



Annual Meeting of Stockholders
Friday, August 31, 2012
Raleigh, NC

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Addressing the Clinical Hold

FDA has two major concerns: thrombocytopenia and immunocompetence

- **OBI has planned preclinical program to address all concerns.**
 - Effects of platelet transfusion in treating thrombocytopenia in ICH rat model
 - Platelet distribution in non-human primates with acute systemic inflammation
 - In vitro platelet function (activation and aggregation) studies, in vitro, comparing normal vs. TBI blood
 - Immunocompetence studies: effects of Oxycyte on bacterial opsonization and resistance to infections
- **Studies scheduled to begin 1Q12 and complete in 2013.**
- **Work being funded by \$2.0m Department of Defense grant.**

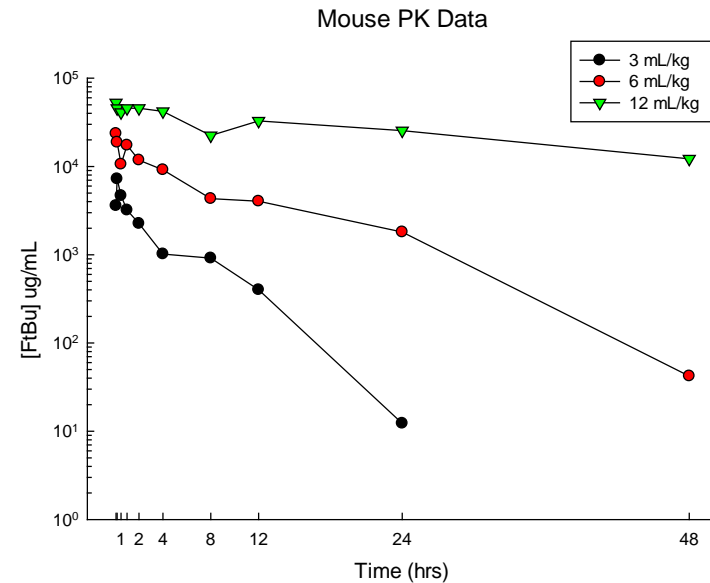
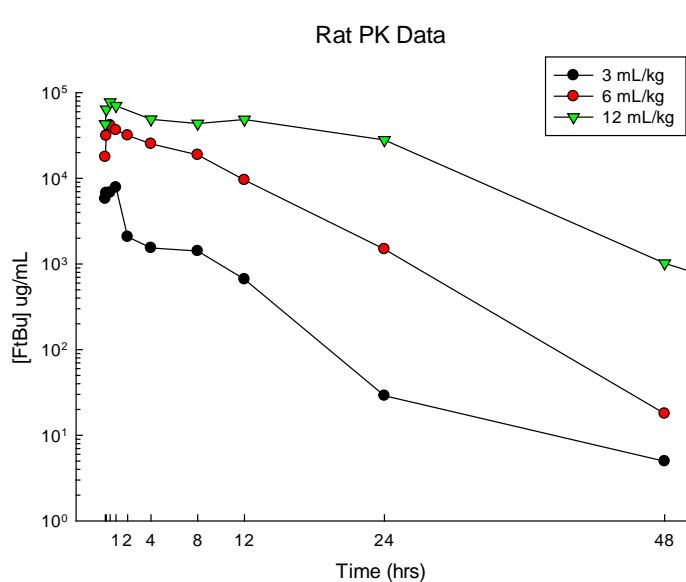
DoD-funded Preclinical Studies—Goal to Lift FDA Hold

■ **Bioanalytical Method Development:**

- GLP-validated bioanalytical method for detection of FtBu in rat whole blood was completed in June 2012. Method used to analyze rat PK study samples.
- Qualified bioanalytical method for detection of FtBu in mouse whole blood was completed in June 2012. Method used to analyze mouse PK study samples.

■ **Pharmacokinetics (PK):**

- Rat and mouse studies to determine the pharmacokinetics of FtBu in whole blood following a single intravenous administration of Oxycyte were completed July 2012.
- PK data analysis underway. Draft bioanalytical data provided below.



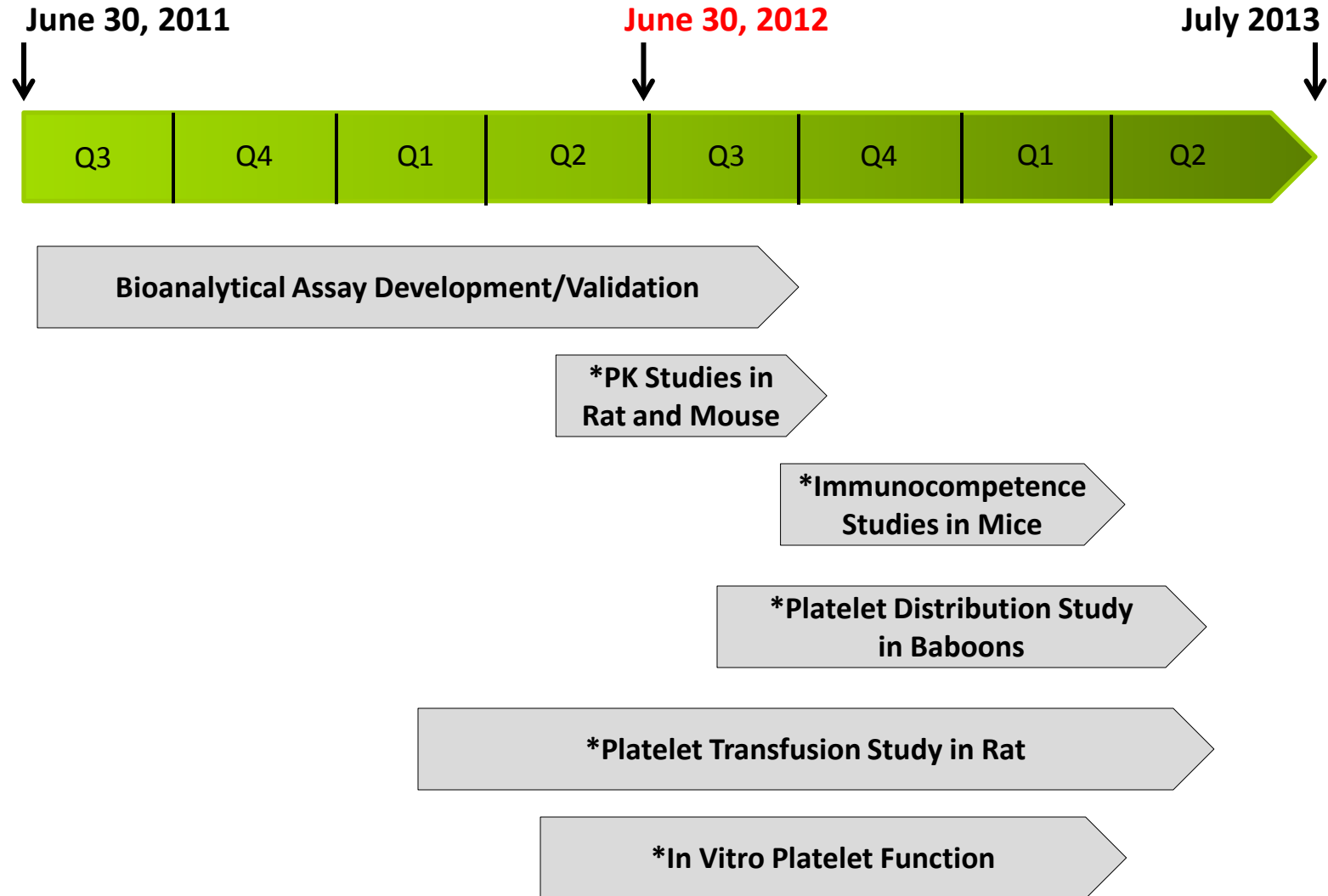
DoD-funded Preclinical Studies—Goal to Lift FDA Hold

- ***In Vitro Platelet Function using Blood from Normal Healthy Volunteers (NHV) and TBI patients:***
 - NHV protocol completed Jan. 2012; IRB approval Feb. 2012; FDA approval received April 2012. Protocols contain 5 *in vitro* platelet function assays.
 - NHV enrollment started in May 2012; completed July 2012 at Children's Hospital in Boston (CHB). Draft data pending.
 - Protocol using blood from TBI patients submitted to IRB at Brigham Women's Hospital in Boston Sept. 2012; *in vitro* experiments will be carried out at CHB.
- ***Immunocompetence:***
 - Designed proposal submitted to FDA March 2012; approval received May 2012; DoD approval received June 2012;
 - Protocols for 4 studies in mice. Submitted for ACURO approval Aug 2012.; all studies to be completed Sept-Dec. 2012.

DoD-funded Preclinical Studies—Goal to Lift FDA Hold

- ***Platelet Biodistribution Study in Baboon model of Acute Systemic Inflammation:***
 - Baboon study to be conducted at SNPRC/THSI. Site visit completed.
 - Model development protocol undergoing IACUC review. ACURO review planned for Sept. 2012. Determination of Oxycyte MFD, LPS dose, and PLT profiles following protocol approvals (Sept.-Oct.)
 - Development of imaging study protocols (whole body gamma scintigraphy and diffusion-weighted imaging of brain) underway; Will require review and approval of SNPRC IACUC, DoD ACURO, and FDA prior to study start.
- ***Effects of platelet transfusion on hemostasis in a rat model of intracranial hemorrhage (ICH)***
 - Model being developed in 3 phases: Phase 1, determining platelet and hemostasis profile, completed; Phase 2 ICH model development underway; Phase 3 protocol completed and submitted for ACURO review;
 - Definitive study protocol will be submitted to FDA for review and approval 4Q2012.

Army Funded Research Program



* Arrows are start of in-life to delivery of final report .



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Thank you.

