Report Submitted 4/10/2019 to the Vermont Office of the Attorney General for Introduction of a New Prescription Drug to Market
Janssen Pharmaceuticals, Inc.
Information required pursuant to 18 VSA § 4637(c),(d)
SPRAVATO™

Requirement	Submission - Spravato NDC 50458-0028-02	Submission - Spravato NDC 50458-0028-03
18 VSA § 4637(c)(1) A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally	While specific marketing and pricing plans are not available in the public domain, generally we are marketing in the US with print distribution and digital advertising in the mental health community, as well as promoting to appropriate healthcare professionals, systems of care and behavioral health clinics who treat individuals living with treatment resistant depression. The pricing plan has WAC set at $590 per package of 2 inhalers. The list price of SPRAVATO™ is not reflective of discounts and rebates which may be available through Medicaid, Medicare, and commercial insurance. SPRAVATO™ will also be discounted as required under the 340B program, the Federal Supply Schedule, and other government programs. Internationally, we are pursuing regulatory approvals for SPRAVATO for the treatment of treatment resistant depression. No approvals have been granted at this time.	While specific marketing and pricing plans are not available in the public domain, generally we are marketing in the US with print distribution and digital advertising in the mental health community, as well as promoting to appropriate healthcare professionals, systems of care and behavioral health clinics who treat individuals living with treatment resistant depression. The pricing plan has WAC set at $885 per package of 3 inhalers. The list price of SPRAVATO™ is not reflective of discounts and rebates which may be available through Medicaid, Medicare, and commercial insurance. SPRAVATO™ will also be discounted as required under the 340B program, the Federal Supply Schedule, and other government programs. Internationally, we are pursuing regulatory approvals for SPRAVATO for the treatment of treatment resistant depression. No approvals have been granted at this time.
18 VSA § 4637(c)(2) The estimated volume of patients who may be prescribed the drug	While Janssen's estimated volume of patients who may be prescribed SPRAVATO is not available in the public domain, according to the National Institute of Mental Health, there are approximately 16.2 million patients with major depressive disorder (MDD) in the United States, and approximately 1/3 of MDD patients have treatment resistant depression (TRD). SPRAVATO will be clinically appropriate for a subset of patients with TRD.	While Janssen's estimated volume of patients who may be prescribed SPRAVATO is not available in the public domain, according to the National Institute of Mental Health, there are approximately 16.2 million patients with major depressive disorder (MDD) in the United States, and approximately 1/3 of MDD patients have treatment resistant depression (TRD). SPRAVATO will be clinically appropriate for a subset of patients with TRD.
18 VSA § 4637(c)(3) Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	The drug was granted breakthrough therapy designation and priority review.	The drug was granted breakthrough therapy designation and priority review.
18 VSA § 4637(c)(4) The date and price of acquisition if the drug was not developed by the manufacturer.	Not an acquisition	Not an acquisition
Note: as provided in 18 VSA § 4637(d), we are limiting the information reported to that which is in the public domain or publicly available		