Fluidigm Appoints Steve McPhail General Manager of Production Genomics Business

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Industry Veteran to Drive Growth in Dynamic Production Genomics Market

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Fluidigm Corporation (NASDAQ:FLDM) has recruited industry veteran Steven C. McPhail to lead its new organization specifically focused on serving its production genomics customers. Production genomics remains a key strategic opportunity for Fluidigm to diversify the company's product lines and end-customer mix.

"For years, production genomics has been a growth driver for Fluidigm, and this opportunity continues to expand. An organization concentrated on this market, ably led by Steve, will help maximize our performance and contribute to the success of our production genomics customers in clinical, biorepository, biopharmaceutical, and Ag-genomics markets, to name a few," said Gajus Worthington, Fluidigm President and Chief Executive Officer.

Industry Veteran to Lead Fluidigm's Production Genomics Business

"We are very excited to introduce Steve McPhail as the General Manager of our new production genomics effort. I've been an admirer of Steve for many years. As President and CEO of Expression Analysis, a genomic services business, he was both a customer and a trusted advisor," said Worthington. "Under Steve's leadership, Expression Analysis enjoyed substantial growth and success, serving a wide range of production genomics customers. I can't think of anyone else better suited to lead this exciting growth opportunity for Fluidigm," Worthington concluded.

Prior to joining Fluidigm, McPhail dedicated 12+ years to Expression Analysis, which was acquired by Quintiles Transnational Corporation in 2012, where he served as President of the post-acquisition operation. Prior to Expression Analysis, McPhail spent his career serving companies in the diagnostic, biotechnology and medical device markets, including ArgoMed, Xanthon, TriPath Imaging, Dynex Technologies and Abbott Laboratories. He has significant senior management, scientific and operational experience and excels in strategy development, tactical execution of operational plans, building outstanding management teams, establishing distribution networks, as well as managing mergers and acquisitions.

"As a Fluidigm customer for several years, I have had the opportunity to watch the company grow from a genomics tool provider to a diversified high-growth life sciences company supporting genomic, next generation sequencing, single cell and proteomic applications. I am delighted to be joining an excellent management team in an entrepreneurial environment, with significant production genomics application opportunities in a variety of large markets. This is a very exciting time for Fluidigm and I look forward to playing a role in the future success of the company," said McPhail.

Fluidigm to Register Certain Products with FDA

In conjunction with Fluidigm's production genomics business, the company plans to register as a medical device manufacturer with the United States Food and Drug Administration, list certain of its products as Class I (general purpose laboratory equipment) devices, and expand its CE mark for sales of its products in the European Union, within the next 12 months. In addition, Fluidigm intends to seek FDA 510k premarket clearance and other registrations with other regulatory agencies throughout the world on certain of its products on a selected basis, and will continue to work closely with its customers to identify regulated applications, as appropriate.

Fluidigm products have been sold throughout the world to labs conducting demanding research applications. Although some clinical labs may decide to use Fluidigm products as part of applications developed in-house (known as "Laboratory Developed Tests" or LDTs), Fluidigm systems are currently labeled and marketed for research use only - not for clinical diagnostic applications.

The clinical testing market is an important part of the company's production genomics pursuit. The announced future oversight of LDTs by the FDA and revised directives expected from European regulators have created increased regulatory challenges for genetic testing labs. By electing to become a medical device manufacturer for applicable platform products, Fluidigm will provide greater value to the clinical testing market by providing labs with instruments to support their test development and deployment efforts, and ease their path to comply with anticipated changes in FDA and applicable European regulatory requirements. Fluidigm intends to focus on addressing the need in the LDT space for general use platforms with exceptional data quality, high-throughput workflows, scalability and platform robustness, and does not plan to produce molecular diagnostic tests.

Use of Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to Fluidigm's plans, objectives, expectations, and strategies for its production genomics business, Fluidigm's anticipated opportunities within the production genomics market, and Fluidigm's plans to seek and obtain clearance or approval of certain of its products with the FDA and other foreign regulatory authorities. Forward-looking statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from currently anticipated results, including challenges inherent in developing, manufacturing, launching, marketing, and selling new products; the possible loss of key employees, customers, or suppliers; intellectual property risks; competition; Fluidigm's sales, marketing and distribution capabilities; Fluidigm's planned sales, marketing, and research and development activities; interruptions or delays in the supply of components or materials for, or manufacturing of, Fluidigm products; seasonal variations in customer operations; unanticipated increases in costs or expenses; and risks associated with international operations. Information on these and additional risks, uncertainties, and other information affecting Fluidigm's business and operating results are contained in Fluidigm's Annual Report on Form 10-K for the year ended December 31, 2014, and other filings with the Securities and Exchange Commission. Additional information will also be set forth in Fluidigm's Quarterly Report on Form 10-Q for the three months ended March 31, 2015 to be filed with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof and Fluidigm disclaims any obligation to update these statements except as may be required by law.

About Fluidigm

Fluidigm (NASDAQ:FLDM) develops, manufactures, and markets life science analytical and preparatory systems for growth markets such as single-cell biology and production genomics. We sell to leading academic institutions, clinical laboratories, and pharmaceutical, biotechnology, and agricultural biotechnology companies worldwide. Our systems are based on proprietary microfluidics and multi-parameter mass cytometry technology, and are designed to significantly simplify experimental workflow, increase throughput, and reduce costs, while providing excellent data quality. Fluidigm products are provided for Research Use Only. Not for use in diagnostic procedures.

We use our website (www.fluidigm.com), corporate Twitter account (@Fluidigm), Facebook page (https://www.facebook.com/Fluidigm), and LinkedIn page (https://www.linkedin.com/company/fluidigm-corporation) as channels of distribution of information about our products, our planned financial and other announcements, our attendance at upcoming investor and industry conferences, and other matters. Such information may be deemed material information and we may use these channels to comply with our disclosure obligations under Regulation FD. Therefore, investors should monitor our website and our social media accounts in addition to following our press releases, SEC filings, public conference calls, and webcasts.

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