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Mesa Biotech provides corporate update

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Mesa Biotech Inc., a privately-held, molecular diagnostic company that has developed an affordable and easy to operate PCR (polymerase chain reaction) testing platform designed specifically for point-of-care (POC) infectious disease diagnosis, provides an update on notable accomplishments and corporate priorities for the remainder of 2018.

"In 2017, we focused on preparing our Accula Test System for commercialization, strengthening key corporate partnerships that will build the foundation for our global distribution channel strategy, expanding manufacturing capacity, and building an experienced team. In the first half of 2018 we launched our first product in both the EU and US and secured additional funding to execute on our mid-term and long-term strategic plans," said Hong Cai, Co-founder and Chief Executive Officer, Mesa Biotech, Inc. "We are now positioned to further expand manufacturing capacity and move our pipeline products forward."

2017 and Early 2018 Highlights

2017 was a year of pre-commercial preparation for Mesa Biotech. To facilitate global expansion, the company received an internationally recognized ISO quality certification. This designation marked the completion of a critical step for commercialization of Mesa Biotech's novel Accula System in the European Union (EU) and the United States (US). The company hired Steven Sepulveda for the vital role of Vice President Global Business Development and Channel Management. Sepulveda is directing and overseeing all aspects of global commercial sales, business development, strategic alliances and distributor management.

Rounding out 2017, Sekisui Diagnostics became a strategic partner and exclusive distributor for Mesa Biotech products in the US and Canada, ensuring immediate access to established distribution in North America due to their market strength and excellent reputation among distributors and healthcare providers.

The first quarter of 2018 was pivotal for Mesa Biotech. The company obtained CE Mark in the EU for its Accula System. The first available test in the EU market was the company's Flu A/Flu B Test. Several weeks later, Mesa received 510(k) clearance and Clinical Laboratory Improvements Amendments (CLIA) waiver from the U.S. Food and Drug Administration (FDA) for their Accula Flu A/Flu B test. The CLIA waiver is significant as it allows for use and commercialization in the wider segment of alternate care including the physician office lab (POL) market.

Mesa Biotech raised $20 million in a Series B financing round in early July, following a $3 million Series A financing from earlier in the year. These two rounds bring the company's total year funding to $23 million, leaving Mesa debt free.

2018 Priorities

With a solid foundation, Mesa Biotech is well-positioned for continued progress in the second half of 2018. The company intends to invest recent funding in new assay development, increased production capacity, commercialization activities, facilities expansion and key hires.

"Unlike other available molecular POC products in the market, our Accula System has a low-cost entry point and operating cost, requires no calibration or refrigeration of components and minimal maintenance. These are significant benefits for a point of care clinician," said Cai. "Our POC product solution offers the?simplicity, convenience and procedural familiarity?of traditional rapid immunoassays; while delivering the excellent sensitivity, specificity and information of laboratory-based PCR testing."

Near term, the company is planning to further develop its respiratory infectious disease product portfolio as well as expand into sexually transmitted diseases and women's health. Mesa has completed the RSV (respiratory syncytial virus) assay clinical trial and expects to obtain CE Mark later this summer and launch in time for the EU's RSV 2018-2019 season. In the US, a dual submission for 510(k) clearance and CLIA-waiver for the Accula RSV test has been submitted to the FDA.