AEROSURF is an investigational combination drug/device product that combines our proprietary KL4 surfactant with our novel aerosol delivery system (ADS), which is based primarily on our capillary aerosol generator technology. We are developing AEROSURF to enable administration of aerosolized KL4 surfactant to premature infants receiving nCPAP, without invasive intubation and mechanical ventilation. We believe that, if approved, AEROSURF will have the potential to transform the treatment of RDS, allow for earlier treatment of those premature infants who currently receive surfactants later in their course of treatment, decrease the morbidities and complications currently associated with surfactant administration, and reduce the number of premature infants who are subjected to invasive intubation and delayed surfactant therapy as a result of nCPAP failure.

The current surfactant market for RDS is estimated to be approximately $75 million annually in the U.S. and $250 to $300 million annually worldwide; however, we believe that this market has been constrained, in part, by the risks associated with surfactant administration and lack of medical innovation. Treatment options for RDS have not improved significantly, nor have mortality and morbidity rates for RDS meaningfully improved over the last few decades. We believe that the neonatal medical community would respond favorably to the introduction of a synthetic, peptide-containing (KL4) surfactant and a less-invasive method of surfactant administration. By enabling delivery of our aerosolized KL4 surfactant using noninvasive methods, we believe that AEROSURF, if approved, will address a serious unmet medical need and potentially provide transformative clinical and pharmacoeconomic benefits. We believe that AEROSURF has the potential to create a worldwide annual market opportunity of $600 million to a $1 billion per year. *See,* "– Surfactant Therapy – The RDS Market."

The drug product component of our AEROSURF product candidate is a lyophilized (freeze-dried) dosage form of our KL4 surfactant liquid instillate drug product that was approved by the U.S. Food and Drug Administration (FDA) in 2012 under the name SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS. In the second quarter of 2015, we determined to cease commercial and manufacturing activities for SURFAXIN to focus our limited resources on advancing the AEROSURF clinical development program and our aerosolized KL4 surfactant pipeline. We believe that gaining the approval of SURFAXIN provided us valuable experience to support the further development of our KL4 surfactant product candidates, beginning with AEROSURF.

Beyond RDS

In the future, we believe that we may be able to leverage the data and know-how that we gain from our development activities for our KL4 surfactant, in liquid, lyophilized and aerosolized dosage forms, to support a potential product pipeline of KL4 surfactant products to address serious critical care respiratory and other conditions in children and adults in pediatric and adult intensive care units. While we remain focused on AEROSURF, we have supported and plan in the future to support potential opportunities to explore the utility of our KL4 surfactant to address a variety of respiratory conditions. Although there can be no assurance, we would consider supporting such efforts in the future if we are able to secure separate funding, including through potential government-supported and other grant programs that are dedicated to advancing research and development initiatives.

We believe that our aerosolized KL4 surfactant, alone or in combination with other pharmaceutical compounds, has the potential to be developed to address a range of serious respiratory conditions and may be an effective intervention for such conditions as acute lung injury (ALI), including acute radiation exposure to the lung (acute pneumonitis and delayed lung injury), chemical-induced ALI, and influenza-induced ALI. In addition, although there can be no assurance, we may explore opportunities to apply KL4 surfactant therapies to treat conditions such as chronic rhinosinusitis, complications of certain major surgeries, mechanical ventilator-induced lung injury (often referred to as VILI), pneumonia, diseases involving mucociliary clearance disorders, such as chronic obstructive pulmonary disease (COPD) and cystic fibrosis (CF). There can be no assurance, however, that we will secure the additional capital needed to undertake such explorations, that we will undertake such explorations or that, even if we do, that we will be successful.

BUSINESS STRATEGY

We continue to focus our drug research and development activities on the management of RDS in premature infants. We are currently conducting a clinical development program for AEROSURF for the treatment of RDS. Our