field of pain management         • Elevate awareness of Cephalon dedication to advancing the science pain therapy         • Expand Pain Franchise product offerings         • Expand Pain Franchise product offerings	6	Р
understood by health care professionals	Educate patients about safe use of FENTORA and allay fears of opioids	6	Q
As the commencement of	Continue to implement risk minimization tools	6	R
	Maximize SECURE outreach program initiatives	6	S
Cephalon Pain Franchise is considered to be a leader in	<ul> <li>Partner with KOLs and key professional/advocacy societies to advance the field of pain management</li> </ul>	7	T
the pain market	<ul> <li>Elevate awareness of Cephalon dedication to advancing the science of pain therapy</li> </ul>	7	U
	Expand Pain Franchise product offerings	7	V
Target KOLs and societies	Improve and expand select KOL and society relationships	8	W
support FENTORA as an effective treatment option for BTP	<ul> <li>Continue to consult KOLs to better inform Cephalon on the optimal design of FENTORA clinical studies, as well as the positioning of the brand</li> </ul>	8	х



Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
3039 Launch PCSF Selling Tools	Tactics updated to include 3039 data • Rev Enlarged PI • Core Sales Aid • File Card • Rev Regional TT Panels • Rev Local TT Panels • HCP FAQ • Product Monograph	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists	Field driven	Q2 - Q4	3	Ĩ
Launch Ads	4-page and 2-page launch ads updated to include 3039 data	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q2 - Q4	3	1
Online Advertising	<ul> <li>Banner advertising, primarily focused in rich media, will be aimed at driving site traffic;</li> <li>Rich media advertising has the ability to deliver multimedia content including video, database registrations, and animated content in an expandable, near micro-site format</li> </ul>	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q1 - Q4	3	1



Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Targeted Media	PDR Pain Management Prescribing Guide PDR Addendum Direct Mail The Little Blue Book ePocrates - DocAlert Campaign Rep Triggered Mail MPR Prescribing Alert Physicians Weekly Triple I Prescription Pad Blitz Mailer Triple I Prescription Pads (or MediScripts) Medsite Catalina Newsletters NEJM Coverwrap Rx PROvisions Office Suite	Actiq and Non- Actiq Users Oncology Nurses Physical Medicine and Rehab Managed Care Executives	Non-field driven	Q2 Q4	2 3 5	H I O
Launch Booth	Booth at major professional meeting to facilitate interaction with customers and provide information on FENTORA. Booth will be 40x40 and capable of breaking down into both 20x20 and 10x20	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Field driven	Q1 Q4	3 4 5 6	I,J,K L,N O P,Q
Convention Media and Sponsorship Opportunities	Identify opportunities such as programs books, room drops, airport advertising, and association event sponsorships	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q1 Q4	3 7	I T



Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Convention Follow Up Letters	Letter thanking HCPs for visiting the booth to find out information about FENTORA. Letter will also include key selling messages	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q1 - Q4	3 4 5 6	I,J,K L,N O P,Q
Launch Mailers	Launch Letter and Direct Mail (4) updated to include 3039 data	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q2	2 3 5	H I,J,K O
3-D Stereo or Animation	Video will communicate the key selling messages of FENTORA (ie, BTP, OV, Bio, PK, Efficacy, etc.) Video incorporated into the following:         – Diamond Touch - interactive game within launch booth         – Booth Handouts - CD Rom and packaging         – Direct Mailer - possibly included within one of the launch mail pieces         – Rep Deliverable         – Animation Clips - incorporated onto the Website, patient video, booth panels         – Speaker Presentations	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q2 - Q4	23	H I,J,K



Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Patient starter kit	Patient Starter Kit (English and Spanish) includes the following: – Holder – Patient Video – Placebo Pack – Patient FAQ – Pain Diary with Calendar – Caregiver Brochure – Voucher	Patients	Field driven	Q2 Q4	2 3 4 5	H – MO
Rev WebSite	<ul> <li>Phase II of FENTORA site, focused on Physicians and Patients, will round out content truncated for the early release of the drug and the accompanying web site.</li> <li><u>New content includes:</u> Physicians:         <ul> <li>Pain Identification Tool; OraVescent Technology, Thought Leadership section (KOL videos, Reference links and PDF Resources)</li> </ul> </li> <li>Patients:         <ul> <li>Pain Identification Tool; Living with Pain section (Coping Strategies, Talking with Your Doctor, Addiction concerns, Treatment options)</li> </ul> </li> </ul>	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives Patients	Non-field driven	Q2 Q4	2 3 4 5 6 7	H L,M,N O PQ T
eNewsletters	<ul> <li>2 Quarterly newsletters will target Physicians and Patients;</li> <li>Content will be generated by Palio, Blue Diesel, and Cephalon</li> <li>Delivering timely product, disease and treatment information;</li> <li>Long-term Goal: Leverage sales channel and trade shows to help increase registrations and participation</li> </ul>	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives Patients	Non-field driven	Q1 Q4	2 3 4 5 6 7	H I L,M,N O PQ T



Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Search Engine Marketing Management	Provides a tracking site as well as search parameters to help stay on top of search engine changes and competitive landscape as it relates to search criteria	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives Patients	Non-field driven	Q1 - Q4	3	I
Online Usability Study	Usability study to focus on the areas of the site to which identified target markets navigate and reach primary, secondary & tertiary content; – Can be facilitated through 1:1 interviews and computer activities; – Integration of eye-tracking usability for visual and quantitative results	Actiq and Non- Actiq Users Physicians & Assistants Nurses Pharmacists KOLs Managed Care Executives Patients	Non-field driven	Q2	3	1
Actiq Users Switch Selling Tools for PCSF	Tactics updated to include 3039 data – AUS Sales Aid – AUS Cling Posters	Actiq Users	Field driven	Q2 - Q4	2 3 5	H I,J O
Actiq Users Direct Mail and Email	Tactics updated to include 3039 data – AUS Direct Mail (7) – AUS Launch Letter – AUS Email	Actiq Users	Non-field driven	Q2	2 3 5	H I O



Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Key Pain Meetings via Webcast	Utilize web channel to deliver key meetings via webcast and downloadable podcasts; Can be used for Key meetings across the pain franchise where & when appropriate to primary audiences of HCPs and Patients	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Field and Non-field driven	Q1 - Q4	2 3 4 5 6	H I L,M,N PQ
Hospital Program	The first goal of the program would be to establish awareness of FENTORA via Grand Rounds or possibly Tumor Boards. Second goal would be to get FENTORA on the hospital formulary by providing pricing, packaging, and other formulary-related information. Once awareness and formulary are established, the reps can provide in- servicing by utilizing the detail aid, clinical reprints, leave behinds, table tops, etc.	Physicians Residents Fellows Nurses Patients	Field driven	Q3	2 3 4 5	H I,J,K L O
300 mcg materials	Various tactics regarding the launch of the 300-mcg tablet will be developed and implemented. Most sales materials will also be updated to include the 300-mcg dose	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Field driven	Q3	2 3 5	H I O
Revised Med Guide	Med Guide updated with new language, 3039 data, and 300-mcg dose	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Field driven	Q2 - Q4	3 5	0



Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Revised PI	PI updated with new language, 3039 data, and 300-mcg dose	Patients	Field driven	Q2 - Q4	3 4 5	I M O
Quarterly Case Studies	On-demand audio case studies. Physicians dial in once each quarter to hear new case study highlighting FENTORA	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists	Non-field driven	Q1 Q4	2 3 5	H I O
Reprint Folders	Folders will be produced highlighting the key findings of the studies and also include a copy of the article	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Field driven	Q1 Q4	3	Ţ
Pharmacy Article	Article will be written about rapid onset opioids (ROOs) to educate pharmacists on how ROOs can be used to treat BTP. Article will run in key pharmacy journal	Pharmacists	Non-field driven	Q4	2 4	H N
Product Monograph	Monograph will help educate healthcare professionals on the use of FENTORA in the treatment of BTP in cancer; includes 3039 data	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q2 Q4	3 5	0



Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Cephalon Pain University.com	In conjunction with top pain specialists, Cephalon to create a virtual pain university that would conduct clinical studies, generate position papers, fund fellowships, as well as provide current product information/materials and promotional activity updates. Could include Speakers' Corner - a password protected resource for speakers only, driven by eVites, provides online registration for training. Activities could be carried out to create awareness for this initiative as well	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists KOLs Managed Care Executives	Non-field driven	Q3 - Q4	2 3 4 5 6	H I,N O P,Q



# **Dosing and Administration Tactics**

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Administration Poster	Wall poster includes the "peel it, place it, feel it" information/illustrations. Placed within the physician office to help educate patients on FENTORA administration	Actiq and Non- Actiq Users Physician Assistants Nurses Patients	Field driven	Q2 - Q4	5	0
Administration Wallet Card	Small card could be placed inside patients wallet or even pocket. Includes the "peel it, place it, feel it" information/illustrations. Can also include information on "what not to do." Could possibly be included as part of the Patient Starter Kit	Patients	Field driven	Q2 - Q4	5	0
Administration Magnet	Small magnet could be placed within the patient's home. Includes the peel it, place it, feel it information/illustrations. Could possibly be included as part of the Patient Starter Kit	Patients	Field driven	Q2 - Q4	5	0



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# **Dosing and Administration Tactics**

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Administration Script for Cephalon Professional Services/Medi cal Information	Cephalon Professional Services and/or Medical Information could have a script available to help answer physician and patients questions/concerns with regard to the administration of FENTORA	Actiq and Non- Actiq Users Physician Assistants Nurses Patients	Non-field driven	Q2 - Q4	5	0
Revised Pain Diary	Current Pain Diary would be revised to help patients with the titration phase. This can then be used as a tool to help physicians with redosing	Actiq and Non- Actiq Users Physician Assistants Nurses Patients	Field driven	Q2 - Q4	5	0
Flip Chart	Incorporating the copy/tabs from the Patient FAQ, Flip Book will be developed so that physicians, nurses, and PAs can educate patients on FENTORA, including the titration and administration information	Actiq and Non- Actiq Users Physician Assistants Nurses Patients	Field driven	Q2 - Q4	5	0



# **Dosing and Administration Tactics**

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Catalina Newsletter	Newsletters could be created to focus on patient titration and administration	Patients	Non-field driven	Q2 - Q4	5	0
eDetail	Administration animation can be incorporated into the eDetails	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists	Field driven	Q2 - Q4	5	0
Podcast	Titration and administration information/animation could be downloaded as Podcasts	Actiq and Non- Actiq Users Physician Assistants Nurses Patients	Non-field driven	Q2 - Q4	5	0
Blackberry Download	Titration and administration information/animation could be downloaded within the booth	Actiq and Non- Actiq Users Physician Assistants Nurses	Non-field driven	Q2 - Q4	5	0



# **Managed Care Tactics**

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
National Managed Care Advisory Boards	Advisory boards to enhance relationships with MCOs, disseminate positive clinical FENTORA information, and aid in lessening PA obstructions. Build a steering committee to address key issues. Identify and create possible value proposition statements. Influence on a national level to then tier-down on a regional/local level	P&T Committee Members from larger MCOs	Non-field driven	Q2 - Q4	1	A
Office Manager Advisory Boards	Advisory boards with office staff to gain feedback and insights on education, specific training, and appropriate tools to reduce PA resubmission and rejection rates	Office-based administrators	Non-field driven	Q2	1	A
Payer / Prescriber Data	Payer/Prescriber Data for Field Force to tailor messages regarding formulary coverage by regional plans	Actiq and Non- Actiq Users Physician Assistants Nurses Patients	Field driven	Q1 - Q4	1	A
Contracting	Ongoing assessment of contracting options.	Pharmacy & Medical Directors	NAM driven	Q1 - Q4	1	A
AMCP Booth	Booth at spring and fall AMCP meetings. Disceminate product literature and educational materials.		Nam driven	Q2 Q4	1	A



## **Managed Care Tactics**

						_
Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Office Manager Training	<ul> <li>Regional Office Manager PA Training: Workshop training program with office staff in top 25 markets to facilitate PA compliance and reduce resubmission and rejection rates</li> <li>Local Office Manager Luncheon Programs: Luncheon programs to provide education, training, and appropriate tools to facilitate PA compliance and reduce resubmission and rejection rates.</li> <li>Office Manager Training DVD and/or Booklet: 30-minute interactive presentation for office managers who review the PA process, methods on facilitating reimbursement, and typical completion of required managed care forms</li> <li>Office Manager Online Training: Online training reviews the PA process, methods on facilitating reimbursement, and typical completion of required managed care forms</li> </ul>	Office-based Administrators	Field Driven	Q1 - Q4	1	A
Educational materials	Provide both CME and Non-CME educational materials to facilitate enhanced understanding of BTP and its appropriate assessment and treatment	MCO staff	Non-field and NAM driven	Q1 - Q4	1	A



## **Managed Care Tactics**

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
NAM Slide Kit	Provide NAMs with 3039 supplemental slides	P&T Committee Members	NAM driven	Q1	1	A
Formulary Kit	Updated to include all new data, new concepts and messages.	P&T Committee Members	NAM driven	Q1 - Q4	1	A
Key Reprints	Once studies are published, clinical reprint carriers will be produced and distributed to the NAMs	P&T Committee Members	NAM driven	Q1 - Q4	1	A



#### Market Development Market Research

Research	Description	Target Audience	Implementation	Timing	CSF	Strategy
Rep Advisory Board	Brand Team, PCSF, and Agency can all meet at the National Sales Meeting to discuss what issues they are encountering, what's working/what's not, what materials they need, how the messages are working, etc.	Actiq and Non- Actiq Users	Field driven	Q1	2	F
Segmentation Study	Segmentation research with physicians to determine attitudinal, emotional, etc. reactions to FENTORA	Non-Actiq Users	Non-field driven	Q1	2	F
Path to Rx	Research to identify the dynamics and flow of the path to Rx. Target each area to identify points of entry: barriers, triggers, and leverage points	Actiq and Non- Actiq Users	Non-field driven	Q1	2	F
Message Refinement Research	Based on feedback from the rep ad board and path to Rx research, messages can be revised and tested with multiple segments	Actiq and Non- Actiq Users	Non-field driven	Q1	2	F



#### Market Development Market Research

Research	Description	Target Audience	Implementation	Timing	CSF	Strategy
Hospital Landscape Study	Determine points of use, attitudes, how FENTORA would fit within the hospital system, etc.	Non-field driven	Non-field driven	Q1	2	G
Consumer Identification and Connection	Includes the following Client and Agency development: – Brand Revolution Research – Target Delineation Research – Heart and Soul Research – Media Usage Analysis – Target Portraiture	Non-high prescribers, determined based on research results	Non-field driven	Q1	2	G
Brand Insight Synopsis	Includes a Brandscape Summary - Compilation of all the primary research that helps frame the forthcoming Positioning and Vision Development.	N/A	Non-field driven	Q1	2	G
Communication Strategy Development	Includes the following Client and Agency development: – Illumination Brief Development – Illumination Brief Client Review/Approval	N/A	Non-field driven	Q1	2	G



# **Market Development Tactics**

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Sales Training Materials	Based on findings from the path to Rx research and message refinement research, training tools for the PCSF will be developed. Tools will help educate them on the customer portrait matrix, ie, what multiple physician segments feel and what motivates them. Examples of materials might include specialty reference sheet and targeted messages by segment	Pain Care Sales Force	Non-field driven	Q2	2	F
Communication Platform and Tactical Plan Development	Includes Brand Arc Development - The Brand Arc bridges the gap between the current and desired mindsets, outlining realistic interim target mindsets necessary to reach the end goal. Also, new tactics will be incorporated into the master tactical plan	Determined based on research results	Non-field driven	Q2	2	G



P-03610\_00136

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
BTP Physician Materials	<ul> <li>Take findings from Futurescape and Brand Revolution Research to broaden reach to physicians. Once research is complete and targets have been identified, various types of materials can be implemented, such as the following: <ul> <li>Journal Ad</li> <li>BTP Treatment Differentiator Flashcard</li> <li>Differential Diagnosis: Identifying BTP Case Study</li> <li>DM Wave 1: BTP Pamphlet and Holder</li> <li>DM Wave 2: BTP Poster</li> <li>DM Wave 3: BTP Assessment Sheet</li> <li>Best Practices Meeting and Enduring Materials</li> <li>Advertorial Series</li> <li>Letters to the Editor Series</li> </ul> </li> <li>Determine how all tactics translate to online activities</li> </ul>	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q3 - Q4	4	L,M
Targeted Media	ePocrates - DocAlert Campaign IMNG KOL Series The Patient Counselor WebMD Booklets Catalina Newsletters	Actiq and Non- Actiq Users Oncology Nurses Physical Medicine and Rehab Managed Care Executives Patients	Non-field driven	Q3 - Q4	4	L,M



Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Revised www.BTP.com	<ul> <li>Phase II of BreakthroughPain.com site, focused on Physicians and Patients, to expand the initial HCP-only focused site currently live. Site will be focus on 1 destination, with a specialized section for HCP content offerings.</li> <li><u>New content includes:</u> Physicians: <ul> <li>Pain Identification Tool; Thought Leadership section (KOL videos, Reference links and PDF Resources); keyword-rich content development</li> </ul> </li> <li>Patients: <ul> <li>Pain Identification Tool; Living with Pain section (Coping Strategies, Talking with Your Doctor, Addiction concerns, Treatment options); Education for Pain and Breakthrough Pain, Conditions affected by BTP; viewing/ordering The Path of Pain DVD; keyword-rich content development</li> </ul> </li> </ul>	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q3 - Q4	4	L,M
Online Usability Study	<ul> <li>Usability study to focus on the areas of the site to which identified target markets navigate and reach primary, secondary &amp; tertiary content;</li> <li>Can be facilitated through 1:1 interviews and computer activities;</li> <li>Integration of eye-tracking usability for visual and quantitative results</li> </ul>	Actiq and Non- Actiq Users Physicians & Assistants Nurses Pharmacists KOLs Managed Care Executives Patients	Non-field driven	Q2	4	Ν



Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
BTP Content Feeding	<ul> <li>Focus on identifying those sites and potential partners willing to accept content generated through a PR development effort;</li> <li>Sites will be categorized by those requiring internal support for content inclusion, those accepting of automated syndication feeds, and those which can be updated by the PR team;</li> <li>Maintenance will continue through 2007 to continue to generate and feed content to the identified sites, along with any new entities deemed as worthy sources of pain information</li> </ul>	Actiq and Non Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q1	4	L
Online Advertising	<ul> <li>Banner advertising, primarily focused in rich media, will be aimed at driving site traffic;</li> <li>Rich media advertising has the ability to deliver multimedia content including video, database registrations, and animated content in an expandable, near micro-site format</li> </ul>	Actiq and Non Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives Patients	Non-field driven	Q1 Q4	4	Ľ
Online Viral Campaign	Implement an advertorial/sweepstakes/campaign or some other form of engaging, HCP-focused material that is compelling enough that users/viewers are included to forward on to colleagues; Material will help drive users back to the websites and create "buzz" about topic of BTP and FENTORA	Actiq and Non Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives Patients	Non-field driven	Q1 Q4	4	L,M



Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
3rd Screen Downloadable Application	Includes information on BTP, as well as pain identification tool	Actiq and Non- Actiq Users Physician Assistants Nurses	Non-field driven	Q1 _ Q4	4	L
Direct to Patient via Physician Pain Care Centers of Excellence Program	Pilot program with the top 25 PCCE to help educate healthcare professionals, patients, caregivers, and their families on BTP. Program components could include the following: <b>Pain Day Patient Seminar/Community Outreach</b> – Posters – Slides – Handout materials – Testimonials <b>In Office Informational Center</b> – Holder with pain related pamphlets – "How to Talk to Your doctor about Pain" brochure <b>Reach a Patient Counseling Tools</b> – Flipbooks – Path of Pain acetate tool – Take-home brochures – Acetate education tool – Patient Video – Video Take Away Brochure Tactics will be coordinated with PR efforts as well	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Patients	Non-field driven	Q3 - Q4	4	М



Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Direct to Patient via Physician	<ul> <li>Take findings from Futurescape and Brand Revolution</li> <li>Research to broaden reach to patients. Once research is</li> <li>complete and targets have been identified, various types of</li> <li>materials can be implemented, such as the following:</li> <li>– KOL Advisory Board Slide Deck: Improved Dialogue</li> <li>between physicians and patients</li> <li>– Physician and Patient Speaker Program: Gain feedback</li> <li>from patients on improved Dialogue</li> </ul>	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Patients	Non-field driven	Q3 - Q4	4	Μ
Direct to Patient Journal Ad	Journal Ads in Publications (ie, Coping and Cure) Tactics will be coordinated with PR efforts as well	Patients	Non-field driven	Q3 - Q4	4	М



## **Convention Tactics**

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Convention Media and Sponsorship Opportunities	Identify opportunities such as programs books, room drops, airport advertising, and association event sponsorships	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q1 - Q4	3 7	I T
FENTORA Booth	Booth at major professional meeting to facilitate interaction with customers and provide information on FENTORA. Booth will be 40x40 and capable of breaking down into both 20x20 and 10x20	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Field driven	Q1 - Q4	3 4 5 6	I,J,K L,N O P,Q
Convention Follow Up Letters	Letter thanking HCPs for visiting the booth to find out information about FENTORA. Letter will also include key selling messages	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q1 - Q4	3 4 5 6	I,J,K L,N O P,Q



## **Advisory Boards Tactics**

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Consultant Meetings	Consultant Meetings: – 4 regional meetings – Including topics related to BTP, FENTORA – Segmented by behavior and geography – 50 MDs/meeting – 200 MDs total	Opioid prescribers KOLs	Non-field driven		8	Х
Health care Providers Advisory Board		RN PA	Non-field driven	Q2	8	х



## **Publication Tactics**

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Journal Articles	Top priority manuscripts for key clinical data: 3042, 3041, 3039, 99-16, 1037	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q1 - Q4	1 3 4	A I,J,K L
Journal Articles	Second wave manuscripts of clinical data: 99-11/99-18, 99-15, 1043, 3040, 3052, 1046, 3054, 3055, 3056	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q1 - Q4	1 3 4	A I,J,K L
Other manuscripts	Additional manuscripts to support education efforts: •Statistical support paper •Expert Opinion in Investigational Drugs •ADIS Drugs Profile •FBT Drugs of Today Monograph •Patient/Physician Attitudes research •Case Histories	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q1 	1 3 4	A I,J,K L
Abstracts	Abstracts of clinical data at congresses: 3040,3041,30,42	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q1 	3 4	I,J,K L


# **Promotional Education Tactics**

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Promotional CSPs	Field-Driven Medical Education Programs (CSPs)	Actiq and Non- Actiq Users	Field driven	1Q	3	I,J,K
		Physician Assistants		4Q	5	0
		Nurses Pharmacists Hospitalists			6	P,Q
Promotional	National Speaker Training with online follow-up	Actiq and Non-	Non-field	1Q	3	I,J,K
Programs Speaker		Actiq Users	driven		5	0
Training					6	P,Q
					6	Ρ,



# **Non-Promotional Education Tactics**

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Independent Medical Education- CME (see SciCom Medical Education Plan)	<ul> <li>Examples of potential medical education initiatives:</li> <li>Live events: Satellite Symposium, Teleconferences, regional meetings</li> <li>Print and Enduring Materials, i.e., Monographs, special reports</li> <li>WEB based initiatives, i.e., Medscape, Pain.com</li> </ul>	Opioid Prescribers Physician Assistants Nurses Residents Hospital MDs Pharmacists Managed Care Executives	Non-field driven	Q1 - Q4	4	L,M,N
Emerging Solutions in Pain (see SciCom Medical Education Plan)	Examples of potential medical education initiatives: -2006 Monograph collection -Monograph series with PPM -Expert Commentary -"In the know" abstract summaries -Ask the Expert -State Your Case -Pain and Addiction 101 -Urine Drug Testing Tool -E-Journal Club -Live symposium (TBD) -Convention presence (booth) -Scholarship Fund	Opioid Prescribers Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q1 - Q4	4	L,M,N



## **Public Relations Tactics**

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
BTP Awareness Campaign: Local Events	Roll out local campaign in three cities; selection based on presence of top 25 pain center, medical meeting, and/or other national/regional/local venue highlighting health issues. Elements may include: Traveling exhibit/booth with computer kiosks linking to BTP site, self- assessment tools; appropriate giveaways Local panel discussions for patients with chronic pain led by pain expert, patient, etc.; Use of media and local celeb to promote activities, BTP as a health topic. Utilize existing website to raise awareness of events, and help develop appropriate content such as patient case studies, Ask-the-Expert section, articles by health care professionals (4) on BTP and help with repurposing videos into video vignettes for site. Develop patient BTP materials (to include brochure, fact sheet, identity materials, logo and stationary suite).	Patients with Chronic Pain Who Experience BTP General Public FENTORA, Actiq and Non Actiq Users Physician Assistants Nurses Pharmacists	Non-field Driven	1Q 4Q	3	l,J,K
Third-Party Relationships: Organizations	Identify opportunities to maintain and extend relationships with third- party organizations; monitor follow through with activities funded through unrestricted 2006 education grants, including appropriate dissemination of information to patients and HCPs; host event for patient advocates at the American Pain Society to highlight data presentations (Advocacy Group Clinical Update)	Patients with Chronic Pain Who Experience BTP Patient Advocate Groups	Non-field Driven	1Q 4Q	6 7	Q T
Third-Party Relationships: Health Care Professionals Advisory Board	Coordinate 2-day meeting – in collaboration with the Marketing team – of the Health Care Professional Advisory Board; agenda to include topics such as BTP awareness campaign, product-related education activities, clinical developments, etc. Board will be consulted for expertise in patient communication.	Actiq and Non Actiq Users Physician Assistants Nurses	Non-field Driven	2Q 4Q	6 7	Q T,U
Third-Party Relationships: Bylined articles and Educational Materials	Work with selected HCPAB members to develop content on BTP for newsletters and online outreach.	Patients with Chronic Pain Who Experience BTP General Public FENTORA, Actiq and Non Actiq Users Physician Assistants Nurses Pharmacists	Non-field Driven	1Q 4Q	3 6 7	I,J,K Q T



## **Public Relations Tactics**

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Media Relations: Abstract/Posters and Journal Articles	Work with investigator/author(s) and clinical to develop key messages. Coordinate media training when necessary; develop media materials, conduct media outreach.	Patients with Chronic Pain Who Experience BTP General Public FENTORA, Actiq and Non Actiq Users Physician Assistants Nurses Pharmacists	Non-field Driven	1Q 4Q	3 6 7	I,J,K Q T,U
Media Relations: Publicize sNDAs and Regulatory Milestones	Identify <i>FENTORA</i> investigators and patients, develop media materials including media alerts or press releases and fact sheets. Conduct outreach with key media outlets to publicize milestones.	Patients with Chronic Pain Who Experience BTP General Public FENTORA, Actiq and Non Actiq Users Physician Assistants Nurses Pharmacists	Non-field Driven	1Q 4Q	3 6 7	I,J,K Q T
Issues Management: Media Monitoring	Incident-related media monitoring of FENTORA and OTFC-related stories including monitoring and coverage reports.	Internal	Non-field Driven	Q107- Q407		
Issues Management: Letters to the Editor	Draft media letters to the editors related to inaccurate coverage of <i>FENTORA</i> or BTP. Includes identification of appropriate KOL or internal spokesperson (if appropriate).	Patients with Chronic Pain Who Experience BTP Patient Advocates FENTORA, Actiq and Non Actiq Users	Non-field Driven	Q107- Q407		
Issues Management: Proactive Preparation	Prepare company spokespersons on intermittent basis and identify outside experts as needed. Help to develop or edit issues management materials containing key messages related to abuse, diversion, cost, and supply issues.	Internal	Non-field Driven	Q107- Q407		



## **RiskMAP Tactics**

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Lunch and Learn	PCSF can utilize a turn key kit that incorporates some of the RiskMAP tools as well as includes table top panels on the RiskMAP only	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Hospitalists	Field driven	Q1	6	R
RiskMAP Tools	Continue usage of all tactics within the RiskMAP plan (ie, patient FAQ, PharmAlert, RiskMAP flashcard, etc.)	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Patients	Field driven	Q1 - Q4	6	R
SECURE Program	Brand the SECURE program with logo, colors, etc. and roll out into the following: – RiskMAP flashcard – Web page – eNewsletter – Other sales and booth tactics where appropriate	Actiq and Non- Actiq Users Physician Assistants Nurses Pharmacists Patients	Field driven	Q2 - Q4	6	S







Appendix A

#### **Publications Plan**



## FENTORA<sup>™</sup> Publication Plan\*



Final data tables available



Abstract submission (1 primary, 2 secondary endpoints)



Congress presentation



- Manuscript submission
- M Journal publication





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## FENTORA<sup>™</sup> Publication Plan Overview (1)

	2006			20	07		2008			
Study	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
1027 PK	м									
1028 PK		М								
3042 Low Back		A <sub>1</sub> A <sub>2</sub> M M								
3041 NeP	0	A <sub>1</sub> A <sub>2</sub> M								
3040 Interim		<b>A</b> <sub>1</sub> <b>A</b> <sub>2</sub> <b>A</b> <sub>3</sub>								
3040/41/42 Pt Pref										
3041/42 Comb efficacy										
3041 vs 42 Efficacy										
3041/42 ATC corr										
3039 Ca Pain		0	AM							

## FENTORA<sup>™</sup> Publication Plan Overview (2)

2006			20	07		2008				
Study	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
3039/99-14 NeP		0	A	Μ						
3039/99-14 ATC corr		0	A							
3039/99-14 Dose convers		0	A							
3039/99-14 Comb efficacy		0	A							
Drugs of Today Review			M							
99-11/ 99-18 Dwell time			M							
99-15 Ca OL safety				М						
Ca PK Model			0	AM						
NonCa PK Model			0	AM						
99-16 Mucositis			AM							
Dosing review: all studies			0	AM						

## FENTORA<sup>™</sup> Publication Plan Overview (3)

2006			20	07		2008				
Study	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
Ca/NonCa FBT comparison			$\bigcirc$	A	м					
Safety review: All studies			0	A	м					
1043 Bucc vs subl				0	AM					
Mkt Res Physicians				М						
Mkt Res Nurses				Μ						
99-19 Jpn PK				М						
99-20 Jpn PK				м						
99-21 Jpn PK				м						
PK review: All studies					M					
BTP awareness review					м					

## FENTORA<sup>™</sup> Publication Plan Overview (4)

	20	006	2007				2008				
Study	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	
BTP definition review					м						
Evolution of Tx review					м						
3054 Pain & Anxiety					0	AM					
BTP spectrum review						м					
BTP Tx review						м					
1046 Relative potency							Μ				
3040 Final data							A <sub>2</sub> M <sub>1</sub>	M <sub>2</sub>			
3052 Pivotal NonCa							A <sub>2</sub>	M <sub>2</sub>			
PK Model All pts								М			
3055 vs oxycodone									М		
3056 vs oxycodone											

## FENTORA<sup>™</sup> 2007-2008 Congress Plan

Congress	Proposed Abstracts
ONS April 2007	3039/99-14/ Lack of ATC/rescue dose correlation 3039/99-14 Dose conversion from ACTIQ to FENTORA 3039/99-14 Combined efficacy and safety
AAN April 2007	3041 Secondary efficacy measures
APS May 2007	3041/3042 Side by side efficacy 3041/3042 Combined efficacy 3040/3041/3042 Patient preference 3041/3042 Lack of ATC/rescue dose correlation 3040 Mood, functioning, and QOL 3040 Patient preference
ASCO June 2007	3039 Primary efficacy and safety 3039/99-14 Efficacy and safety in neuropathic pain patients 99-15 OL safety (late breaker) 99-16 Mucositis



## FENTORA<sup>™</sup> 2007-2008 Congress Plan

Congress	Proposed Abstracts
NeuPSig June 2007	3041 Primary efficacy and safety
AAPMt September 2007	Cancer PK Model (or ASA) Noncancer PK Model (or ASA) 3041 Secondary efficacy measures (encore) 3041/3042 Side by side efficacy (encore) 3041/3042 Combined efficacy (encore) 3040/3041/3042 Patient preference (encore) 3041/3042 Lack of ATC/rescue dose correlation (encore)
AAPMR October 2007	3042 Secondary efficacy measures (rejected by AAPM) 3040 Interim safety and efficacy (rejected by AAPM) 3040 Mood, functioning, and QOL (encore) 3040 Patient preference (encore)
ASA October 2007	1043 Buccal vs. sublingual All studies – Dosing



## FENTORA<sup>™</sup> 2007-2008 Congress Plan

Congress	Proposed Abstracts
Dworkin Neuropathic Pain Mtg November 2007	3041 CPRA analysis
AAPM/APS 2008	3040 16 month analysis 3052 Primary safety and efficacy
IASP 2008	PK Model all patients 1046 IV potency 3052 Secondary efficacy measures 3040 Final safety and efficacy 3054 Primary safety and efficacy Safety analysis all patients



## Appendix B

#### **Public Relations Plan**



# Cephalon Pain Franchise 2007 Public Relation Plan

Thursday, November 16, 2006 **FENTORA™** fentanyl buccal tablet €

### **Key Audiences**

hird-party groups - patient support and advocacy

KOLs/Clinicians - professional societies, pain specialists, PCPs (high opioid prescribers), oncologists

**C**HRONIC PAIN PATIENTS AND CAREGIVERS



P-03610\_00162

### **CSF: Improve BTP Awareness**

### Strategy:

• Launch national *n*on-branded DTP education campaign

#### Tactics:

- National media launch
- Multiple city tour
- Traveling exhibit/booth
- Local events
- Breakthroughpain.com content



P-03610\_00163

- Roll out activities targeting chronic pain patients through multiple city tour in:
  - Cities with identified top 25 pain center
  - Cities where pain meeting will occur (e.g., APS in Washington, DC, ASPMN in Dallas)
  - Other national, regional and local venues
  - Venues such as:
    - AARP Life @ 50+
    - NBC Health Fairs
    - Regional patient group meetings such as Cure Patient Survivor Forums (4 per year)

#### • Venues feature:

- Traveling exhibit/booth
- Local events
- Publicity activities

- September Pain Awareness events at local pain clinics
- Support group meeting at NCI designated cancer centers
- YMCAs and senior living facilities, NCOA chapters



#### • Campaign components can be extensive\* or discreet

- Traveling exhibit/booth
  - Guest appearance by local celebrity\* and FENTORA patient
  - Scheduled presentation by HCP\*
  - Self-assessment questionnaire about chronic pain and BTP available at computer kiosk or hard copy
  - Staffed exhibit (staffing TBD)
  - Computer kiosk stations featuring BreakthroughPain.com
  - Giveaways such as on-site massages, premiums (i.e. stress balls), educational materials/brochures





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#### Local events

- Panel discussion with Health Care Professional Advisory Board (HCPAB) member or local pain expert, BTP patient, local celebrity, patient support group representative
- Open to patients/families and local community (anticipated attendance 20-50)
- Feature booth (contingent on budget/space)





- Promote campaign in each city featuring celebrity/athlete, pain expert and FENTORA patient
  - Conduct media outreach (TV & radio-news/talk shows, lifestyle & health reporters)
  - Coordinate mailings, flyers, print and radio ads
  - Partner with local third-party group
  - Publicize through third-party group newsletters, e-mail distribution lists
  - Revise *Do You Still Have Pain?* brochure; insert in local newspapers



#### Contribute to content for BreakthroughPain.com

- Online feature encouraging patients to share their BTP story
- Promote via:
  - MAT feature article -- distributed to local newspapers and handouts to clinic/practice waiting rooms
  - Links from third-party pain group websites and banner ads
- Include campaign information: city exhibit and event schedule, BTP patient case studies
- Ask-the-Expert section
- Utilize compelling stories for various national and grassroots outreach opportunities:
  - Media

· Feature stories on third-party websites and in newsletters

Speaking events

Video vignettes posted on BreakthroughPain.com

#### All activities could be source for patient database building



#### **CSF: Improve BTP Awareness**

#### Strategy:

Strengthen third-party and KOL relationships

### **Tactics:**

- Host third-party event at American Pain Society Annual Meeting
- Outreach to third-party and professional organizations
- Conduct Health Care Professional Advisory Board



Host Third-Party Event at American Pain Society Annual Meeting
 – Advocacy Group Clinical Update

- Provide update on non-cancer trials data, response to FENTORA adoption; (Speaker TBD: Cephalon Clinical)
- Educate about differences between rapid onset and short-acting treatments













#### Conduct Health Care Professional Advisory Board

- Provide update on non-cancer data, response to FENTORA adoption
- Conduct media training for participants
- Build agenda collaboratively with Marketing
- Hold focus group for marketing topic TBD
- Host as 2-day meeting





P-03610\_00171

- Outreach to Third-Party and Professional Organizations:
  - Support Media Telebriefing at AAPM meeting on "BTP Treatment Developments" (including *FENTORA*)
  - Sponsor live web chat or teleconference about BTP with BTP patient and HCP
    - Potential partners: APF, CancerCare, PLWC
  - Create feature/filler content on BTP for content for third-party websites and newsletters
    - Work with HCPAB to develop content (i.e., "BTP new treatment options")
  - Conduct a sweep of existing Internet content, especially third-party pain group websites, encourage updates to include *FENTORA* and BTP information



#### Outreach to Third-Party and Professional Organizations:

- Corporate contributions and grants
  - Maintain collaboration with and support for third-parties, including:
    - AACPI conference support
    - ACPA corporate contribution
    - APF corporate roundtable
    - CancerCare industry dinner
    - NCCS Tribute to ASCO President
    - NPF Triumph Dinner
    - OncoLink website development
  - Identify additional opportunities for interaction and other groups



### **CSF: Continue to differentiate FENTORA**

### Strategy:

Raise awareness of science and data of FENTORA

### Tactics:

- Data publicity and milestones
- HCP activities



#### Publicize data:

 Posters/abstracts presented at medical meetings



Journal of

- Journal articles
- Emphasize unique features:
  - Rapid and efficient absorption
  - Faster onset
  - Convenience
  - QOL
  - Functionality
  - Preference
- Work with authors/investigators

#### Publicize sNDAs and Regulatory Milestones





P-03610\_00175

- Work with HCPAB member to increase HCPs understanding of mechanism of action and unique features of *FENTORA*
  - Encourage development of *FENTORA* "Fast Facts" (by The University of Wisconsin) and EPERC (End of Life/Palliative Education Resource Center
    - Proactively encourage similar adoption by other HCPAB members' organizations/institutions
  - Work with HCPAB members on ad hoc basis to deliver consistent and uniform messages on BTP and FENTORA
  - Invite select HCPAB members to join Cephalon's Speaker Bureau



#### CSF: Maintain clear and consistent communication about FENTORA risks

### Strategy:

• Anticipate and prepare messages around potential issues

## Tactics: Internal and external

- Prepare company spokespersons
- Maintain issues management materials
- Monitor media environment



- Prepare company spokespersons on intermittent basis and identify outside experts and groups to enlist, as needed
- Maintain issues management materials containing key messages (i.e., abuse/misuse, diversion, cost, unintended exposure, supply issues)
- Monitor media environment
- Interact with media and submit letters-to-the editor, addressing/correcting serious inaccuracies





# Appendix C

## **Medical Education Plan**

P-03610\_00179

# Pain Medical Education Tactical Plan 2007

Bhaval Shah Bell PhD Senior Manager, Medical Education



180

# **Budget Spend by Audience**



# **Pain Specialists**



P-03610\_00182

# Pain RNs, NPs, Residency



# **Oncologists, Onc RNs, NPs**



# **Multiple Audiences**



# **Managed Care**



# **Emerging Solutions in Pain**

