## **COMPANY UPDATE**



To Our Shareholders, Employees & Partners:

We are pleased to report a new Phase II clinical program!

We have been awarded just over \$1 million in funding from the FDA through their Orphan Drug Grant initiative to advance our ifetroban pipeline. As a result, we have now initiated a Phase II study for the clinical development of ifetroban for the treatment of cardiomyopathy associated with Duchenne Muscular Dystrophy (DMD). DMD is a rare, fatal, genetic neuromuscular disease for which there is currently no universally effective treatment. Our study is the first DMD clinical study approved for FDA Orphan Product Development funding.

Financially, we had a successful third quarter and built on the positive momentum generated earlier this year. Net revenues in the third quarter of 2019 were \$10.4 million, growing 22% over the prior year period. Adjusted Earnings for the quarter were \$0.1 million, or \$.01 per share. Year-to-date net revenues were \$33.9 million, up 24% delivering Adjusted Earnings of \$3.5 million or \$.22 per share. We continue to maintain a strong financial position with total assets of \$103.8 million, including \$29.2 million in cash and investments at the end of the period.

Earlier in the year, we announced a strategic review of our brands, capabilities, and international partners. As a result, during the first half of 2019, we increased our international partners and added to our corporate, sales, and medical teams. During the third quarter, we finalized an agreement with Dr. Reddy's Laboratories for the registration and distribution of **Vibativ**<sup>®</sup> in India. Dr. Reddy's is a multinational pharmaceutical company based in Hyderabad, India, and they currently market over 190 medications through their commercial operations in over 35 countries.

Additionally, during the third quarter, we filed a label update with the FDA in support of a **Caldolor**<sup>®</sup> aiming to further expand the product's label. This update includes geriatric, shortened infusion, pediatric and PK data. In early September 2019, the FDA informed us that our submission was not accepted for their review due to the number of new claims. They have offered a Type A meeting to discuss their recommendations, which we intend to schedule later this year.

We also had several favorable communications with the FDA for our **RediTrex<sup>™</sup>** (methotrexate) product line. The FDA has requested additional time to review our application and has set an approval decision date for December 2019.

Finally, I'd like to acknowledge and thank our team for all their fine efforts, and for doing their part in advancing our mission of improving patient care through the delivery of high-quality pharmaceutical products. We remain focused as we enter the last quarter of 2019, and we look forward to keeping you updated as the year progresses.

All the best,

November 2019