

# Philip Morris International

August 9, 2021

## Philip Morris International Acquires Inhaled Drug Specialist OtiTopic; Growing Pipeline of “Beyond Nicotine” Inhaled Therapeutic Products

*PMI’s expertise and Beyond Nicotine portfolio companies to speed ASPRIHALE® to market*

LAUSANNE, Switzerland--(BUSINESS WIRE)--Aug. 9, 2021-- Philip Morris International Inc. (PMI) (NYSE: PM) today announced its acquisition of OtiTopic, a U.S. respiratory drug development company with a late-stage inhalable acetylsalicylic acid (ASA) treatment for acute myocardial infarction. If approved, the treatment can address the significant unmet medical need of the over 83 million people, in the U.S. alone, at intermediate to high risk for myocardial infarction.

“The acquisition of OtiTopic is an exciting step in PMI’s Beyond Nicotine ambitions,” said Jacek Olczak, CEO, PMI. “We have world-class expertise in the research, development, and commercialization of aerosolization and inhalable devices to help speed the delivery of this exciting product to market.”

This acquisition is part of PMI’s strategic plan to leverage its expertise, scientific know-how, and capabilities in inhalation to grow a pipeline of inhaled therapeutics and respiratory drug delivery Beyond Nicotine. Following the completion of clinical trials and pending approvals by the U.S. Food and Drug

Administration (FDA), PMI can leverage its expertise and the capabilities of other companies in the Beyond Nicotine portfolio to bring ASPRIHALE® to market.

ASPRIHALE®—a patented, dry powder inhalation of ASA delivered through a unique self-administered aerosol—is expected to move from clinical trials to filing with FDA for approval in 2022. Early clinical trials have shown that the product system catalyzed peak plasma concentration and the desired pharmacodynamic effect, i.e., inhibition of platelet aggregation in two minutes compared with 20 minutes for coated chewable aspirin. This speed is unprecedented and has significant potential implications for improving the survival of patients at risk of heart attacks.

OtiTopic will complete its assessment program and filing with the FDA using FDA's 505 (b)(2) pathway, a pathway designed for drugs already available on the market but requesting approval either for a new indication, dosage form or regimen, strength, combination with other products, or other unique traits. This pathway will allow PMI to build on existing data available for ASA reference products and focus on delivering the evidence that the inhalable form, ASPRIHALE®, outperforms the current standard of care—oral delivery—of ASA.

“In the United States alone, someone has a heart attack every 40 seconds. With its inhalable version of acetylsalicylic acid (ASA), OtiTopic has developed an asset that promises to have a much faster onset of effect compared to oral ASA,” said Jorge Insuasty, chief life sciences officer, PMI. “With its acquisition of OtiTopic, PMI looks forward to completing the planned ASPRIHALE® registration program and bringing this important treatment to market to address a significant unmet medical need in a clinical condition where every second counts.”

“This transaction aligns well with OtiTopic's goals of unlocking what we believe to be a significant opportunity in inhaled therapeutics science,” said Kambiz Yadidi, CEO, OtiTopic. “We are entering this transaction to accelerate ASPRIHALE®'s

FDA filing, with the goal of delivering innovative therapies for people with intermediate to high risk for myocardial infarction.”

PMI’s Beyond Nicotine vision is part of a larger transformation that puts health, science, technology, and sustainability at the heart of PMI’s future, delivering products and solutions that aim to improve people’s lives and deliver a net positive impact on society. Building on the company’s investment and expertise in aerosol chemistry and physics, device technology, clinical research, and best-in-class preclinical safety and inhalation models, PMI is developing a pipeline focused on inhaled therapeutics for medical and wellness applications.

To date, PMI has invested more than \$8 billion in building a world-class research and development capability, including pre-clinical systems toxicology and clinical capabilities, behavioral research, and post-market studies. The company has also met the strictest of regulatory requirements, including in the U.S., where the Food and Drug Administration authorized a version of our lead smoke-free tobacco product as a Modified Risk Tobacco Product in 2020.

OtiTopic was founded in 2012 as an innovative pharmaceutical start-up company and holds several key patents, differentiated intellectual property, and has confirmed a 505(b)2 pathway through constructive interactions with the FDA.

PMI expects the impact of the acquisition of OtiTopic on its full-year 2021 adjusted diluted EPS to be immaterial.

### **Forward-Looking and Cautionary Statements**

Statements in this press release that are not strictly historical, including statements regarding the acquisition of OtiTopic, and any other statements regarding events or developments that we believe or anticipate will or may occur in the future, may be

“forward-looking” statements within the meaning of the Private Securities Litigation Reform Act of 1995, and involve a number of risks and uncertainties.

There are a number of important factors that could cause actual events to differ materially from those suggested or indicated by such forward-looking statements, and you should not place undue reliance on any such forward-looking statements. These factors include risks and uncertainties related to, among other things: (1) the possibility that the integration of OtiTopic and its operations with those of PMI may be more difficult and/or take longer than anticipated, and may not accelerate PMI’s desired entry into additional smoke-free and beyond nicotine platforms as quickly as anticipated; (2) the possibility that ASPRIHALE® may not receive FDA approval when anticipated, if at all; (3) the ability of PMI to retain key personnel of OtiTopic; and (4) other factors that may affect future results of the combined company described in the section entitled “Risk Factors” in PMI’s Annual Report on Form 10-K for the fiscal year ended December 31, 2020, PMI’s Form 10-Q for the quarter ended June 30, 2021, and other filings of PMI with the Securities and Exchange Commission. The forward-looking statements made herein speak only as of the date hereof and PMI does not assume any obligation to update or revise any forward-looking statements, whether as a result of new information, future events and developments or otherwise, except as required by law.

### **Philip Morris International: Delivering a Smoke-Free Future**

Philip Morris International (PMI) is leading a transformation in the tobacco industry to create a smoke-free future and ultimately replace cigarettes with smoke-free products to the benefit of adults who would otherwise continue to smoke, society, the company, its shareholders and its other stakeholders. PMI is a leading international tobacco company engaged in the manufacture and sale of cigarettes, as well as smoke-free products, associated electronic devices and accessories, and other nicotine-containing products in markets outside the U.S. In addition, PMI ships versions of its *IQOS* Platform 1 device and consumables to Altria Group, Inc.

for sale under license in the U.S., where these products have received marketing authorizations from the U.S. Food and Drug Administration (FDA) under the premarket tobacco product application (PMTA) pathway; the FDA has also authorized the marketing of a version of *IQOS* and its consumables as a Modified Risk Tobacco Product (MRTP), finding that an exposure modification order for these products is appropriate to promote the public health. PMI is building a future on a new category of smoke-free products that, while not risk-free, are a much better choice than continuing to smoke. Through multidisciplinary capabilities in product development, state-of-the-art facilities and scientific substantiation, PMI aims to ensure that its smoke-free products meet adult consumer preferences and rigorous regulatory requirements. PMI's smoke-free product portfolio includes heat-not-burn and nicotine-containing vapor products. As of June 30, 2021, PMI's smoke-free products are available for sale in 67 markets in key cities or nationwide, and PMI estimates that approximately 14.7 million adults around the world have already switched to *IQOS* and stopped smoking. For more information, please visit [www.pmi.com](http://www.pmi.com) and [www.pmiscience.com](http://www.pmiscience.com).

# # #

View source version

on [businesswire.com](http://businesswire.com): <https://www.businesswire.com/news/home/20210809005323/en/>

**Philip Morris International**

David Fraser

T. +41 (0)79 843 8603

E. [david.fraser@pmi.com](mailto:david.fraser@pmi.com)

Source: Philip Morris Internati