Purdue

Quarterly Report to the Board

July 15, 2008

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SALES & MARKETING



- Graph above depicts actual factory sales vs. forecast.
- YTD Factory Sales through June 2008 were **\$987,586,173**.
- YTD Factory Sales through June 2008 made up 38.99% of the annual forecast, and were 95.36% of first quarter forecast.



 Both factory sales and prescriptions have seen a sharp increase since generic production ended earlier this year with factory sales since February 2008 outpacing prescription data each month as pharmacies and facilities restock their shelves with OxyContin.

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• Beginning with April 2008, we began purchasing additional DDD data from IMS for OxyContin for Nursing Homes, Nursing home pharmacies & providers. This new data is included in all 24 months of this chart.

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OxyContin versus Generics - On a 20 mg Equivalent Rx Basis

- Total Generics have experienced a sharp decline, whereas OxyContin grew significantly from January to June 2008. OxyContin eclipsed the sum of all generics beginning with March 2008.
- Total Oxycodone ER continues to increase at a respectable rate.

OxyContin Prescription Units (Millions of Tablets)



- OxyContin 10, 20, 40 and 80mg strengths continue to grow and are at Rx levels nearly 1.5 times what they were 18 months ago.
- OxyContin 20mg has captured the largest number of prescriptions of any strength since pregenerics. This could be a result of the launch of the new strengths and the drive towards more new patient starts.
- The new strengths of OxyContin are showing steady improvement since launch. OxyContin 30 and 60 mg are on almost identical trend lines, outpacing the 15mg.

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 OxyContin 30mg and 60mg strengths have been accepted into the market at a much faster pace than the 15mg.

MANUFACTURING & SUPPLY CHAIN

OxyContin

Primary Metrics

- Wilson produced 96% of the commercial needs of OxyContin for the domestic and exports markets with the remaining 4% produced at Totowa. Wilson had schedule adherence for OxyContin of 99.1% (112 of 113 batches) and 99.3% (156 of 157 batches) respectively in the Manufacturing and Packaging groups. Totowa obtained 100% schedule adherence in manufacturing while packaging obtained 80% schedule adherence.
- Distribution supported our revenue targets by shipping \$561.5 million of trade orders while maintaining orders shipped On Time and Complete at a rate of 99.8% (908 orders) and 100% (4964 order line items) respectively. Set a new record by packaging 37 export orders during the quarter in support of the international market.
- Vault utilization has increased with OxyContin increased inventory and the acquisition of the Dilaudid product line. Wilson vault capacity as of end of June was 96% utilized. Using the additional vault space in Totowa, our combined vault capacity between the two sites is 70.8% utilized. Will evaluate solutions to extend vault capacity for 2009 budget.
- During the 2nd quarter, three Oxy NF characterization batches were manufactured, 1 60mg strength and 2 – 80mg strengths. In the second quarter, 3,524 direct manufacturing labor hours were dedicated to new product/transfer activities. Clinical batches of OTR were also produced in Totowa during March to support the tech transfer from Wilson.
- Total Purdue inventory as of May, 2008 was \$43M, due to increased inventory of OxyContin raw materials, work in process, and finished goods as a result of the increased sales since January, 2008. Average Finished Goods OxyContin inventory is roughly 1.8 months of supply.

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MS Contin/Uniphyl

• Ten batches of MS Contin manufactured with 100% schedule adherence. No Uniphyl requirement this quarter.

Rhodes Pharmaceuticals

 Activities for Rhodes Pharmaceuticals products are moving forward. Oxy IR 15mg has been identified as the first product for the Wilson site. The blend formulation, tablet design, and indicia have been finalized. Tooling has been ordered.

Export Operations

- Plans are also in the works for handling Dilaudid exports to Purdue Canada and Mundipharma Australia.
- Eight OxyContin orders shipped to Latin America in the second quarter. Of the eight orders, 50% of them were rush orders due to backorders in the country. A meeting is being scheduled with the Miami office to evaluate how we can improve the in country inventory control and order process.

Louisville Distribution

• Louisville continues with excellent performance in the Distribution of our OTC products. The RF Project for Pick, Pack, and Ship has completed Blue Printing and Development. We are currently in the testing phase with a project "go live" date of August 2008.

<u>Dilaudid</u>

- Six Dilaudid batches were manufactured, 4 2mg strengths, 1 4mg strength, and 1 8mg strength. Three of the six batches were registration batches. Bottle packaging in support of stability studies was also completed. Modifications to the Lodige Mixer are being designed and will be implemented in 3Q 2008. Qualification of manufacturing equipment will be completed 4Q 2008.
- Effective as of the end of June, Purdue will have a direct relationship with Hospira for the supply of Dilaudid injectable products. Abbott has assigned the supply agreement they have with Hospira to Purdue.
- Abbott Second quarter activities peaked for the Dilaudid transition from Abbott. Monthly joint
 planning meetings took place with Abbott as well as many internal activities to support the new
 product integration into the Purdue systems. On target to meet the 1st week of July Dilaudid
 launch from Wilson and the end of September transition from Abbott trade dress to Purdue.

Compliance

- Totowa: A successful IMB (Irish Medicine Board) inspection occurred during the past quarter that resulted in only 5 minor observations. A General FDA Inspection covering all six quality systems also occurred this past quarter, yielding three minor 483 observations. Reponses for both inspections were prepared and forwarded to both regulatory agencies.
- Wilson: The facility received an inspection by the North Carolina Department of Agriculture and Consumer Services (Food and Drug Protection Division). No citations issued.
- Chilworth conducted a combustible dust audit at the Wilson site. Several good practices were noted (eg. equipment grounding and housekeeping). Areas of improvement were noted and an official report is pending.

Facilities and Infrastructure

<u>Totowa</u>

• The Garret Mt. / Totowa relocation project continued this past quarter with the completion of the internal facility moves, issuance of the construction contracts, completion of the asbestos

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remediation, completion of the demolition work, and commencement of construction. The project is proceeding on-time and on budget. Staff transfers in Q3 2008.

• A number of calibration, maintenance, and facility / equipment enhancement projects have been scheduled for execution and completion during this year's annual shutdown.

Wilson

- The 60 Cubic Foot GEMCO Blender Upgrade project was to replace the seals and sanitary agitator assembly to a simplified design that will result in less change parts. It accomplished faster disassembly, cleaning and reassembly time. It was also aimed at dissipating heat build up during extended blending of OTR. The blender was modified and tested in June. Overall, the project is on schedule and within budget. The current schedule is to complete installation and qualification in 4Q 2008. Process validation completion is planned for 2Q 2009.
- Pilot Plant Coating Pan Project Factory Acceptance Testing for the Compu-Lab 24 was completed in April. The 24 inch tablet coating pan was delivered in May. Facility modifications (electrical requirements and dust collector changes) were completed in June. Equipment qualification is scheduled for 3Q 2008.
- Incoming RFID Gen2 project was to install equipment in the warehouse for third party incoming RFID labeled bottles. An FAT (factory acceptance test) was completed in April 2008. The equipment installation and qualification was completed in May.
- Fuel Oil Storage Project Proposals will be solicited for the design of approximately (2) 30,000 gallon tanks for diesel fuel to be used in the generator and boilers. Plans are to locate the tanks underground.

Logistics (3rd Party) - Contract Manufacturing & Packaging

- Anderson Packaging Second quarter marked the successful completion of packaging and release
 of Colace 100mg 10ct blisters and the packaging of Colace 100mg 2ct samples. OTR blister stability
 work was executed for the 10mg 40mg and the 80mg. We are also currently working with them
 on three new packaging projects on our horizon: Slow-Mag 60ct, Slow-Mag 2ct pouches, and
 Senokot Chewable Tablets (from Modi).
- Canadian Senokot Project Analytical and Regulatory path is identified and moving forward.
 Detailed project planning meeting scheduled for 7/29 with US and Canadian teams.
- Delpharm With the contract expiring January 2009 work is continuing to switch supply sources from Delpharm to Time Cap Labs.
- Thatcher Pharmaceutical Supply agreement amended for 1 year (new expiry July 2009). We received RFQ's from both Xttrium and Aplicare, both of which were unfavorable. Thatcher remains a very competitive supplier for this product line. We anticipate a price increase in July.
- Time Cap Labs Project team is on-going to support Time Caps Labs supplying a slow release magnesium product to replace Slow Mag currently supplied by Delpharm. Current project timeline has manufacturing beginning in October 2008.
- Wellspring Scheduling delays and a multitude of changes in Wellspring's packaging schedules have resulted since Purdue made their case count changes, inner pack changes, and new artwork implementation.

DEA Manufacturing/Procurement Quota Status

- Oxycodone: The 2008 Procurement Quota for Oxycodone is 19,518 kgs (hcl) YTD which includes an allocation of 982 kgs to manufacture multiple product development projects. This represents 70% of the API Purchasing Plan of 27,923 kgs based on the current DIP. Actual sales will continue to be reviewed monthly and additional allocation requests submitted, in order to reduce the gap between the existing quota and the API purchasing plan.
- Morphine: The 2008 Initial Commercial Quota for Morphine was issued at 2,292 kgs, all of which was purchased during the first two months. Watson's annual requirements from Purdue are

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approx. 3,100 kgs. Based on the actual sales for Jan-June, an allocation request will be made in July.

Hydromorphone: The 2008 Initial Procurement Quota for Hydromorphone was established at 125 kgs (hcl) to support the manufacture of TR Scale-up/Clinical and Validation batches. An additional 29 kgs was granted to support the Tech Transfer of Hydromorphone IR Tablets from Abbott to Wilson.

Supply Management Highlights

- Supplier Savings YTD PPV thru May was \$369K. This is due largely to our Morphine ordering from Mallinckrodt vs. Noramco. Other negotiated savings include:
 - 1. Completing negotiations on a three year contract for Polyox used in the OTR formulation. Negotiations position Purdue to save in excess of \$4.7 million during the 3 year term of the agreement.

QUALITY

Compliance Status

- Each of the PPLP sites continues to have a favorable compliance status resulting in no significant observations from regulatory inspections.
- The CQA 2008 compliance program (internal and external vendor audits) continues to be effective in identifying and correcting compliance gaps in the areas of GMP, GCP, GLP, and Information Systems. There were no critical observations for audits conducted in 2Q2008, and corrective action plans are in place for all audit observations.
- It is anticipated that the Stamford Drug Safety department will have a regular biennial FDA inspection sometime in the next six months. All corrective actions from the 2006 inspection have been completed and verified. Work continues on improving the timeliness of Adverse Event reporting from the associated companies.

FDA 483 Commitments

- Wilson All commitments from the January 2007 ANVISA (Brazilian) inspection, and the verbal commitments made during the August 2007 FDA inspection are being addressed by Wilson personnel, tracked by CQA and will be independently verified by CQA.
- OTR NDA Commitments made in the November 2007 submission (stability and process controls) are identified, tracked and independently verified by CQA.

Commercial Product Complaints

- The systems for managing complaints and conducting investigations are currently under control. There is no trend in product complaints evident at this time, and no actions are required. The actual number of complaints is well within statistical expectations based on historical results since 2004.
- For OTC products, the number of complaints received per million tablets sold is stable in the area of 1 complaint received per million tablets sold through May 2008.
- For prescription products the ratio of complaints is comparable and low. The ratio of complaints to million tablets sold has dropped below 0.4 complaints per million of tablets sold for OxyContin, and approximately 0.6 complaints per million tablets sold for MSContin.
- Nine Dilaudid complaints have been investigated since December 2007. This number is consistent with historical information received from Abbott.

Wilson QA & QC

- Wilson Quality Assurance was reorganized to meet key challenges including increased production and development demands, and infrastructure for Wilson process improvement and project teams. Under a new program, two process improvement initiatives were launched in support of change management and development support.
- Laboratory qualification of new equipment and stability chambers is underway in the Quality Control area. This will result in increased capacity for stability and increased efficiencies in the laboratory for testing of product.

Cranbury Research Quality Assurance (RQA)

• The RQA Organization successfully prepared and led the Cranbury site through the OTR FDA Pre-Approval Inspection of the Analytical Sciences Operation. The Inspection was conducted on May 1-5, 2008, by FDA Investigator Paul Bellamy. Investigator Bellamy reviewed all critical analytical documentation related to the OTR 10-40 NDA submission, including Method Validation, Method Transfer, Stability Registration data, and Laboratory Investigations. He also reviewed all of the applicable GMP quality systems at the site. There were no 483 observations issued, and Investigator Bellamy stated that he would recommend approval of the OTR NDA. This was confirmed in the Establishment Inspection Report issued by Investigator Bellamy on May 14, 2008.

Totowa QA & QC

- The Totowa Quality Organization successfully led an EU Inspection by the Irish Medicines Board. The Inspection was conducted on April 7-11, 2008, by IMB Inspector Gerard Sheridan. At the close-out meeting, Inspector Sheridan stated that he was impressed with the knowledge of the individuals he interacted with; that the Totowa Site shows a strong commitment to GMPs; and that the site clearly meets high standards in the area of documentation, especially in the area of the thoroughness of investigations. There were only two minor observations that were directly related to GMP operations at the site. Inspector Sheridan recommended the Totowa facility be certified as GMP compliant by the Irish Medicines Board.
- The Totowa Quality Organization also led the site through a two week unplanned general GMP Inspection of the facility by the FDA. This inspection was conducted on May 5 -16, 2008, by FDA Investigator Karen D'Orazio. This inspection was extensive due to the fact that Investigator D'Orazio was being certified to perform international GMP audits. The Investigator stated that the reason the inspection was so extensive was that it was very difficult to find deficiencies. The Inspector issued a total of three 483 observations, none of which reflected any quality system deficiency but rather very specific areas within a system to improve upon.
- As a result of the recent Uniphyl Yield and Packaging Reconciliation investigations, the Totowa Quality Council, which includes Totowa site management, has initiated a comprehensive and aggressive action plan to improve and maintain procedural compliance at the site. The first step of the plan consists of a full review of all Master Formulas, Test Methods, and older SOPs to address any immediate risks for non-compliance to those procedures. The action plan will also address group training methodologies and the long term controls for the oversight, measurement, and continuous improvement of procedural compliance at the site. This action plan will not only improve the robustness of the site's Documentation and Training systems, but will also strengthen the foundation for sustainable procedural compliance at the Totowa facility.

Supplier Quality Assurance (SQA)

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• On May 26-30, 2008, Mundipharma GmbH was inspected by the FDA. The inspection was to complete a planned GMP PAI (Uniphyl) inspection of the facility. No significant 483s were issued, and the site was deemed approvable.

NON-CLINICAL DEVELOPMENT & TECHNICAL SERVICES

<u>Projects</u>

OxyContin Tamper Resistant (OTR)

- Successful FDA pre-approval inspection of Cranbury facility. No 483s.
- 60-80mg 10 and 120 counts, stability data through 12 months at RT meet acceptance criteria.
- 60-80mg documentation preparation for sNDA filing completed.
- 10-40mg validation batches manufactured and tested. All validation data passed acceptance criteria.
- Additional testing performed by QC indicated potential for segregation that is being investigated as part of the 60/80mg pre-validation and by external consultants Jenike & Johanson and Servolift. Validation of the 10-80mg strengths is being conducted at Wilson plant between June and November 2008 and is not expected to affect OTR launch.
- Tech Transfer of OTR process to Totowa has clinical supplies for the bio batches (10, 40 and 80 mg) released and available to the clinic by 7/31/08. Stability requirements are revised based on the FDA's response to the SPA document. Six additional batches (2x10 mg, 2 x40 mg and 2 x80 mg) will be manufactured and on stability by end of 3Q08.
- Scientific and logistical support was provided to Taylor Technologies Inc during an FDA audit of OTR bio-analytical data generated at their facility in Princeton, NJ. A nonclinical safety assessment was completed for a Noryl contaminant in OTR

Hydrocodone Q24h Tamper Resistant (HYD)

- Bi-layer tablets, coated tablets and pre-granulation of active evaluated in addition to standard TR tablets, as a means of increasing the probability of achieving a release profile meeting the requirements of the PPLP hydrocodone Q24h patent.
- Analytical methods established for monitoring dissolution profile, assay and degradation product for experimental stability. Preliminary experimental stability studies initiated
- Import/export permits were completed to complete procurement of 5 kg of Active Pharmaceutical Ingredient for the planned toxicology studies. Timelines for conduct of the reproductive toxicology and safety pharmacology studies at CRL Montreal and at MPI were finalized.

<u>BuTrans</u>

- Packaging, testing and release of Campaign 2 supplies for BUP 3025 (OA trial) completed by target date of June 12.
- Orders placed and documentation prepared for manufacture and packaging of supplies for BUP 3027 (additional strengths). This was the first clinical manufacture and packaging program which utilized the ordering system developed from the Continuous Improvement initiative
- Draft responses to the non-clinical biology items in the non-approvable letter were prepared for inclusion in the briefing document for the Sept 15 pre-NDA meeting at FDA.
- Draft responses for CMC items in the non-approvable letter were prepared for inclusion in the briefing document for the Sept 15 pre-NDA meeting at FDA.
- Draft TPP and letters of agreement have been developed for 2nd generation BTDS

BTDS (Japan)

• To meet the Oct 2008 submission date, revised drafts of CTD Modules 2.4 and 2.6 for the pending J-NDA submission were completed and circulated for internal technical review and for review by Mundipharma KK consultants. These modules will complete end of July 2008. Documentation and logistics to support QA of the nonclinical CTD sections was provided to Mundipharma KK.

Hydromorphone Tamper Resistant (HTR)

- The studies being conducted to determine if addition of BHT gives a more stable product remain inconclusive after 6 months. The data do not show a meaningful difference between tablets with and without BHT, but the values obtained continue to be significantly lower than those obtained from previous stability batches.
- Formulation will commence 3Q08. The methods to control release rate being evaluated for hydrocodone Q24h will be applicable to hydromorphone Q24h.

Oxycodone/Naloxone (OXN)

- Manufacturing processes and analytical methods have been evaluated and sections of the Due Diligence report completed.
- Two OXN bio-analytical reports for Europe were reviewed and finalized.
- The in-life part of the pharmacokinetic study in monkeys was completed. Analysis of plasma sample and dosing solutions was coordinated with qualified CROs
- The non-clinical section of a draft letter to the FDA requesting a pre-IND meeting was completed.

POA (V113741)

- The study report for the tissue distribution study in monkeys (POA-P-032) was finalized.
- The in-life phase of an acute and 7-day repeat dosing mouse study was completed.
- Protocols for a 4-week mouse study and non-pregnant rabbit and rat dose-range-finding studies were completed for initiation in Q3 2008.

Modi-Mundipharma

- The decision was made not to undertake preliminary clinical trials of the Q24h morphine product in India following the non-approval of the proposed protocol by the advisory board at the clinical facility. A development report will be prepared for use by Rhodes Pharmaceuticals.
- Senokot Pediatric Chewable formulation development is complete and stability data is acceptable for three batches after 6 months storage under accelerated conditions.
- Natural senna product will be monitored through stability while evaluation is on going for bringing Canadian Senokot to US.

Rhodes Pharmaceuticals

• Oxy IR reformulation to smaller tablet sizes complete. All but one strength are round, all are uncoated, white tablets. Tooling/indicia design and drawings completed.

Dilaudid

- Registration batches manufactured (2mg, 4mg, 8mg).
- Generated packaging records for registration stability.
- Registration stability packaging started 6/23.

<u>Uniphyl</u>

• CMC-RA submitted all the additional information requested by FDA for the Site Transfer supplement of Uniphyl 400 and 600 mg Tablets to Purdue Canada.

Colace Gel Capsules

 Process validation schedule for the 50 mg was moved to 4Q08 due to current business requirements. Confirmation batch for the 100 mg did not meet the stability criteria for appearance at accelerated conditions. Back up samples are currently being evaluated at intermediate conditions

Slow Mag

 Technology transfer assessment of Slow Magnesium Tablets from DelPharm, France to TimeCaps, NY was completed. Manufacture of PV batches and qualification of the packaging process are on schedule to support product launch on 1Q09.

DHE Mundipharma Research Ltd. (UK)

Protocols for genotoxicity and repeat dose toxicology studies were provided to the CRO.
 Requirements for API characterization were transmitted to the analytical laboratory, and the protocol for the in vitro metabolism study in different species was reviewed and finalized

Non-Project

• The patent on the use of polycaprolactone in tamper-resistant controlled release products has been prepared, and is scheduled to be filed during the week of 23 June.

PROJECT MANAGEMENT

Package Design & Development

OxyContin® Tamper Resistant

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• A successful line trial was executed utilizing a new outsert to accommodate pending labeling requirements from FDA. This will accommodate a significantly larger outsert (up to twice as much copy as the current OxyContin outsert + Patient PI), and the addition of three patient medication guides per bottle.

<u>RFID</u>

- In bound RFID project was completed at the Wilson NC site. The first RFID-tagged lots of OxyContin from Totowa were received in Wilson with no performance issues.
- New label test copy was received from both Nosco and Challenge Printing to test their digital printing capabilities (short run Latin American requirements). They are also being evaluated as RFID back-up suppliers with the ability to supply a redundant 2D data matrix barcode that would contain redundant serialization of the RFID tag data.

Dilaudid®

- The following activities have been completed during the second quarter in support of the transition to the 7/1 Supply Period stipulated in the agreement with Abbott:
 - 1. Notification sent to all Wholesalers and direct customers notifying them of the supply transition and order placement requirements to Purdue effective 7/1.
 - 2. GPO and federal contract amendments have been finalized. LTC customers have also been surveyed, with only 44% response rates based on current Abbott customers. Non-responders are being pursued.
 - 3. SAP and other satellite IT systems updated to accommodate the Dilaudid brand.
 - 4. Inventory transferred from Abbott-Chicago to the Purdue Wilson NC facility to begin shipments to customers 7/1.
- Wilson Manufacturing completed all development tech transfer activities and has manufactured/packaged all 2mg, 4mg, and 8mg registration batches. Commencing stability studies.
- Finalized all Purdue labeling to implement at the Abbott Whippany, NJ site and Hospira McPherson, KS site. Product to be labeled with Purdue name/NDCs beginning in July. Transition from Abbott trade dress to Purdue trade dress will take effect with shipments to wholesalers September 29th 2008.
- Tech transferred all on-going injectable stability studies from Abbott-Chicago to Hospira.
 Coordinated activities with Purdue Canada and Australia to consolidate study activities to reduce overall costs.
- Initiated qualification requirements to support Noramco API qualification for the oral liquid product.
- All Purdue artwork, updated per FDA discipline review letter, and specifications have been approved for introduction in Q3.

Product Assessment Group

• A complete clinical, non-clinical, regulatory, marketing and financial assessment was completed to evaluate Durect's Eladur[™] bupivacaine patch. Medical Research and non-clinical biology also developed a global development approach that included IAC input.

ALLIANCE MANAGEMENT

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<u>Labopharm</u>

- Labopharm received a response from the FDA Regarding the Formal Dispute Resolution on Tramadol Contramid OAD on June 29th
 - 1. The FDA did not over turn the appeal, and Labopharm submitted its complete response to the Review division and is awaiting an action letter (timing range 2-6 months). Work continues on an agreement regarding sharing of costs for patent defense litigation.

DISCOVERY RESEARCH

CLINICAL RESEARCH & DEVELOPMENT

Project

BTDS US Submission - US

- Significant progress continues towards completing activities for NDA submission in 2 to 3Q2009
- Pre-NDA meeting with FDA is scheduled for September 15, 2008
- Briefing package and meeting preparation is ongoing
- Non-Clinical, CM&C, Risk Management and Supply Chain activities are progressing and off the critical path

Pivotal Study Update

- #1 BUP3015 (Completed, positive study); e-published study completed Tuesday, April 1st 2008
- #2 BUP3024 (Ongoing, enrollment completed); all major study milestones are ahead of plan, LPLV scheduled for end of July 2008
- #3 BUP3025 (Ongoing, back-up pivotal study); actively enrolling, enrollment rates have improved with current enrollment at 58%; recruitment vendor has initiated a central advertising campaign

BTDS / BuTrans Ex-US

Support ongoing to Mundipharma K.K. in support of October J-NDA submission in Japan

HTR Project (Palladone Reformulation)

- Stability experiments have not shown hydromorphone N-oxide (HNO) formation at the higher rate seen previously under control conditions. Therefore assessment of measures to reduce HNO formation cannot yet be made. Additional stability test results will be obtained in 3Q08.
- Synergies with formulation development for once-daily hydrocodone (HYD program) may allow identification of possible TR-based formulation changes for HTR.

Palladone® NDA Phase IV Commitment

• HMP4009 Pediatric PK study enrollment at 84, with 54 subjects dosed of a planned total of 100

HYD Project (Once-Daily Hydrocodone TR)

- HYD Target Product Profile approved by the R&D Operating Committee.
- HYD Formulation development efforts underway focusing on monolithic and dual layer TR platform variants.
- Detailed study plans for Phase 1 and Phase 3 under discussion. Product Development Plan approval slated for 3Q08, with possible start of
- pilot pharmacokinetic study in 1Q09.
- 'End of Phase 2' meeting with FDA anticipated 3Q09

OXY/OTR/OXN

OxyContin-NF OTR

- NDA action letter delayed in new FDA NDA review process
- Responses in preparation for various outcomes of FDA Advisory Committee meeting
- Acceptable outcomes of FDA inspections of Taylor Labs, Cranbury, and Totowa
- sNDA poised for submission to FDA once NDA is approved
- Tech transfer supplies made available and clinical study site initiations conducted
- Blister packaging now on stability
- Isolated, acute noryl contamination of granulate investigated with uneventful outcomes
- Re-manufacture and re-validation planned without disruption of anticipated Q1'09 launch
- Initial portion of internet 'chatter' monitoring completed and internet survey now in progress
- Long-term epidemiology protocol revised in response to Advisory Committee

<u>OXN</u>

- Internal due diligence completed and report issued
- Meeting request submitted to FDA; anticipate 3-4Q08 meeting date

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- FDA pre-meeting package and IND, including Investigators Brochure and protocol, in preparation
- "Accelerated" and "traditional" development programs planned for discussion with FDA meeting
- Options in development for abuse deterrence testing from in vitro to animal and human studies

OxyContin and other oxycodone

- Revised RiskMAP submitted to FDA
- Four Clinical Study Reports of legacy studies submitted to FDA
- Pediatric exclusivity clinical program being planned
- Noramco API being qualified as a backup

<u>POA</u>

First-in-man experiment (POA1001) began dosing in May 2008. To date, 4 cohorts have been dosed including 24 subjects. Dose levels studied to date include 1, 3, 10 and 30 mg. Pharmacokinetic analyses of the first three cohorts reveal linear kinetics.

Non-Project

Clinical Systems

Implemented version 2 of the Medical Research Repository. The repository is the single system
used to collect and manage all documents generated in the planning, execution and reporting
stages of our clinical studies. This improvement will increase operating efficiency by enhancing
the CRO's ability to search and access stored project data

Document Management

 Trained all personnel and implemented the process for the management of all hard-copy study documents created by Medical Research personnel (a function previously handled by Regulatory Clinical Archives)

CRO Strategic Collaboration

• In collaboration with our colleagues in Clinical Supplies, we initiated a pilot of the new Clinical Supplies ordering process utilizing BUP3027 (BuTrans High-Dose Efficacy Study) as a test case.

RISK MANAGEMENT & HEALTH POLICY

Health Policy

Meetings & Presentations:

- PhRMA: Meeting to discuss the diversion and abuse of prescription medicines with Sharon Brigner MS, RN, Deputy Vice President, Affordability & Access, PhRMA in Washington, DC on April 1, 2008.
- Presented on behalf of Purdue Pharma L.P. at the FDA Advisory Committee Bethesda, MD on May 5, 2008.
- Presented a poster titled: Diffusion of Tamper-Resistant Prescription Pad Usage Among Opioid Analgesic Prescribers in the U.S.: 2001-2005 at 2008 American Pain Society (APS) Annual Scientific Meeting in Tampa, FL on May 8 - 10, 2008.
- Presented two presentations to the Invitation-Only Executive Task Force at the Institute for International Research Drug Safety and Risk Management (IIR) in National -Harbor, Maryland on May 22, 2008:
 - 1. A Case Study on Drugs Containing a Controlled Substance: Real-Life Pharmaceutical Risk Management-The OxyContin[®] Story.

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- 2. Balancing the Benefit/Risk Ratio: Considerations Regarding Abuse Liability.
- Presented The Assessment and Management of Chronic Pain with an Emphasis on the Appropriate Use of Opioid Analgesic at the Tufts University, Master of Science Program course in Pain in Boston, MA on April 25, 2008.
- Presented a poster titled: Prescription forgery of OxyContin[®] Tablets in the USA for the College on Problems of Drug Dependence 70th Annual Scientific meeting in San Juan, Puerto Rico on June 15 -19, 2008.
- Presented *The Role of Urine Drug and other Biofluid Assays in Pain Management* presentation at the Tufts Health Care Institute's program (THCI) on Opioid Risk Management in Boston, MA on June 26 - 27, 2008.

Risk Management

Supported NDA Filing of OxyContin® (New Formulation)

- Prepared slides and background briefing materials for FDA Advisory Committee Meeting for OTR.
- Prepared OTR RiskMAP.
- Submitted manuscript on study assessing the validity of self-reported abuse of OxyContin[®] to <u>Addiction</u>.
- Revised Protocol OTR9001 ("Long-term epidemiology study") in response to comments from Advisory Committee; revisions approved by Protocol Review Committee.
- Prepared response to FDA Office of Epidemiology and Surveillance's questions concerning the OTR RiskMAP.

Supported Continued Marketing of OxyContin® (Original Formulation)

- Risk Management presented the following posters at the College on Problems of Drug Dependence 70th Annual Scientific meeting in San Juan, Puerto Rico on June 15 19, 2008:
 - 1. *Prescription forgery of OxyContin*[®] *Tablets in the USA*. Authors: Meredith Y. Smith, MPA, PhD; J. David Haddox, DDS, MD.
 - 2. Routes of nonmedical use/abuse of OxyContin[®] (Oxycodone HCI controlled-release tablets.) Author: Meredith Y. Smith, MPA, PhD.
 - 3. *Systems dynamics modeling as an approach to understanding the abuse and diversion of opioid analgesic products: Implications for risk management systems.* Authors: J.P. Fitzgerald; M. Y. Smith, MPA, PhD; A. T. Kline, MS; J. D. Haddox, DDS, MD.
 - 4. *The Abuse and Diversion of OxyContin*[®] (*Oxycodone HCI Controlled-Release*) *Tablets, October* 2005 *February* 2008. Authors: Ann T. Kline, MS; Melinda A. Philbrook; Meredith Y. Smith, MPA, PhD; J. David Haddox, DDS, MD.
- Attended RADARS[®] System Annual Meeting in Bethesda, MD on May 1, 2008.

Supported NDA Filing BuTrans[™]

- Developed BuTrans RiskMAP.
- Prepared Risk Management section of the Briefing Document for the September 15, 2008 BuTrans
 ™ meeting with the FDA.

Monitored Abuse and Diversion of PPLP Marketed Opioid Analgesics

- 890 Repots of Concern (ROCs) regarding abuse and diversion of PPLP marketed opioid analgesics reviewed and entered into the Risk Management DataMart for 2nd Quarter 2008.
- 25 field inquiries conducted in response to signals of abuse or diversion of OxyContin® as identified via review of ROCs, and RADARS® System data for 2nd Quarter 2008.

Healthcare Grants and Giving Review Committee

-	Total grant requests reviewed:	2Q08 =	144	YTD =	312
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•	Total approved (approval rate): Total amount funded (approval rate): (13%)	2000	=	45 (31%) \$290,285 (11%)	YTD YTD		104 (33%) \$982,326
:	In-kind Funding (monetary value): Approved Product Requests : \$5.050.37	2Q08	= 2Q08	\$138 = \$2,502.	YTD 72	= YTI	\$138 D =

Alliance Outreach

- Placed an article highlighting RxPatrol[®] in *National News* from National Association of Boards of Pharmacy. Expected reach: 146,000 state board members/pharmacists in 34 states from July – September.
- Collaborated with National Accounts in meeting with a major pharmacy chain and a regional wholesaler to outline two strategic pain and risk management education initiatives for pharmacists in the New York City market
 - Collaborated with professional associations to post or distribute Purdue educational resources:
 - 1. Milwaukee County Medical Association, Milwaukee, WI posted *Addressing Substance Abuse and Prevention* Order Form on the members' website.
 - 2. Tennessee Medical Association posted the *Addressing Substance Abuse and Prevention* Order Form on the Tennessee Prescription Drug Safety website.
 - 3. California Pharmacists Association
 - a. Electronic copy of the *Pharmacy Security Checklist* to 8,000 California pharmacists during National Pharmacy Week
 - b. Electronic copy of the May *RxPATROL Fact Sheet* to 8,000 California pharmacists
 - 4. Florida Pharmacy Association 1,800 copies for annual meeting attendees
 - 5. Tennessee Pharmacy Association 900 copies for annual meeting attendees

Strategic Education

Coordinated the development and production of *Pain Partnership and Care Today*TM (*PACT*), a comprehensive education initiative designed to assist healthcare professionals who provide education for staff in the long-term care setting.

Library & Information Services

- Aggregated Rhodes and Cranbury licenses to SciFinder from Chemical Abstracts Service. This single agreement enables us to control costs, increase value, deliver significantly more content and provide predictable and stable pricing. This builds on the \$17,000 savings we realized earlier this year with Crossfire Beilstein.
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Redacted

 Initiated coverage of buprenorphine in the PharmaSearch database to support research efforts and preparation of the Integrated Summary of Safety.

REGULATORY AFFAIRS, DRUG SAFETY & PHARMACOVIGILANCE

Regulatory Affairs

<u>OTR</u>

On May 5, 2008 there was a Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee Meeting, which

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specifically discussed our OTR product. The Committee voted against adding in vitro tamper data to the Prescribing Information.

• FDA contacted Purdue to explain that the PDUFA date was not met due to the new review procedures instituted following enactment of FDAAA. Action letter was returned to the Review Division but needs to go back to the Office of Chief Counsel for further review.

BTDS Development Activities

- The IND Annual Report was submitted for BTDS on May 2, 2008. This submission was the first BTDS submission in eCTD format. Going forward, all submissions will be electronic and in this eCTD format.
- In response to our meeting request letter of April 23, 2008, FDA has granted us a meeting scheduled for September 15, 2008 to discuss our plans for the complete response to the not approvable action letter. Development of the briefing document for a submission prior to August 1, 2008 is well underway.

Labeling, Advertising & Communication

• On April 22 and 24, 2008, RAPL completed the labeling transition for all Abbott and Hospira component labeling needed for the summer 2008 launch of the Purdue labeling product.

Chemistry, Manufacturing and Controls

FDA Approvals

• Special Protocol Assessment to IND #29,038 for Totowa as alternate manufacturing site – FDA agreed with our protocol with the proviso that three registration batches of 10, 40 and 80 mg tablets are included in the supplemental application instead of our request for one batch per strength.

LA Approvals

- Restiva Argentina: Change in Package Insert approved by ANMAT 30 May.
- OxyContin Renewal for Chile: Product licenses renewed for 5 years; 30 April (20 & 40 mg), 19 May (10 mg).
- OxyContin Renewal for Uruguay: Renewal which includes change in licensor approved 15 April.

Regulatory Document Management

FDA Submissions

- During 2Q08 there were approximately 100 Submissions to the FDA including but not limited to 25 IND Safety Reports for buprenorphine, 8 Annual Reports as well as the PSUR for OxyContin. We also submitted 8 Protocol Amendments, 13 Study Reports [4 Clinical/9 Non Clinical] as well as numerous documents regarding the Advisory Committee Meeting for OTR.
- 40 Total eCTD submissions were processed and submitted to FDA

Regulatory Systems

• The full migration of content from the GRASP system to the upgrade G2 system is complete. 830,100 files (353.3 GB) were migrated to date. Migration updates from GRASP will occur on a scheduled basis until user accounts are transferred to G2. Production rollout is scheduled for completion by end-August. Migration of the Regulatory Affairs Database (RADB) to G2 is ongoing. RADB is the database housing the chronology of submissions to the health authorit(ies). eCTD submissions filed through the electronic gateway will be permanently archived into the G2 system

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Drug Safety and Pharmacovigilance

- DSP maintained approximately 99% YTD operational compliance in USA-origin expedited submissions to FDA for 1,902 total USA case report volume processed from 01 March 2008 30 June 2008, and a YTD total of 3,596 USA reports
- Managed and expedited submission (where required) of 1,996 safety reports from outside the USA (measured independently from YTD volume count above)
- In 2 Q 2008, 1,613 initial and follow-up telephone calls were handled by Product Monitoring. Of the 1,613 calls, 1,241 concerned adverse events (or reports of concern) and 372 calls were related to product complaints. Ninety nine per cent of the initial 164 product complaints received by Product Monitoring were processed on time in accordance with SOP.
- In this quarter there has been implementation of a new DSP validated Adverse Event Email Management system (SWIFT) to enhance tracking and management of electronic adverse event sources
- Proposals are being prepared for the purchase of software to data mine Drug Safety databases (both ARGUS and FDA AERS) and consequently enhance our ability to perform signal detection on Purdue products

LICENSING & BUSINESS DEVELOPMENT

Completed Projects

Abbott: Dilaudid (hydromorphone); completed Phase II U.S. 3/31/08

Late-stage Products In-Licensing

Continued evaluation and commercial discussions

- Durect: EladurTM (bupivacaine 3-day patch) and PosidurTM (bupivacaine long-acting injection)
- Hisamitsu: NDA OTC patch (1-day methyl salicylate)

Marketed Products - Acquisition Discussions

• Thermacare: P&G heat patch; terminated auction process

Due Diligence - Terminations at Late-Stage

ProEthic – diclofenac sachet for migraine

TR Technology

Cephalon – They declined a hydromorphone development project

HUMAN RESOUCES

Staffing Overview

• A total of 169 employees have been hired as of June 30, 2008. Turnover YTD is 2.0% compared to 3.2% as of June 30, 2007.

Growth

• The search for a President & General Manager continues for Rhodes Pharmaceuticals (the generic business) with a new search firm, modified job description and title change.

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- New Field District Managers received training on effective interviewing, sexual harassment, affirmative action verses diversity, and how to effectively deal with employee relation issues.
- All new supervisors and managers are offered, upon promotion, one-to-one training on the development of effective management skills.
- A recent New Hire Survey yielded a very high response rate of 86% and revealed that the majority of Purdue's new hires found the pre-employment and the new hire processes to be very effective. Key reasons for joining Purdue included compensation, Purdue's reputation as a good employer, alignment of the position to work interest, and professional development opportunities. Wilson, Rhodes and Cranbury new hires indicated that location was a major factor in their decision to join Purdue. Field Sales colleagues were not included in this survey although a customized Field Sales New Hire Survey is planned following the 2008 Sales Force expansion.
- A Performance Culture Survey is currently underway for all US, non-union employees. Results will be compared to survey results from top companies across the country to identify ways in which performance and retention activities can be optimized to assure Purdue's productivity and growth.

Productivity

 The SAP Human Capital Management implementation (PeopleSoft replacement) is on schedule for a go-live date of December 1, 2008, and will achieve its first major project milestone concluding the first week of July.

Compensation

- Enhancements to the Exempt Compensation Program for 2008 to expand the linkage between
 performance and compensation have been implemented along with changes to the Exempt Salary
 Structure. The Annual Bonus Program will include a portion of the payment based upon the
 attainment of Company objectives including Net Branded Sales, Operating Efficiency, Product
 Diversification and Compliance. The second portion will be based upon Individual Performance.
- The historic salary grade system has been replaced by a Broadband system, utilizing fewer levels
 which correspond to the more streamlined levels of management. This will result in fewer
 management level promotions, reducing salary growth over time and creating more meaningful
 promotional opportunities corresponding to significant job responsibility and accountability growth.
- The Long-Term Incentive Plan (LTIP) has been replaced by the Long-Term Results Plan (LTRP) for eligible management employees. The new program includes the same performance elements as the annual bonus program, creating a link between sustained Company performance and LTRP payments.
- Communication and training sessions were held to discuss these program changes. Following a presentation to the Vice Presidents, management level meetings were held to inform all affected employees, explain program components and respond to their questions.
- All promotional requests will now be reviewed by an HR Committee to ensure promotions meet the higher standards of the new program and recognize job expansion.

Employee Health & Safety

- Flammable liquid handling assessments have been completed at all sites; combustible dust handling reviews have started, with a recent review conducted at Wilson. Our goal is risk reduction, compliance assurance and a review of hazardous operations. Tracking and follow up steps have been set in place.
- The sites have experienced several successful regulatory inspections during the quarter. The New Jersey Department of Environmental Protection conducted a Stormwater Permit inspection in Totowa. This included a thorough review of the written Pollution Prevention Plan; monthly compliance inspections, training documentation, and annual reports filed with the state. All were found to be in good order and as a result, there were no adverse observations or issues identified. The Cranbury site was inspected by a member of the New Jersey Radiological Health Branch in June. The purpose of the visit was to inspect the X-Ray Diffraction Unit in the Analytics

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Department. This was also a very thorough inspection of the laboratory, equipment safety interlocks, training and personal dosimetry records. The inspection was successful and documented 100% Compliance. Notably, the Wilson site was awarded the City of Wilson Wastewater Pretreatment Program Gold Award for outstanding compliance during 2007. This award is given to significant industrial users of the City of Wilson wastewater pretreatment program who have outstanding compliance with their permit requirements. This is the ninth annual award received by Purdue Pharmaceuticals.

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Full-Time Turnover Projection March YTD 2008

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CORPORATE COMPLIANCE

Corporate Integrity Agreement

- By letter dated May 2nd we received confirmation that the OIG was satisfied with Purdue's Implementation Report, and confirmed that "it appears that Purdue has successfully implemented the initial requirements of its Corporate Integrity Agreement."
- By exchange of emails and telephone calls, OIG advised of agreement, based on information we provided, that Par employees involved with the Rhodes distribution arrangement are not covered by the Purdue CIA (similar to OIG's decision in Watson AG distributorship).
- In the second quarter, we completed an audit of the Medical Services department, one of the areas
 to be reviewed by Purdue's Independent Review Organization, Huron Consulting, with respect to
 the first Transactions Review of the CIA. No critical findings were found, and those issues raised
 are being successfully addressed by that department.
- Beginning in August, we will be hosting representatives of the IRO who will be on site conducting field work in connection with the First Transactions Review.

State Filings

- All required filings concerning sales and marketing expenditures on prescribers and others have been timely filed, for Minnesota (on 4/30), the State of Maine (on 6/27), and the District of Columbia (on 6/27).
- Pursuant to state law requirements, Purdue submitted to the Nevada State Board of Pharmacy information regarding Purdue's compliance with the PhRMA Code and other details regarding Purdue's compliance program (on 5/21).
- Pursuant to California state law, a timely certification of Purdue compliance program was posted to the Purdue internet (on 6/30)

No "Major Issues"

 Hotline and Other Inquiries - We investigated a total of 93 Hotline and other matters during the second quarter of 2008. None of these matters were of significant concern or indicative of compliance failures sufficient to warrant reporting to the Board or to applicable regulatory or other authorities.

FINANCE DEPARTMENT

Financial Performance

- Year-to-date June 30 net sales were \$823 million, almost double the sales for the same period last year and \$56 million or 6% under budget. The \$56 million under budget was primarily due to \$118 million lower trade inventory of OxyContin than budget (timing) offset by \$70 million higher OxyContin demand.
- Purdue ended Q2 with \$488 million of unrestricted cash plus \$82 million of restricted cash. This cash earns between 2% and 3% and is invested in US Treasury debt/US Agency debt and high grade commercial paper. The maturities of these investments are short, the credit quality is high and maturities are coordinated with our anticipated financial obligations.
- See also Purdue year-to-date June 2008 Financial Results published separately.

Banking

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- Purdue continues to provide Goldman Sachs with business, IP, financial and other data in support of a possible \$1 to \$2 billion financing to fund potential future acquisitions, make distributions or a mix of the two.
- As part of this process Purdue, Management Revisions and counsel evaluated moving from US GAAP to International Accounting Standards. After extensive research, training, etc. it was recommended and agreed that financial reporting continue under US GAAP.

Insurance Renewals

- Purdue's General Liability and Property Insurance policies renew in the third and fourth quarters, respectively. Market conditions remain soft and rate reductions are anticipated. However, with the return towards exclusivity, premium calculations will take into account business growth and will likely result in an increase in dollar premiums.
- Purdue planned to attempt to buy Product Liability insurance in Q2, based on OTR's features. This
 is now delayed since OTR's approval is on hold pending FDA feedback on the new formulation of
 OxyContin.

Authorized Generic / Settlement License Agreements

• We have engaged Deloitte Financial Advisory Services to conduct an audit of Watson's records to assure compliance with the October 2005 Distribution and Supply agreement and the related February 2007 Termination agreement. Deloitte is currently reviewing Watson records and an update will be provided as information becomes available.

OxyContin Patent License Agreements ("PLAs")

Accounts Receivable Status

- Accounts receivable collections remain strong with year-to-date DSO averaging less than 35 days, no invoices greater than 60 days and deductions less than \$3 million (or approximately 1.25% of open receivables. We currently have two accounts on watch:
- <u>HD Smith</u> is a middle tier wholesalers and a private company. In evaluating their credit against their peers, HD Smith has more debt (\$220 million outstanding on a \$275 million facility) and is less profitable. In mid-May Purdue changed its payment terms for this customer to 3% 14 net 15 EFT and by so doing we have dropped our average exposure to this customer from approximately \$10 million to approximately \$3.5 million. We are in regular contact with their CFO and will continue to adjust terms and their credit line as necessary.
- <u>Rite Aid</u> posted a loss of \$156 million in Q1 and affirmed guidance for full year of sales of \$27 billion and a loss of between \$260 and \$375 million (results reflect the integration of the Brooks Eckerd acquisition in June 2007). Rite Aid currently has a debt load of \$6 billion with \$240 million available on a \$1.75 billion revolver. Their stock price has decreased from approx \$6 to \$1.50 in the past year. We are monitoring the account closely and will implement restrictions if necessary. Our current credit limit is \$1 million.

Product Liability Insurance Proceeds

Purdue continues to submit claims (primarily for defense costs) under the 2nd excess layer policies of the Oxy Tower (127 million to 227 million layer) in which three insurers participate: Zurich (25%); Gerling (25%); and XL/Winterthur (50%). While Zurich and Gerling continue to pay their respective shares we have yet to collect from XL/Winterthur. Our legal team is exchanging letters

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with XL/Winterthur but, at the moment do not expect to collect their respective share of this layer for some time.

• Cumulatively, we have now collected approximately \$325 million under our \$1 billion product liability insurance tower.

Real Estate Taxes / Personal Property Taxes

• The City of Stamford revaluation of One Stamford Forum has resulted in the following increase in real estate tax:

From: \$1.8 million To: \$2.9 million

Of this increase 60% would be absorbed by UBS, but the remaining 40% (or \$440,000) would be absorbed by One Stamford Realty. Working with Greg Servididio of Pullman and Colmey, we filed an appeal with the City of Stamford on May 22nd. We expect a hearing later this year and we have been advised that an outcome would likely be through a settlement (possibly first half of 2009) or full litigation and trial which could take 2-3 years.

<u>Tax</u>

- The IRS audit of BR Holdings Associates L.P. began on April 28 and the Agent and Computer Audit Specialist have been at Purdue for a total of eight days. Five Information Document Requests have been completed and have been/will be submitted to the Agent. The Agent plans on being at Purdue the first and third weeks of July. So far, the audit has been limited to the 2004 tax year.
- The agent will be issuing an audit plan shortly which will preliminary indicate the areas that he plans to initially focus on. The agent will be bringing in an R&D tax credit engineer to review the R&D tax credit which was taken in 2004. The R&D tax credit position that Purdue took in its return was based on work performed by PricewaterhouseCoopers LLP. In addition, the Agent has verbally indicated that he may look at consultant and legal expenditures for 2004.
- The sales and use tax audit of Illinois went well and we are expecting a "no change" determination. The only other open audit at this time is Florida sales and use tax.

PROCUREMENT

2nd Quarter Accomplishment for Corporate Procurement

- Corporate procurement completed the printing and delivery of 525,000 revised \$60 patient co-pay savings cards. The cards, redesigned to include the revised brand graphics, were distributed to the sales force in time for a July program kickoff. These cards also feature a more efficient multi use format for the patient.
- Corporate Procurement and IT successful negotiations with Network Appliance on the purchase of new IT storage equipment for TSO Production Group resulted in a savings of \$479,947 or a 50% discount to Purdue.
- The Fleet Department negotiated with GM to arrange for one hundred 2009 Pontiac Vibes to be manufactured and available for the recent Sales Force expansion. Fleet was able to negotiate a price that was 6% below invoice or \$114, 000 in savings.
- Corporate Procurement selected a new Procurement card (AMEX) which provides a 1% rebate on spend and a \$500,000 incentive signing bonus.

INFORMATION TECHNOLOGY DEPARTMENT

Sales & Commercial Systems

Longitudinal Patient Data reports were created and distributed to the sales force during 2Q 2008. These reports highlight prescriber writing behaviors, showing the number of new and continuing prescriptions, as well as changes to or from a particular prescriber. Access to this data increases sales representative pre-call planning capability and aids marketing in developing unique messaging.

R&D Systems

- A Drug Safety Email Tracking system was developed, validated and deployed in May. The implementation closes an internal audit finding and provides oversight for the disposition of all emails received in the Drug Safety mailbox. The new system ensures a timely response to all emails by triggering an alert mechanism that notifies appropriate levels of management if an email is not assigned and triaged within the specified time period.
- The R&D Insight project was delivered in June. The new system centralizes study and submission related documents and provides enhanced search capabilities across four R&D disciplines: Project Management, Medical Research, Regulatory Affairs, and PKDM/NDSE. In addition, R&D Insight enhances access to source material, enables extensive cross-discipline analysis, shortens response time to FDA and litigation inquiries, and maximizes information sharing among fewer resources.
- The Drug Safety system upgrade is due Q1 2009 and the team is working to shorten delivery to Q4 2008. During Q2 2008 development was completed and validation is currently underway. The upgrade was undertaken to maintain compliance with regulatory requirements, including electronic submission, FDA and European regulations. The Drug Safety system upgrade is estimated to save ~\$635K per year.

Manufacturing & G & A Systems

- The Learning System project (LSO) went live in April, providing self-service training functionality to Totowa and Garret Mountain, in addition to employees already using the system in Wilson. New functionality enables users to view and train on controlled documents and procedures, thus enforcing greater compliance. Users now have greater visibility into regulatory training requirements associated with their job functions and can view in real-time their level of compliance.
- The Radio Frequency Identification (RFID) inbound solution was successfully rolled out in Wilson. This new step in the RFID program enables Purdue to receive and scan RFID-tagged product from third-party packagers and Totowa. The first batch of RFID-tagged product packaged outside of Wilson was successfully received.
- An off-shore vendor was selected for the PeopleSoft HR system migration to SAP. The team is conducting blue printing sessions with business owners to identify user requirements and map HR business processes to SAP. Project completion is scheduled for December of this year.

Continuous Improvement

• The FDA Submission Process Quality project will save approx \$200,000 to \$3.5 million by reducing FDA submission errors and rework. The project was initiated with members and sponsorship across all submission-related organizations. A "Submission Central" web-based portal was developed to provide submission-related reference materials and information.

- The Technology Transfer Process reengineering project reduced batch record approval from 15 days to 2 days and decreased by half the number of people reviewing related documentation in Wilson. The team developed a first draft of the Purdue tech transfer "Blue Book," which captures all tech transfer processes, tasks, roles, milestones, metrics, and SOPs. The project reduces tech transfer cycle times and ensures a single source of project visibility.
- The Clinical Supplies Delivery project accelerated new clinical supplies ordering by an average of six weeks. It reduced cycle time for new orders by two months, and finalized a new clinical supplies order form, process and role.

Legal Systems

 Legal IT Finance team (LIFT) efficiency initiative has saved is \$3.6 million through May. Savings are based on \$0.5 million in litigation support using in-house personnel, as well as \$0.9 million volume discount, early payment discount and billing guidelines enforcement.

IT Security & Architecture

 In Q2 2008 IT Security, HR, Legal and Corporate Security responded to a data breach incident brought to our attention by an external contact. The team quickly interviewed all parties involved and identified what information was exposed and who had access to it. IT Security engaged our External Security Partner, SMP, to determine where the data came from and how to change our procedure to ensure the incident is not repeated. Purdue is currently updating procedures and policies to enhance security around its handling of sensitive data.

Infrastructure

- Year-to-date the IT infrastructure has grown and as a result the IT datacenter will expand into the P1West area of 1 Stamford Forum by September 1st. Areas of growth include the following:
 - 1. Storage infrastructure increased by 44% to 387 TB
 - 2. Server infrastructure increased by 20% to 607 Intel Servers
 - 3. 238 new or upgraded client computers (desktops or laptops) were deployed this year
 - 4. 650 new computer accounts have been created to support Purdue FTE and Non-FTE growth
 - 5. Coventry phone system was replaced with a Cisco Voice over IP-based system in line with the new standard installed at 1600 Summer Street. This new installation will result in estimated cost savings of \$90,000 per year

RHODES

<u>Financial</u>

• YTD financial results are in line with budget.

Dronabinol Launch

• The Dronabinol ANDA was approved on Friday, June 27, 2008 and the product was launched. This is in line with our budget. The revised supply and distribution agreement with Par is finalized and all our goals were achieved.

Narcotic Raw Material (NRM) Registration

On Friday June 20th the DEA granted Rhodes a Narcotic Raw Material Import Registration. This is a significant achievement for Rhodes and Purdue and is the result of a 3+ year effort by people from Rhodes, Purdue and outside legal counsel. Most importantly, Rhodes and Purdue are now strategically positioned with a vertically integrated, world wide, cost competitive supply chain, for narcotic raw materials. This registration enables Rhodes to source narcotic raw materials at world wide competitive pricing and be a viable competitor in supplying API's to the Independent Associated Companies and 3 parties. Rhodes Technologies is now able to provide a cost competitive API platform to support our Rhodes Pharmaceuticals generic dosage form initiative.

Rhodes R&D

- <u>Oxycodone Ultra Low ABUK program</u>: In support of Purdue's OTR submission, Rhodes R&D agreed with the FDA to determine if FDA's new proposed limit on ABUK's (essentially <1 part per million vs. the current level of <10 parts per million) can be achieved. Rhodes is adding staff to do this work. Rhodes advised the FDA that this process could take 18 months to complete, but hopes to complete the work sooner.
- Hydrocodone:
 - 1. Process development is nearing completion
 - 2. Method transfer to QC began in Q1 2008
 - 3. Analytical method development and validation is underway
 - 4. Commercial scale validation of the first 3 steps of the process is planned for mid-2008 and began in June.
 - 5. Validation of the final process step will be in Q4, 2008.
- <u>NALS</u>: This project is being progressed by four (4) process chemists. These chemists are assigned to complete synthetic route scouting and selection. Current efforts are focused on naloxone to support Targin in the EU. Validation of the process is currently planned for the first half of 2009.
- <u>Hydromorphone</u>: Development work is scheduled to start in Q3 2008.
- <u>Clariant Infrastructure</u>: During the 2nd quarter an \$8.3 million 2 year capital investment was approved. This will allow Rhodes Technologies to operate independently as it relates to steam, waste water and other critical utilities, which is necessary following Clariant's decision to cease manufacturing operations on the site by the end of 2008.

Rhodes Pharmaceuticals (New Gen Co)

- During Q4 2007, agreement was reached to create Rhodes Pharmaceuticals, a generic-based finished dosage pharmaceutical company. Recruiting for the CEO is in process.
- A working group has been tasked with developing and maintaining timelines for all products and overseeing the new product development process. A revised economic evaluation is also being developed to take into consideration an increase in the number of products the group would like to launch in the next 2 to 3 years.
- Bob Kupper is progressing the effort to generate ANDA's for the new company as quickly as possible. For example, technical transfer of the first product (immediate release oxycodone) from Canada to Wilson is planned for ~mid-2008. Shortly there after, combination products (oxy/APAP) will follow.

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