Commercial Collaborators

Exact Sciences

In 2010, MDxHealth entered into an exclusive license agreement with Exact Sciences Corporation for stool-based screening of colorectal cancer. Under the terms of the agreement, Exact Sciences obtained exclusive, worldwide rights to use up to two of MDxHealth's DNA methylation biomarkers in stool-based detection of colorectal cancer, as well as non-exclusive access to MDxHealth's MSP platform technology for use with those biomarkers. In return, MDxHealth received an upfront license payment and is entitled to receive, subject to certain conditions, milestone payments and royalties on net sales.

Exact Sciences completed the development of their Cologuard test with the goal to provide a more accurate, non-invasive diagnostic test to screen for the early stages of colorectal cancer, as compared to the current standard of care, Faecal Immunochemical Testing (FOBT), which aims to detect small amounts of blood in stool samples. In December 2012 and January 2013, Exact Sciences submitted the first and second modules, respectively, of its modular premarket approval application (PMA) to the U.S. Food and Drug Administration (FDA) for Cologuard. Exact Sciences submitted the final clinical module with the FDA in 2013 and the FDA's Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee will review the premarket approval application (PMA) for the company's Cologuard stool-DNA-based, non-invasive colorectal cancer screening test on March 27, 2014. Based on the outcome of PMA review, the product could be on the market in 2014, which will start a royalty stream and certain milestone payments to MDxHealth.

PLUS Diagnostics, now a division of Miraca Life Sciences

In April 2012, MDxHealth entered into an agreement with PLUS Diagnostics to co-promote MDxHealth's ConfirmMDx® for Prostate Cancer assay in the United States. PLUS Diagnostics, a leading U.S. anatomic pathology company that offers a full range of multi-specialty services, is helping to supplement the efforts of MDxHealth's direct sales force to build awareness of ConfirmMDx for Prostate Cancer through its national network of urologists. In late 2013 Plus Diagnostics was acquired by Miraca Life Sciences. MDxHealth is extending its partnership agreement with Miraca thereby further expanding the network.

Bostwick Laboratories

In July 2013, MDxHealth entered into an agreement with Bostwick Laboratories to co-promote MDxHealth's ConfirmMDx® for Prostate Cancer assay in the United States. Bostwick Laboratories is a leading national, full-service laboratory specializing in anatomic and clinical pathology, with a focus on uropathology. Bostwick will assist MDxHealth to continue building awareness and access for ConfirmMDx within the urology community. Bostwick views MDxHealth's epigenetic test as providing additional clinical utility for their urology clients and patients.

Teva Pharmaceuticals Ltd

In January 2014, MDxHealth signed a partnership with Teva Pharmaceuticals Industries Ltd. a leading global pharmaceutical company in Israel, for commercialization of ConfirmMDx® for Prostate Cancer and PredictMDx® for Glioblastoma tests in Israel. Teva Pharmaceuticals Industries will be the exclusive distributor of both tests in Israel. Samples will be sent to MDxHealth's CLIA-registered laboratory in Irvine, California for testing. Teva will reimburse MDxHealth for all the testing services.

Summit Pharmaceutical Ltd. (a subsidiary of Sumitomo Corporation)

In July 2013, MDxHealth entered into a partnership with Summit Pharmaceuticals International Corporation (SPI) a subsidiary of Sumitomo Corporation to gain access to the Japanese market with its pharmaco molecular diagnostic (PharmacoMDx) epigenetic technologies and products. The partnership aims to provide companion diagnostic solutions, or theranostics, to pharmaceutical companies in the Japanese market. Summit Pharmaceuticals International Corporation is a group of specialists in Japan that provides high-quality integrated services from drug discovery research to the production stage of pharmaceuticals and chemicals. SPI is a subsidiary of Sumitomo Corporation which is a leading general trading company with 140 locations in 66 countries throughout the world.

HistoGeneX

On July 16, 2013, MDxHealth entered into Pharmaco Molecular Diagnostic services collaboration with HistoGeneX. The collaboration enables MDxHealth to combine its epigenetic technologies with HistoGeneX's well-established pharmaco diagnostic services to provide pharmaceutical companies and oncologists with integrated molecular diagnostic testing services. HistoGeneX's laboratory in Belgium will also perform MGMT service testing on behalf of MDxHealth's current and future clients.

Veridex

In December 2010, MDxHealth entered into two non-exclusive licenses with Veridex LLC (a Johnson & Johnson Company) for the use of certain of MDxHealth's proprietary DNA methylation products in colorectal and prostate cancer screening. Under the agreements, Veridex licensed non-exclusive rights for the performance of service testing at its own laboratories worldwide using MDxHealth's DNA methylation biomarkers for use in blood-based detection of colorectal cancer, as well as tissue- and urine-based detection of prostate cancer. In return, MDxHealth is entitled to receive, subject to certain conditions, milestone payments and royalties on net sales. The new license agreements replace prior agreements first entered into with Veridex LLC in 2004 granting exclusive worldwide rights to prostate cancer testing services and kits. These license grants to Veridex were the result of an agreement between MDxHealth and Ortho-Clinical Diagnostics, Inc. (OCD, a Johnson & Johnson Company) that was entered into in 2003, when MDxHealth acquired certain methylation markers and technology from Tibotec-Virco (a Johnson & Johnson Company). Under the terms of this 2003 agreement, MDxHealth agreed to first offer to OCD the exclusive right to license, at commercially reasonable terms, any product in the human in vitro diagnostics field that contains those technology components that were once owned by Tibotec-Virco. Since 2003, MDxHealth has offered products under this first right to license option in the fields of prostate, lung, colon, cervical,

brain and bladder cancer, of which Veridex has exercised its license rights only for Prostate and blood-based colon, each on a non-exclusive basis for service testing.

LabCorp

In 2008, MDxHealth granted to LabCorp a royalty bearing sublicense to the MGMT test (for the North American market only, of indefinite duration, and limited to service testing only). MDxHealth retained certain rights to develop and commercialize the MGMT test as a companion diagnostic on a worldwide basis. In 2007, LabCorp obtained a non-exclusive license to perform laboratory-based diagnostic testing services in North America on prostate tissue samples using selected MDxHealth DNA methylation biomarkers. Sales of this prostate test remain limited as LabCorp does not appear to be actively promoting the services or investing resources to sponsor clinical trials further validating the utility of the test. In 2008, LabCorp began to commercialize the two afore-mentioned tests in North America.

GlaxoSmithKline Biologicals (GSK)

MDxHealth continued its existing relationship with GlaxoSmithKline Biologicals (GSK) to pursue the development and testing of new companion diagnostic tests that can potentially be used with GSK's immunotherapeutic oncology program. MDxHealth's collaboration with GSK was initiated in 2007 under a Wallonia-BioWin grant concerning mutual research in the immunotherapeutic oncology field. Under the expanded agreement signed in 2010, GSK is collaborating with MDxHealth to assess the potential use of one of MDxHealth's DNA methylation specific PCR biomarkers in GSK's immunotherapy development program.

Clovis Oncology

In 2010, MDxHealth entered into a collaboration agreement with Pfizer to pursue the identification and development of an MDxHealth biomarker predicting response to Pfizer's cancer drug candidate for PARP inhibition, PF-01367338. However in 2011, Pfizer out-licensed their compound to Clovis Oncology, effectively handing over the entire program and future development rights. After the transfer, MDxHealth continued to work with Clovis on the identification and feasibility stage of a cancer drug candidate for PARP inhibition, PF-01367338. Newcastle University (UK) also participated in the collaboration. The collaboration is assessing the potential to develop an MDxHealth test as a companion diagnostic test to guide treatment decisions in treatment of ovarian and breast cancers with the PARP drug candidate.

Self-Screen

In 2010, MDxHealth entered into an exclusive joint-venture agreement with Self-Screen B.V. for confirmation testing of cervical cancer. Under the terms of the agreement, Self-Screen and MDxHealth each contributed certain intellectual property rights and research and development efforts in the field of cervical cancer testing in vaginal swab and scraps, fluids washes and other body fluids, MDxHealth received the worldwide commercialization rights to any cervical epigenetic cancer test developed in the joint venture, and Self-Screen obtained a limited non-exclusive license to use MDxHealth's MSP platform technology and certain cervical cancer biomarkers to provide cervical cancer testing services in certain identified northern-European countries. In 2014, Self-Screen plans to submit its application to obtain CE approval for its cervical cancer test.

Merck Serono

In 2012, MDxHealth entered into a renewed collaboration agreement with Merck KGaA for the commercial development of MDxHealth's MGMT diagnostic test as a companion diagnostic to Merck's drug candidate cilengitide. However, Merck has recently announced that the Phase III trial for cilengitide did not meet primary endpoints, and therefore it is unlikely that Merck will continue its development of cilengitide or its support for the development and commercialization of the Company's MGMT test as an FDA-approved companion diagnostic to cilengitide. In June 2013, Merck KGaA's cilengitide drug failed to meet the primary endpoints for their Phase III clinical trial. As a result, Merck discontinued the cilengitide drug development and discontinued its support for the development of the MGMT companion diagnostic for cilengitide. MDxHealth was compensated for the termination of the agreement, however discontinuation of the program reduced the Company's revenue in 2013 versus expectation.

Predictive Biosciences

In 2010, MDxHealth entered into an exclusive U.S. license agreement with Predictive Biosciences for diagnostic applications in bladder cancer. MDxHealth received an upfront license payment along with specific milestone payments and royalties on net sales. In June 2013, due to the loss of Medicare coverage for their CertNDx, Predictive Biosciences ceased business operations.

MSP Platform Technology – Various Partners

To support the increasing worldwide adoption of our MSP platform technology, MDxHealth has granted non-exclusive licenses to a number of multinational corporations to supply research-use kits designed for use on the MSP platform. Licensees include EMD Serono (formerly Millipore, a division of Merck Serono), Qiagen and Takara, each of which have obtained royalty bearing, non-exclusive, worldwide, and of indefinite duration sublicenses to the MSP methylation platform technology for use in the scientific research market only. MDxHealth receives a royalty fee on all current and future sales for this market segment.