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FENTORA Budget Review


FENTORA[®]
fentanyl buccal tablet @
optimize onset

Budget Planning in November 2009

REMS launch assumed April 2010

Requested & approved for \$20m for *FENTORA* 2010 Marketing budget

- Assumptions:
 - REMS launch in April 2010
- Strategy:
 - Maintain minimal level of non-personal promotional efforts & keep sales force promotional support tools in tact to continue to remind HCPs of the benefits of *FENTORA* for the appropriate patient
 - Utilize REMS budget for tactics to quickly educate & enroll HCPs
- Budget Breakdown of \$20m:
 - PR spend ~\$1.2m
 - Promotional spend ~\$11.9m
 - REMS spend ~\$6.8m
- These are the amounts currently in the finance system (as of April 2010):

	Total	Q1 2010	Q2 2010	Q3 2010	Q4 2010
REMS	\$ 6.8m	\$1.3m	\$2.5m	\$1.4m	\$1.6m
Promo	\$11.9m	\$3.9m	\$2.9m	\$2.4m	\$2.7m

Revised REMS Budget in March 2010

REMS launch delayed to October 2010

- Revised Assumptions:
 - REMS launch delayed
 - “Enrollment only” launch to occur in October 2010 (pharmacy systems lock-down to occur in April 2011)
- Revised Strategy:
 - REMS budget reduced because of delayed launch and phased launch approach (“Enrollment only” launch)
- Revised REMS Budget Breakdown:
 - Spend pushed to later in 2010 and reduced by \$3.6m given phased approach
 - Any unspent REMS funds from \$3.2m allocation can be given back

Nov 2009	Total	Q1 2010	Q2 2010	Q3 2010	Q4 2010
REMS	\$ 6.8m	\$1.3m	\$2.5m	\$1.4m	\$1.6m

Mar 2010	Total	Q1 2010	Q2 2010	Q3 2010	Q4 2010
REMS	\$ 3.2m	\$0m	\$0m	\$1.5m	\$1.7m



Revised Promotional Budget in March 2010

REMS launch delayed to October 2010

- Revised Assumptions:
 - REMS delay allows more time for promotional focus
- Revised Strategy with REMS launch delayed :
 - *Increase* the level of promotional efforts & sales force promotional support tools to re-establish brand growth
 - *Increase* frequency of details on targets to increase unaided awareness to 50%
 - Stay top of mind and continue to establish the value proposition of *FENTORA* before REMS launch

FENTORA Situation Analysis

as of March 2010

Situation:

- ROO market / FENTORA declining
- Shrinking prescriber base
- Less productive prescriber base
- Few new patient starts

Contributing Factors:

- Safety Update 9/07
- Pricing / managed care
- Cancer BTP not well understood
- Value proposition not well established
 - SAOs “do the job”
- Loss of promotional focus

2010 MICPs:

- Re-establish Brand Growth
- Enhance Brand Messaging and Increase Unaided Awareness to 50%
- Execute Flawless SECURE Access Launch

Strategic Imperatives:

- Re-establish growth
- Focus on selling fundamentals
- Leverage burden of Illness data
- Efficient SECURE Access at launch

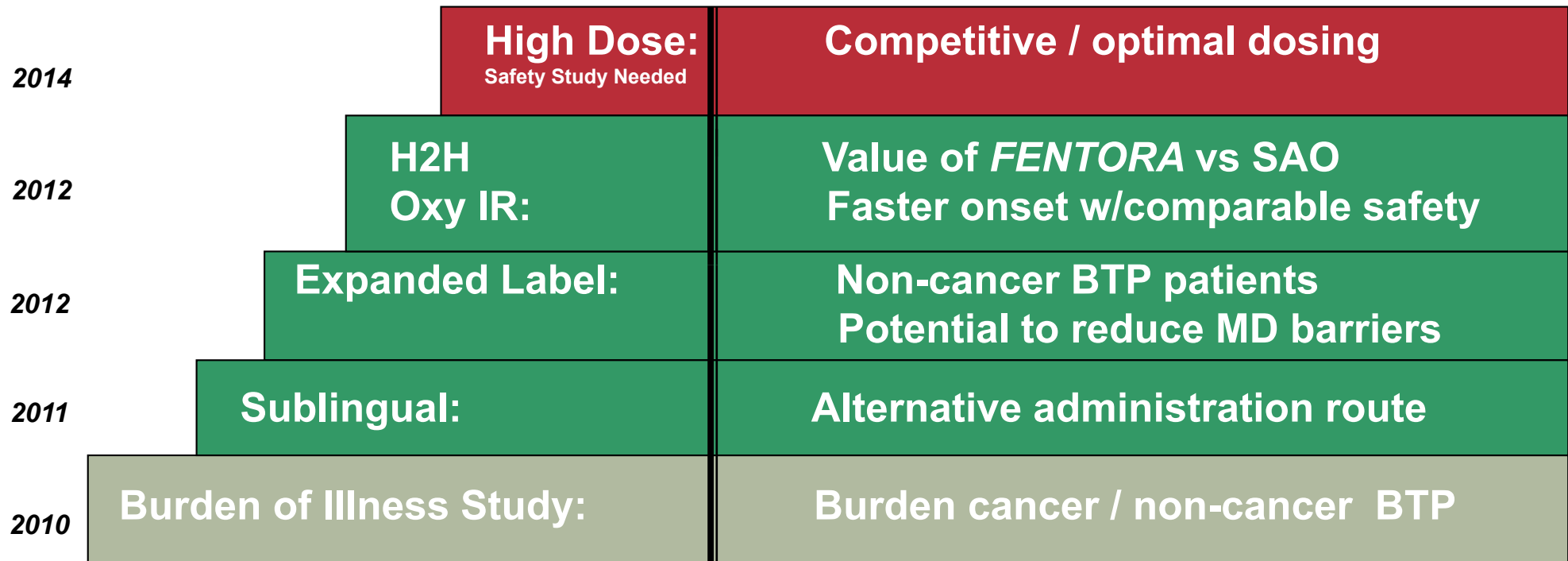
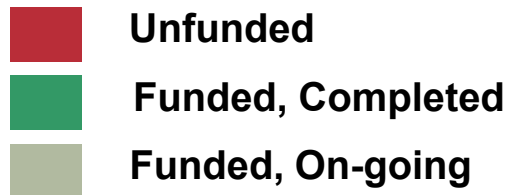
Approach:

- Focus on targets with consistent message
- Enhance representative knowledge & interaction
- Bridge the communication gap
- LCM / product enhancements

FENTORA Life Cycle Plan

- Objectives:**

- Optimizing *FENTORA* competitive profile
- Build the body of evidence to support *FENTORA*
- Remove barriers to prescribe *FENTORA*





Revised Promotional Budget in March 2010 (cont'd)

REMS launch delayed to October 2010

- Move \$1.9m of the \$3.6m REMS reduction into promotional spend
- This increases promotional spend from \$11.9m to \$13.8m
- The incremental spend is for programs to help us exceed the current revenue target of \$175m and achieve \$200m
 - eDetail with call center to recruit targets \$425,000
 - Non-personal promotional program designed to remind called-on HCPs and writers of the benefits of *FENTORA* to raise unaided awareness
 - Analogs indicate a return of 10,345 incremental TRx
 - Clinical Connect Program \$550,000
 - Rep support program with rep-triggered customized information sent to called-on HCPs to keep *FENTORA* top of mind between details
 - Analogs indicate a return of 3,400 incremental TRx
 - Allied Health Program (pilot) \$800,000
 - Peer-to-peer education with influencers of treatment decisions to educate on BTCP and benefits of *FENTORA*
 - TeleDetail Program with patient assistance card (pilot) \$150,000
 - Full promotional detail given over the phone to target called-on HCPs and writers to supplement sales force efforts; HCPs detailed receive a patient assistance card
- All programs will be tracked and monitored closely for success
- Additional \$1.9m to generate \$25m in sales

Summary

- Revised budget requires less than \$20m originally requested
- Revised Budget Breakdown of \$20m:
 - PR spend ~\$1.2m
 - Promotional spend ~\$13.8m
 - REMS spend ~\$3.2m (any unspent is available for give back)
 - Give Back \$1.8m
- Additional programs are designed to support sales force efforts as well as reach beyond rep called-on *FENTORA* writers for increased detail frequency
- The additional \$1.9m in spend will generate \$25m in sales
- Revised Budget Breakdown:

Nov 2009	Total	Q1 2010	Q2 2010	Q3 2010	Q4 2010
Promo	\$11.9m	\$3.9m	\$2.9m	\$2.4m	\$2.7m
REMS	\$ 6.8m	\$1.3m	\$2.5m	\$1.4m	\$1.6m

Mar 2010	Total	Q1 2010	Q2 2010	Q3 2010	Q4 2010
Promo	\$13.8m	\$3.3m	\$4.5m	\$3.5m	\$2.5m
REMS	\$ 3.2m	\$0m	\$0m	\$1.5m	\$1.7m

FENTORA eDetail

2 Wave eDetail

- Audience:
 - Primary Target: *FENTORA* Prescribers deciles 2-10, PS Nurses, ONC Nurses
 - Secondary Target: SAO Prescribers deciles 8-10
- Key Message:
 - Prove burden of BTCP; Show rapid onset/ideal offset to match the episode; minimal impact between flares
- Execution:
 - Wave 1: PK Q&A - Participant question response/answer data presentation, & peer comparison
 - Understanding BTCP, the importance of treatment, *FENTORA* PK core data
 - Wave 2: Know the BTCP Patient- KOL moderated, audio/visual patient case study, participant guides, treatment functionality
 - Identifying BTCP, recognizing suboptimal treatment, realizing the *FENTORA* patient
 - Opt-out communication approval to serve as recruitment for future professional programs (REMS)
 - Re-purpose at convention kiosk, *FENTORA.com*, and CSPs
- Recruitment:
 - Email, rep delivered invitation, call center
- Timing:
 - Wave 1: June 2010
 - Wave 2: August 2010
- Cost: \$425K
 - Pay per completion

FENTORA eDetail

2 Wave eDetail estimated contribution to stretch goal

2008 Euro eDetail program as benchmark:

- Specialty market, generic presence, 4 competitive brands
- 2 Waves, ~7 minute completion time per wave
- 6,000 Targets recruited; 3,312 enrolled (55%); 2,369 completed 1 wave (39%), 1,638 completed 2 waves (**27%**)
 - Recruitment channels: paid call center, 6 wave email, 2 rep invites
- Twins Methodology ROI assessment:
 - Average 7% increased TRx/Target completing 1 wave, **12%** increased TRx/Target completing 2 waves
 - ROI 4.2:1, net incremental revenue \$897K

Potential incremental *FENTORA* Rx:

- 27% of 4070 current prescribing targets yields 1099 prescribers completing 2 waves
- Current prescribers average 15 TRx, so 12% increase is 1.8 TRx increase per prescriber
 - We assume majority of scripts from 1,099 completing prescribers come in month of wave launch with diminishing activity following the launch month, but still monthly refill through end of year:
 - June- 50%: 550 (50%) prescribers writing 1.8 Rx recurring 7 times yields 6,930 Rx
 - July- 10%: 110 (10%) prescribers writing 1.8 Rx recurring 6 times yields 1,188 Rx
 - August- 30%: 330 (30%) prescribers writing 1.8 Rx recurring 5 times yields 2,970 Rx
 - September- 10%: 110 (10%) prescribers writing 1.8 Rx recurring 4 times yields 792 Rx
- **Yields 11,880 incremental TRx June-December 2010**
- Goal is 10,345 incremental Rxs in 2010 to get to \$200m



FENTORA Clinical Connect Rep Support Program

Cephalon Clinical Connect

- Audience:
 - Called upon prescribers
- Key Message:
 - Clinical evidence supports *FENTORA* as the optimal treatment for BTCP
 - Natural history data, rapid onset, ideal offset, minimal impact between flares, patient financial support
- Execution:
 - Rep triggered call report topic indicator, automated personalized email delivered as follow up from Cephalon Medical/Clinical Affairs
 - Foundation of future professional programs via prescriber driven email communication stream
 - Potential for virtual “conversation” between rep visits
- Recruitment:
 - Rep triggered via call reporting
- Timing:
 - July 2010
- Cost: \$550K

FENTORA Clinical Connect Rep Support Program

Cephalon Clinical Connect estimated contribution to stretch goal

2009 Euro identical program as benchmark:

- Specialty market, generic presence, 5 competitive brands
- 13,000 Call targets; 2,730 participating prescribers (21%)
- Rep triggered via sales reporting system link to fulfillment database
- Twins Methodology ROI assessment:
 - Average 14% increased TRx/Target
 - ROI 6.5:1

Potential incremental Rx:

- 1,320 recommended prescribing targets (per targeting recommendation)
- @21% rate (277 targets) and increasing TRx 14% (current average prescriber = 15 TRx x 14% = 2.1 TRx)
- **Yields 3,490 incremental TRx July-December 2010**
- Goal is 10,345 incremental Rx in 2010 to get to \$200m

Allied Health* Speaker Programs

- This NP and Nurse pilot program is intended to provide education to an audience of their peers
- Create an Allied Health (NP's & Nurses) Speaker Bureau & CSP program. At the end of these programs allied health professionals will have a greater understanding and applicable knowledge around:
 - Evaluation of BTCP
 - Patient communication/education about BTCP
 - Appropriate treatment regimens for BTCP
- Market research qualitative insights highlight the role of the Oncology Nurse as a key influencer to address the unmet need
 - The Oncology Nurse is best positioned to spot the signs of BTCP
 - Patients spend the majority of their time (visits, treatment) in the company of the nurse – “95%”
 - The Oncology nurse tends to have a much broader vocabulary as it relates to pain compared to physicians, and can pick up on patient concerns
 - The Oncologist respects and is open to recommendations from the Oncology Nurse as relates to patient care, including pain management
 - The oncology nurse can be the trigger or “nudge” for alternate treatment options and/or referrals

* Allied Health Professional refers to ONC NP's, Nurses & NP/Nurses from Pain Specialty practices

Marketplace environment: Report from Datamonitor illustrates the unmet need related to BTCP management

- Market dynamics

- Incidence of cancer to (including breakthrough)
 - Pain assessment should location, severity, precise treatments and side effects
- Rx treatment of cancer pain is suboptimal due to underreporting of pain by patients, inadequate pain assessment, concern for opioid analgesics and awareness of breadth of Rx options (including ROOs)

- Stakeholder perceptions

- Rx treatment of cancer pain is suboptimal due to underreporting of pain by patients, inadequate pain assessment, concern for opioid analgesics and awareness of breadth of Rx options (including ROOs)
- Opioid addiction in cancer pain patients much less of a concern

- Unmet Needs

- Physician education on pain assessment & availability / appropriate use of opioid analgesics
- Guidelines to support (around)
- Opinion Leader endorsement

- Recommendations

- Pain Team involvement / referrals
- Emphasis of medication side effects (impact on QOL; patient ability to function)
- Support identification of appropriate patients (including those w/ BTP) for specific Rx therapy for cancer pain

Pain Team involvement / referrals

Support identification of appropriate patients (including those w/ BTP) for specific Rx therapy for cancer pain



TeleDetail

- Will get from CC

REMS Budget November 2009 vs. March 2010

	Budget as of:	Budget as of:	Comments
REMS Projects	Nov-09	March-10	REMS timing changed from a Q1 10 launch to a possible 'enrollment only' launch in Q4 10
Market Research	\$200,000	\$120,000	REMS mandated research removed
Consultants	\$0	\$0	
Journal Reprints	\$100,000	\$0	No REMS journal reprints available
Convention	\$75,000	\$50,000	REMS convention sponsorships removed; remaining funds held for booth reconfiguration and panels
A&P	\$4,221,000	\$1,911,220	
Ad Agency Strategic Planning	\$175,000	\$123,750	Includes agency day to day staffing (\$61k) for projects & procurement reporting requirements, other staffing (\$61k) for creative/brand planning/MCO support
FENTORA REMS Personal Promotion	\$2,400,000	\$1,039,553	Includes updates to submission materials, updates to Actiq submission materials, additional enrollment and communication pieces, promo deck & CSP invitations updated, office staff materials, label change (Removed extra projects such as nurse in-service kit, spanish label/MG, managed care tools). NOTE: If BBW warning changes all pieces will need updating.
FENTORA REMS Non-Personal	\$1,621,000	\$731,250	PDR supplement for label change, web/online projects (Euro 4D), online outreach (Quantia/Epocrates)
Promo Mats Warehousing/Distr	\$25,000	\$16,667	Reduced to 2 quarters of REMS rep & patient/HCP materials housing
Vouchers/Debit Cards	\$0	\$0	N/A for REMS
Speaker Programs - CSPs	\$1,575,000	\$450,000	Q4 Rep and/or Marketing driven CSP programs for REMS enrollment
Medical Education	\$720,000	\$720,000	Live and WebX speaker training & potential prelaunch HCP ad board for communication materials & plan feedback
Corporate Contributions	\$0	\$0	N/A for REMS
Total Expenses	\$6,891,000	\$3,251,220	With REMS delayed, \$3.6M moved to promo budget for personal & NPP initiatives
Public Relations	\$1,200,000	\$1,200,000	\$1.2M Department Budget Transfer to PR - Does not factor into quarterly spend

Promo Budget November 2009 vs. March 2010

	Budget as of:	Budget as of:	Comments
Promotional Projects	Nov-09	March-10	REMS timing changed from a Q1 10 launch to a possible 'enrollment only' launch in Q4 10
Market Research	\$1,070,000	\$1,051,570	Post REMS launch feedback research removed
Consultants	\$0	\$0	
Journal Reprints	\$106,000	\$0	No journal reprints available (ex. Sublingual)
Convention	\$558,050	\$657,325	Slight increase due to nurse program roll-out at ONS & increased activities at Pain Week
A&P	\$4,061,000	\$6,105,000	
Ad Agency Strategic Planning	\$175,000	\$276,000	Includes agency (Euro) strategy support & travel plus interactive (Euro 4D) strategy support and travel
Ad Agency Staffing	\$0	\$660,000	Euro staffing
FENTORA Personal Promotion	\$2,300,000	\$2,882,000	Personal promotion includes agency projects, rep pieces
FENTORA Non-Personal	\$1,211,000	\$1,912,000	NPP includes journals, PDR, all eProjects; much of the REMS NPP spend was moved into promo NPP stretch programs (eDetail, Clin Connect, Teledetail) spend to keep up SOV/awareness leading up to REMS & to support sales force efforts
Promo Mats Warehousing/Distr	\$375,000	\$375,000	
Vouchers/Debit Cards	\$3,200,000	\$2,200,000	Vouchers were reduced based on field input and low 2009 utilization
Speaker Programs - CSPs	\$2,625,000	\$3,375,000	REMS CSP money was moved into promo CSP to support sales efforts leading up to REMS launch with CSPs, the nurse speaker program, & the A/A/D program
Medical Education	\$305,000	\$419,675	Med Ed includes slides, meeting logistics etc. for speaker trainings & ad boards; increase due to nurse program
Corporate Contributions	\$5,000	\$0	HCP association contributions
Total Expenses	\$11,930,050	\$13,808,570	With REMS delayed, incremental spend added to for NPP stretch programs, Nurse program, A/A/D programs & CSPs
Public Relations	\$1,200,000	\$1,200,000	\$1.2M Department Budget Transfer to PR - Does not factor into quarterly spend