UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC

Petitioner

v.

CIPLA LIMITED

Patent Owner

Case No. IPR2017-00807

U.S. Patent No. 8,168,620

DECLARATION OF JOHN C. JAROSZ

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Alexandria, VA 22313-1450

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I, John C. Jarosz, do hereby declare, under penalty of perjury, as follows:

I. INTRODUCTION

1. I am over the age of eighteen (18) and otherwise competent to make this declaration.

A. Assignment

2. I and my firm have been retained by Cipla, Ltd. ("Cipla") to provide expert analysis and testimony, if necessary, in connection with the above captioned *inter partes* review proceeding. I understand that certain claims of U.S. Patent No. 8,168,620 ("the '620 Patent")—claims 1, 4-6, 24-26, 29, 42-44 ("the challenged claims")—have been challenged as being unpatentable by Argentum Pharmaceuticals LLC. ("Argentum") on the ground that those claims are obvious.

3. I have been asked by counsel for Cipla to assess whether 1) Mylan Specialty LP's ("Mylan's") Dymista® ("Dymista") commercial product in the U.S.[1], 2) Cipla's Duonase ("Duonase") commercial product in India, and 3) a number of imitator products launched by Cipla's competitors in India

[1] As stated below, Mylan's predecessor-in-interest to the Dymista® product was Meda Pharmaceuticals, Inc. ("Meda").

("Imitator Products") are marketplace successes, and whether their success is attributable to the inventions described in the challenged claims of the '620 Patent.

4. Based upon my review of the available evidence, it is my opinion that Dymista® and Duonase (and its imitator products) are marketplace successes, and that the success of these products is due, in large part, to the benefits and advantages of the challenged claims. As a result, the challenged claims of the patent at issue have been a commercial success.

B. Qualifications

5. I am a Managing Principal of Analysis Group, Inc. ("AG") and Director of the firm's Washington, D.C. office. AG is an economic, financial, strategy, and healthcare consulting firm with offices in Beijing, China; Boston, MA; Chicago, IL; Dallas, TX; Denver, CO; Los Angeles, Menlo Park, and San Francisco, CA; Montreal, Canada; New York, NY; and Washington, DC. AG provides research and analysis in a variety of business, litigation, and regulatory settings.

6. I received my B.A. in Economics and Organizational Communications, *summa cum laude*, from Creighton University in Omaha, Nebraska. Thereafter, I was a fellowship student in the Ph.D. program in

Economics at Washington University in St. Louis, Missouri. I completed most of the requirements for my Ph.D., but left before finishing my degree. I ultimately was awarded an M.A. in Economics. I worked for some period after that and then enrolled in law school at the University of Wisconsin in Madison, Wisconsin, from which I received a J.D. I am a member of the State Bar of Wisconsin, but have been on inactive status for the past 32 years.

7. I have spent my entire professional career as a practicing economist. Almost all of my work has involved evaluating the economics of intellectual property ("IP") protection. The bulk of that work has dealt with issues of damages estimation, commercial success, FRAND compliance, irreparable harm, and allegations of antitrust violations. I have testified in hundreds of such matters.

8. Among other things, I have published articles in academic and professional journals, edited a treatise on IP licensing, given presentations and speeches to a wide variety of groups, and taught classes at various law schools.

9. Though my firm and I have been engaged in a wide range of industries, the largest amount of my work has been in pharmaceutical

settings, where I have been involved in scores of matters. Those matters often deal with patient, physician, and payer decision-making, as well as supplier actions and reactions to competitive conditions.

10. My resume is attached as CIP2006. It describes all of my testimony (either in deposition or at trial), publications, and presentations.

11. In addition, I was previously an expert and trial witness for Cipla in the related district court litigation concerning the '620 patent against Apotex Inc. and Apotex Corp. (collectively, "Apotex").

C. Evidence Considered

12. In undertaking my study, I considered information from a variety of sources, each of which is a type that is reasonably relied upon by experts in my field. In the table below, I have listed the documents that I and/or people working with me at AG reviewed in preparing this report.

Cipla's Exhibit #[2]	***Description***
2001	Warner Carr, M.D. Declaration
2003	Alexander Dominic D'Addio, Ph.D. Declaration

[2] Throughout this declaration, I will refer to these exhibits as "[Exhibit Number], [paragraph/page number(s)].".

2006	John C. Jarosz *Curriculum Vitae*
2007	Hugh David Charles Smyth, Ph.D. Declaration
2017	Redacted Proposed Joint Pretrial Order, November 10, 2016, *Meda Pharmaceuticals Inc. and Cipla Ltd., v. Apotex Inc. and Apotex Corp.*, Case No. 1:14-cv-01453-LPS (D.I.137)
2021	Bench Trial Transcript, Volume D, December 16, 2016, *Meda Pharmaceuticals Inc. and Cipla Ltd., v. Apotex Inc. and Apotex Corp.*, Case No. 1:14-cv-01453-LPS (D. Del.)
2048	DataMonitor, "Pipeline and Commercial Insight: Allergic Rhinitis," July 2010 (PTX0396)
2049	2006 Cipla-Meda License Agreement with Quality Agreement (PTX1016)
2050	2011 First Amendment to Cipla-Meda Agreement (PTX0282)
2053	GlobalData, "Allergic Rhinitis - Global Drug Forecast and Market Analysis to 2024," September 2015 (PTX0397)
2062	IMS data for U.S. allergic rhinitis products, 01.2012-04.2016 (PTX0929)
2064	2011.11.02 Email and attachment from Ashwini Dumaswala to Bryan Roecklein re: 2012 Dymista® Strategic Plan (PTX1118)
2065	Apotex Website, "All Products - Apotex Products: United States," http://www.apotex.com/us/en/products/ search.asp?qt=All&qs=&t=All%20Products (accessed June 22, 2016) (PTX0420)
2066	Dymista® Prescribing Information 2015 (PTX0024)
2067	Drug Approval Package: Dymista® (PTX0392)
2068	Meda AB Interim Report, Jan.-Sept. 2012 (PTX0393)
2069	Cipla Website, "At a Glance" http://www.cipla.com/en/corporate-information/at-a-glance.html (accessed June 28, 2016) (PTX0379)
2070	Duonase Nasal Spray – Prescribing Information (PTX0134)
2071	Cipla Website, "Respiratory," http://www.cipla.com/en/our-businesses/strategic-business-units/respiratory.html (accessed June 28, 2016) (PTX0380)
2072	Duonase competitor products, February MAT Nasal Sprays, 2005-2016 (PTX0816)

2074	2014.11.14 Email and attachment from Stuart Loeschto Betsy Orrison re: Dymista® US Marketing Plan 2015 (PTX0271)
2075	Dymista® Competitor Benchmarking Presentation 2012 (PTX0926)
2076	Meda – 2016 Dymista® Brand Plan (PTX0406)
2077	FDA Website, "Prescription to Over-the-Counter (OTC) Switch List," http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm106378.htm (accessed June 28, 2016) (PTX0407)
2078	Johnson & Johnson Press Release, "RHINOCORT ® Allergy Spray Now Available Over The Counter Nationally," February 8, 2016, http://www.jnj.com/news/all/RHINOCORT-Allergy-Spray-Now-Available-Over-The-Counter-Nationally (accessed June 30, 2016) (PTX0408)
2079	2011.11.02 Email and attachment from Ashwini Dumaswala to Bryan Roecklein re: 2012 Dymista® Strategy Plan (PTX0267)
2080	MEDA Presentation re: staffing, timelines for expansion, price comparisons (2011) (PTX0871)
2081	FDA Website, "First-Time Generic Drug Approvals - March 2016," http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/ucm489688.htm (accessed June 28, 2016) (PTX0424)
2082	Renavatio Presentation & Meda Presentation - Dymista® Phase II Positioning Exploration (PTX0426)
2083	Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use to the U.S. Food and Drug Administration for Dymista®, June 17, 2015 (PTX0914)
2084	Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use to the U.S. Food and Drug Administration for Dymista®, June 16, 2015 (PTX0916)
2085	Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use to the U.S. Food and Drug Administration for Dymista®, November 26, 2012 (PTX0917)
2086	Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use to the U.S. Food and Drug Administration for Dymista®, June 29, 2015 (PTX0915)

2087	Cipla Duonase Marketing Presentation (PTX0315)
2088	Meda/Cipla Powerpoint – Complete Picture (PTX0412)
2089	University of Utah Health Sciences Radio Website, "The Differences Between Allergic Rhinitis and Sinusitis," https://healthcare.utah.edu/the-scope/shows.php?shows=0_hf3tm0mc (accessed June 28, 2016) (PTX0429)
2090	Family Allergy & Asthma Care of Montana Website, "If one is good, 2 are better… A new nasal spray containing 2 medications!," http://www.familyallergyasthmacare.com/2013/03/if-one-is-good-2-are-better-a-new-nasal-spray-containing-2-medications/ (accessed June 28, 2016) (PTX0430)
2091	Key Opinions in Medicine Website, "Dymista," http://keyopinions.info/downloads/dymista-class-treatment-allergic-rhinitis/ (accessed June 28, 2016) (PTX0431)
2092	Samuelson, Paul A., and Nordhaus, William D. *Economics* (19th ed., 2010), p. 49 (PTX0415)
2093	Dymista® Marketing Plan 2015 (PTX0438)
2094	Dymista® Formulary Coverage Powerpoint 2014 (PTX0892)
2095	Meda Memorandum re: CVS Caremark Formulary Decisions 2015 (PTX0447)
2096	Bagwell, K. "The Economic Analysis of Advertising," *Handbook of Industrial Organization* (2007), eds. M. Armstrong and R. Porter, vol. 3, pp. 1703-1706 (PTX0432)
2097	Ching, A., and Ishihara, M. "Measuring the Informative and Persuasive Roles of Detailing on Prescribing Decisions," April 27, 2010, Working Paper (PTX0433)
2098	Berndt, Ernst R. "The U.S. Pharmaceutical Industry: Why Major Growth In Times of Cost Containment?" *Health Affairs*, 20(2): 100-114; 2001 (PTX0434)
2099	Bloomberg Website, "Pharmaceutical Company Overview of Mylan Specialty L.P.," https://www.bloomberg.com/research/stocks/private/snapshot.asp?privcapId=3346320 (accessed May 19, 2017)
2100	Mylan Press Release, "Mylan Completes Acquisition of Meda," http://newsroom.mylan.com/2016-08-05-Mylan-Completes-Acquisition-of-Meda (accessed May 19, 2017)

2123	IMS data for Indian allergic rhinitis nasal spray products, 12.2010-12.2014 (PTX0823)
2124	IMS data for Indian allergic rhinitis nasal sprays products, March 2013 – March 2017
2126	Duonase competitor products, February MAT Nasal Sprays, 2005-2017
2130	Hitti, Miranda. "FDA Oks Generic Version of Flonase," WebMD, http://www.webmd.com/allergies/news/20060222/fda-oks-generic-version-of-flonase (accessed May 26, 2017)
2131	"What is a Tiered Formulary and What Does it Mean for Me?," Medicare News and Updates, https://blog.medicaremadeclear.com/blog/bid/78229/WhatisaTieredFormularyandWhatDoesitMeanforMe (accessed May 26, 2017)
2132	IMS data for U.S. allergic rhinitis products, May 2011 - April 2017

13. This declaration refers to several Tabs, which are appended to the end of this document. Tabs 1-7, and 9-12 represent summaries of IMS Health ("IMS") data. IMS is one of the largest vendors of physician-prescribing data in the world. Among other things, it reports revenue, prescription, and unit data, and is routinely relied upon by pharmaceutical industry professionals and researchers. The data obtained from IMS are voluminous and are not easily reviewed outside of electronic format. These Tabs are accurate summaries of the IMS data I reviewed.

D. Compensation

14. My firm bills Cipla on a time-and-materials basis for my work and that of my colleagues. My customary and usual hourly billing rate for the

time spent consulting, which includes my study of pertinent issues and materials and which applies in this matter, and any testimony I may give, is $735. I also have directed the efforts of other staff members of AG, whose customary and usual hourly billing rates range from $295 to $590. Our reasonable expenses are being compensated. My compensation is not, in any way, dependent on the outcome of this proceeding or on the substance of my opinion.

II. BACKGROUND

A. Dymista®

15. Mylan Specialty LP ("Mylan") is a wholly-owned U.S. subsidiary of Mylan N.V., and focuses on developing prescription pharmaceutical products. CIP2099, 1. Mylan N.V. acquired Meda in August 2016. CIP2100, 1. Meda (via its predecessor MedPointe Inc.) is the licensee of certain intellectual property from Cipla relating to azelastine hydrochloride ("azelastine") (an intranasal antihistamine) and fluticasone propionate ("fluticasone") (an intranasal corticosteroid) combinations. CIP2049, 1, 3-4. The agreement granted Meda an exclusive license to manufacture and market Dymista® in the U.S. CIP2049, 5-6.

16. Under the Cipla-Meda license agreement, Meda has manufactured and

marketed Dymista®, which was approved by the U.S. Food and Drug Administration ("FDA") in May 2012, and launched in the U.S. in September of that year. CIP2066, 1; CIP2067, 1; CIP2068, 2. Dymista® includes two active ingredients—azelastine and fluticasone. CIP2066, 1.

17. I understand from counsel that Mylan took over responsibility for marketing, advertising, promoting, and selling Dymista® in the U.S. as of March 31, 2017. In my analysis, however, I have relied upon many Meda documents, as indicated below, given how recently Mylan took over commercial responsibility from Meda.

B. Duonase

18. Cipla is a global pharmaceutical company headquartered in Mumbai, India. CIP2069, 2. Cipla develops and markets branded and generic products in a wide range of areas, with a particular emphasis on respiratory therapies. CIP2071, 1. According to its website, "Cipla Respiratory products are available in over 100 countries" and Cipla's products include "[a] variety of nasal sprays for treatment of nasal allergy." CIP2071, 1-2. I understand that Cipla is listed as the owner of the '620 patent.

19. In April 2004, Cipla launched a combination formulation product in India that contains azelastine and fluticasone under the brand name Duonase.

CIP2072; CIP2070, 1.

20. Within two and a half years of Duonase's introduction in the Indian marketplace, at least two other azelastine/fluticasone combination products also launched. Tab 8. Since then, I understand from counsel there have been at least sixteen other imitation azelastine/fluticasone combination products launched in the Indian marketplace, but only six of those azelastine/fluticasone products embody the challenged claims. Tabs 5 and 8. Throughout this declaration, I will refer to these products as "Imitator Products."

C. Allergic Rhinitis Marketplace

21. According to Dr. Carr, there is a range of drug classes and dosage forms available to treat allergic rhinitis ("AR"). CIP2001, ¶¶36-44. The options include antihistamines (both oral products and intranasal products); decongestants (both oral and nasal); anticholinergics (primarily nasal, but occasionally oral); leukotriene receptor antagonists (oral); mast cell inhibitors (nasal); corticosteroids (primarily nasal, but occasionally oral or parental); saline (nasal); and allergen-specific immunotherapy (injection).

22. Patients, both adults and children, exhibit a general preference for oral treatments over nasal treatments. CIP2048, 126 and 131. According to

DataMonitor, "[The AR] market [is] dominated by tablets." CIP2048, 126 and 131. According to GlobalData, that is particularly true for the treatment of milder forms of AR. CIP2053, 70.

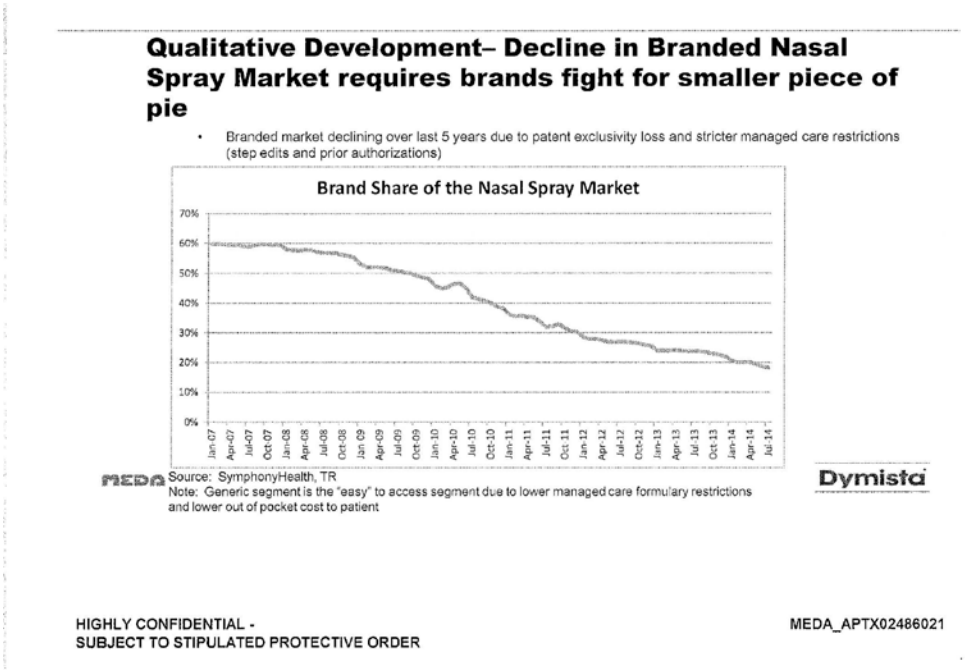
23. For those patients suffering from more severe AR symptoms or where symptoms are not adequately controlled, oral treatments (tablets) are often deemed to be inadequate. CIP2053, 70-71. For those patients, the best treatment options are often nasal sprays, like Dymista® and Duonase.

24. Over time, the marketplace for nasal sprays has become highly competitive and challenging. Two specific trends have made it so: 1) the introduction of generic nasal sprays and 2) the introduction of over-the-counter ("OTC") products.

1. Generic Products

25. In 2007, as shown below in Figure 1, according to a Meda presentation entitled "Dymista® Marketing Plan 2015," (CIP2074, 14), the branded share of the prescription nasal spray marketplace (in terms of total prescriptions) was approximately 60 percent in 2007. By July 2014, that share had fallen to less than 20 percent. CIP2074, 14; CIP2075, 2.

Figure 1



26. Flonase went generic in 2006. CIP2130, 1. Nasonex went generic on March 22, 2016. CIP2081, 1. The branded share of prescription nasal sprays has fallen to 3.9 percent as of the first four months of 2017. Tab 1.

27. Despite the dramatic shift in the ratio of branded to generic prescriptions, total revenues for branded products has continued to outpace generic revenues, according to the Meda presentation entitled "Dymista® Marketing Plan 2015," and as shown below in Figure 2. CIP2074, 11.

Figure 2

28. This phenomenon can also be observed in Tab 2, which shows that estimated revenues for branded prescription nasal sprays accounted for approximately 72.8 percent of the total revenues generated by prescription nasal sprays between 2012 and the first four months of 2016. Tab 2.

29. The fact that the share of *prescriptions* is small and falling for branded treatments, while the share of *revenues* generated by branded treatments is large and has remained quite consistent over time, suggests that the price gap between branded prescription nasal sprays and generic prescription nasal sprays is significant and growing. Tabs 1 and 2.

2. OTC Products

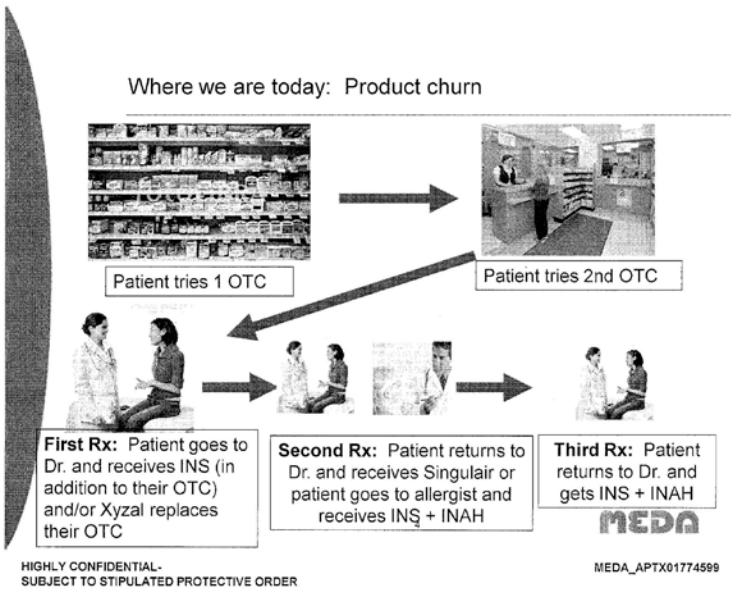
30. In addition to a shift toward generic treatments, the marketplace,

particularly in the U.S., has experienced a marked shift from the use of prescription products to the use of OTC products.

31. Nasacort was approved for OTC in October 2013. CIP2076, 3; CIP2077, 1; CIP2074, 24. Flonase was approved for OTC in June 2014. CIP2076, 3; CIP2077, 1. Rhinocort was approved for OTC in March 2015, and launched in February 2016. CIP2076, 3; CIP2077, 1; CIP2078.

32. As a result, before seeing a physician, over the last several years, AR sufferers generally have used at least one of the available OTC treatments. CIP2053, 67. This is reflected below in Figure 3 (which is contained in a 2012 Dymista® strategic plan). CIP2064, 5.

Figure 3



33. According to GlobalData, the "transition of many prescription AR drugs to OTC status has resulted in many patients being able to access previously prescribed treatments from the local pharmacy." CIP2053, 67. In fact, according to GlobalData, "mild, intermittent AR [is] mostly treated with OTC therapies." CIP2053, 70-71.

34. The easy access to OTC options has increased the prevalence of self-diagnosis among AR patients, thereby enhancing marketplace competition. CIP2053, 23.

35. Dymista® launched (and Duonase has competed) in a marketplace with multiple nasal prescription drug products, and in which a substantial number of lower-priced alternative treatments have become available.

III. COMMERCIAL SUCCESS ANALYSIS

36. As informed by counsel, I understand that, to establish commercial success of a patented invention, the patentee must show that there is marketplace success and that the thing (product or method) that is successful is the invention disclosed and claimed in the patent.

37. Based on the evidence I have seen, it is my opinion that Dymista® is a marketplace success having 1) achieved a significant level of prescriptions and revenues, and 2) achieved a strong share of the marketplace when the

shares of its closest competitors stagnated or shrank. Further, it is my opinion that Duonase and its Imitator Products are a marketplace success having 1) achieved a significant and growing level of units sold and revenues and 2) captured approximately 25 percent of nasal spray units sold and revenues in India.

38. Based on the evidence I have seen, it is also my opinion that the success of Dymista®, Duonase, and the Imitator Products has a nexus to the '620 patent because 1) those products embody the entirety of the challenged claims, 2) the success of Dymista®, Duonase, and the Imitator Products is largely attributable to the benefits of the patented invention, and 3) non-patented features, like pricing, marketing, promotion, company recognition, and reformulation are not the predominant drivers of success for Dymista®, Duonase, and the Imitator Products.

A. Dymista®

1. Absolute Success

39. Since its launch in the U.S. in September 2012, Dymista® has realized substantial and growing success.

40. According to IMS Americas data, total prescriptions of Dymista® increased from approximately 641,212 in 2013 (the first full year that

Dymista® was sold in the U.S.) to 963,299 in 2016 – a compound annual growth rate ("CAGR") of 14.5 percent. Tab 1.

41. For revenues, IMS Americas reported Dymista® U.S. revenues of almost $92 million in 2013 and more than $157 million in 2015. Tab 2. This corresponds to a CAGR of 30.9 percent. Tab 2.

2. Relative Success

42. Dymista® also has been a success relative to other treatments with which it competes.

a. Competitive Environment

43. As discussed above, Dymista® competes in a crowded marketplace in which there are many alternatives for the treatment of AR. *See* ¶¶21, 25-35 above. For the purposes of assessing Dymista®'s performance relative to its direct competitors, I have compared Dymista®'s performance with the performance of two sets of competitors used in the treatment of AR: 1) all branded prescription nasal sprays and 2) all prescription nasal sprays. The difference between the two sets is that the latter set includes generic prescription nasal sprays, while the former does not.

44. Neither competitive set includes OTC treatments. OTC treatments do not require a prescription from a physician, unlike Dymista®. As noted

above (¶32), AR sufferers will typically only visit a doctor as a last resort after having tried OTC options and found them inadequate. The treatment alternatives considered by physicians focus on prescription treatments, rather than medications that can be obtained over-the-counter. CIP2064, 5. And prescription treatments are consistent with the competitors against whom Meda compares Dymista®'s performance in its normal course of business. CIP2079, 36; CIP2074, 15; CIP2080, 12-13 and 20; CIP2075, 3.

b. Relative Performance

45. Since its launch in 2012, Dymista® has established itself as a very successful drug used in the treatment of AR. Its performance in the marketplace – in terms of total prescriptions and revenues – has outpaced the performance of most of its competitors. It now is often perceived as the option with the highest efficacy. CIP2076, 20.

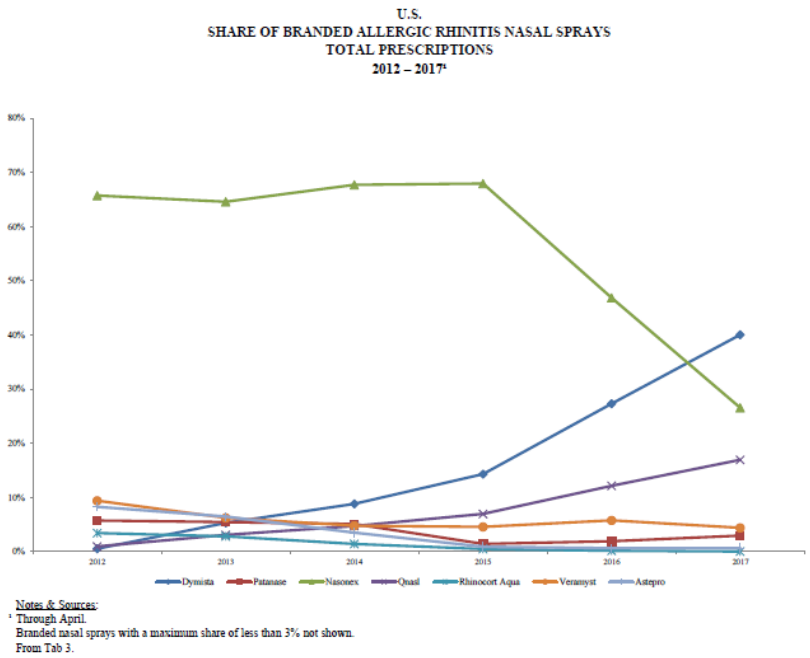
i. Branded Marketplace

46. Dymista® was notable among branded nasal sprays between 2013 and 2016 as the virtually the only branded nasal spray whose share of prescriptions increased every year. Tab 1. In fact, between 2013 and 2016, Dymista®'s share of branded prescription nasal sprays increased from 5.3 percent to 27.3 percent. Tab 3. For the first four months of 2017, its share is

40.0 percent. Tab 3.

47. Moreover, by 2014, its second full year, Dymista® became the second most-prescribed branded prescription nasal spray, following only Nasonex (which accounted for more than 60 percent of all prescriptions of branded prescription nasal sprays) and currently Dymista® is the most prescribed branded nasal spray for the treatment of AR in the United States. Tab 3. The above trends are shown in Figure 4. Tab 11.

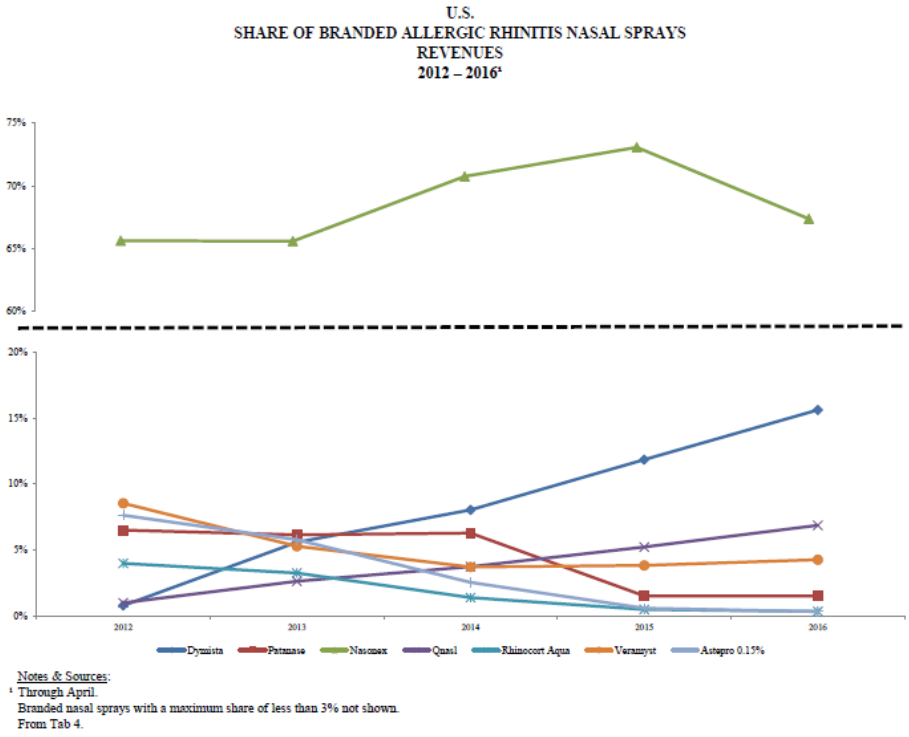
Figure 4



48. On a revenue basis, it has been very successful as well. Dymista® more than doubled its share of IMS-reported revenues generated by branded prescription nasal sprays between 2013 and 2015 – increasing from 5.6

percent to 11.9 percent of such revenues. Tab 4. By its second full year (2014), Dymista® became the second highest revenue-generating branded prescription nasal spray, following only Nasonex (which accounted for between 65.6 and 73.1 percent of all revenues generated by branded prescription nasal sprays). Tab 4. In the first four months of 2016, Dymista®'s share of such branded prescription nasal sprays rose to 15.6 percent. Tab 4. These trends are shown in Figure 5. Tab 12.

Figure 5



ii. Branded Plus Generic Marketplace

49. Among all prescription nasal sprays, Dymista®'s share of

prescriptions has been less than 2 percent. Tab 1. However, Dymista® was virtually the only branded prescription nasal spray whose share of prescriptions in this larger marketplace increased every year through 2016. Tab 1. The share of prescriptions accounted for by generic Flonase increased from 65.9 percent in 2012 to 77.9 percent in the first four months of 2017. Tab 1.

50. Among all (branded plus generic) prescription nasal sprays, Dymista® has a significant share of revenues. In fact, by 2015, Dymista® accounted for approximately 8.8 percent of total revenues generated by all prescription nasal sprays – third only to the dominant branded prescription nasal spray (Nasonex) and the dominant generic prescription nasal spray (generic Flonase). Tab 2. During the first four months of 2016, Dymista®'s share of total revenue generated by prescription nasal sprays exceeded 10 percent, due, in part, to a dramatic drop in spending on prescription Nasonex, after the FDA approved Apotex's generic version on March 22, 2016. CIP2081, 1; Tab 2.

51. Compared with the products with which Dymista® competed most closely, Dymista®'s performance in terms of prescriptions and revenues generation has been significant. Its share has grown, while those of other

competitor products largely have not.

B. Duonase (and Imitator Products)

1. Absolute Success

52. Since its launch, Duonase has experienced substantial success. Between fiscal years ending in 2005 and 2017, the number of Duonase units sold increased from 154,573 to 819,338—with increases in every year. Tab 10. This corresponds to a CAGR of 14.9 percent for more than a decade.

53. During the same period, Duonase revenues increased from approximately 21 million rupees to 174 million rupees, which, after converting to dollars,[3] reveals a CAGR of approximately 15.2 percent for more than a decade. Tab 9.

54. The magnitude and consistent growth of Duonase is particularly notable because Duonase has faced a growing number of competitors that imitated its formulation – with the first such competitor entering in October 2005 and the most recent Imitator Product entering in March 2012. Tab 8.

55. When considered collectively, the success of Duonase and the

[3] To make the Indian growth rates more comparable to those of the U.S., I computed the growth rates for Indian revenues after converting to U.S. dollars.

Imitator Products show consistent and significant growth throughout the period fiscal years 2005 through 2017, both in terms of units and revenues. Tab 9 and 10.

56. Unit sales of Duonase and the Imitator Products, as a whole, increased 1,159 percent (a CAGR of 23.5 percent) over this time. Tab 10. The revenues (in U.S. dollar terms) generated by Duonase and its Imitator Products, as a whole, increased 1,123 percent (a CAGR of 23.2 percent) during this period. Tab 9. Moreover, with few exceptions, all versions of Duonase showed consistent year-over-year growth for all of the years that these products were available. Tabs 9 and 10.

2. Relative Success

57. I understand that the patented technology is incorporated into Duonase and its Imitator Products in the Indian marketplace. CIP2007, ¶¶64-77; CIP2001, ¶¶142-143, 146-152. Under these circumstances, an appropriate way to assess the relative performance of patented products in the Indian marketplace is to compare the collective performance of Duonase and its Imitator Products to the performance of all prescription nasal sprays that contain either an antihistamine or a steroid, and are used for the treatment of AR. Such a comparison provides insights into the extent to

which the use of the patented technology is associated with notable performance among comparable products sold in the same marketplace.

58. Considering Duonase and the Imitator Products as a whole, the performance of these products has been remarkable and consistent since 2004, both in terms of units and the amount of revenue generated compared to other nasal AR treatments. In fact, between calendar year ending 2010 (the earliest year for which relevant comparison data are available) and fiscal year 2017 (the latest year for which relevant comparison data are available),[4] Duonase and its Imitators Products, as a whole, have consistently accounted for approximately 24 to 26 percent of all sales of prescription nasal sprays used for the treatment of AR in India – as measured by both the number of units sold and the amount of revenue generated (according to IMS India). Tabs 5, 6, and 7.

C. Nexus of Patent to Dymista® Success

59. I understand from both Drs. Smyth and Carr that Dymista® is a

[4] Due to data limitations, for Tabs 5, 6, and 7, data for 2010 to 2012 are shown in calendar years, while 2013 to 2017 are shown as fiscal years ending March 31.

commercial embodiment of the entirety of the challenged claims. CIP2007, ¶¶64-65; CIP2001, ¶¶97, 142-143. I further understand from Drs. Smyth and Carr that Dymista®'s patented formulation containing both azelastine and fluticasone:

1) is a stable and operable combination of an azelastine hydrochloride solution and a fluticasone propionate suspension;

2) is a dosage form suitable for nasal administration in that it is tolerable to patients and is able to deposit the formulation on the nasal mucosa;

3) has proven to be more efficacious than the traditional, gold-standard AR treatment—intranasal steroids;

4) has proven to provide more complete symptom relief that is possible with a monotherapy because it combines both fast-acting (due to the antihistamine azelastine) and sustained symptom relief (due to the intranasal steroid fluticasone);

5) has been proven to be faster acting than azelastine monotherapy treatment; and

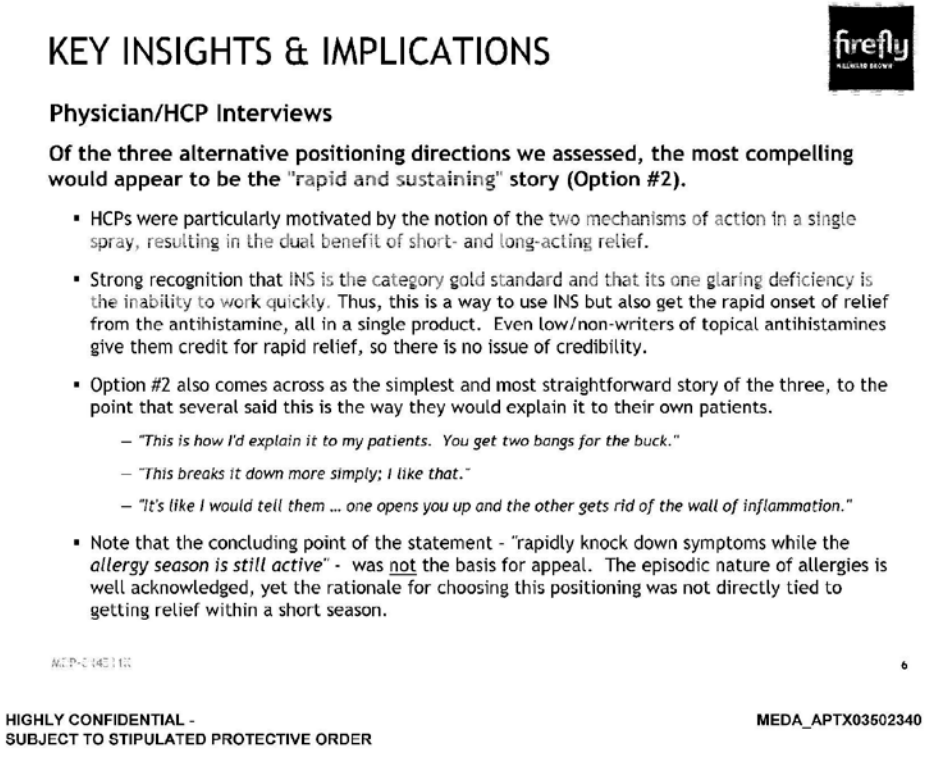
6) has been proven to exhibit fewer side effects than either

azelastine monotherapy or fluticasone monotherapy products.

CIP2007, ¶¶64-65, 83; CIP2001, ¶¶103-126.

60. Even prior to the launch of Dymista®, Meda had identified these same benefits as critical for differentiating Dymista® in the marketplace. For example, in a July 2011 document entitled "Dymista® Phase II – Positioning Exploration" (CIP2082), it was reported that the features tied to the use of the patented technology were those features of Dymista® that were most attractive to physicians. These results are shown in Figure 6. CIP2082, 6.

Figure 6



KEY INSIGHTS & IMPLICATIONS

firefly

Physician/HCP Interviews

Of the three alternative positioning directions we assessed, the most compelling would appear to be the "rapid and sustaining" story (Option #2).

- HCPs were particularly motivated by the notion of the two mechanisms of action in a single spray, resulting in the dual benefit of short- and long-acting relief.
- Strong recognition that INS is the category gold standard and that its one glaring deficiency is the inability to work quickly. Thus, this is a way to use INS but also get the rapid onset of relief from the antihistamine, all in a single product. Even low/non-writers of topical antihistamines give them credit for rapid relief, so there is no issue of credibility.
- Option #2 also comes across as the simplest and most straightforward story of the three, to the point that several said this is the way they would explain it to their own patients.
  - *"This is how I'd explain it to my patients. You get two bangs for the buck."*
  - *"This breaks it down more simply; I like that."*
  - *"It's like I would tell them … one opens you up and the other gets rid of the wall of inflammation."*
- Note that the concluding point of the statement - "rapidly knock down symptoms while the *allergy season is still active*" - was not the basis for appeal. The episodic nature of allergies is well acknowledged, yet the rationale for choosing this positioning was not directly tied to getting relief within a short season.

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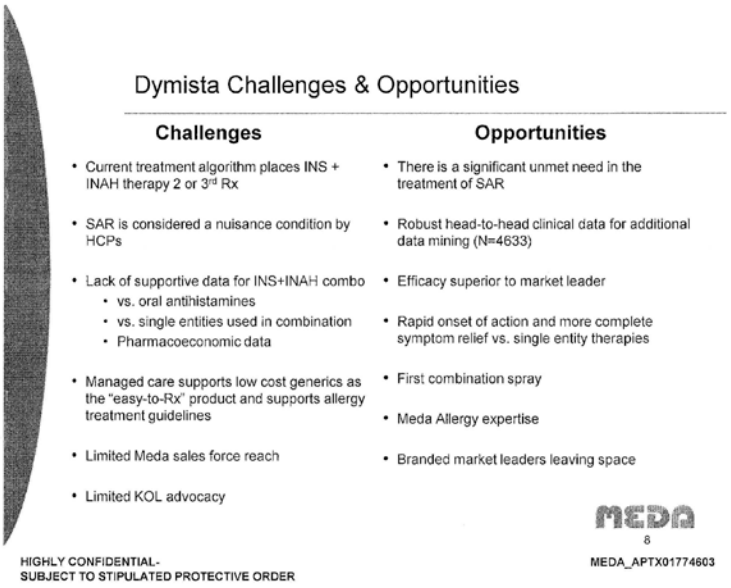
61. The "Key Insights & Implications" continued on to conclude that, of

the 15 proposed marketing statements, "[p]rovides both rapid and sustained relief," "[s]ignificantly better than fluticasone," and "[p]rovides rapid symptom relief in as little as 30 minutes" were ranked by physicians as being among the most impactful. CIP2082, 9.

62. Similarly, in the 2012 Dymista® Strategic Plan, which was presented October 28, 2011, Meda identified several "Opportunities" relating to its marketing of Dymista®, which were "[e]fficacy superior to market leader," "[r]apid onset of action and more complete symptom relief vs. single entity therapies," and "[f]irst combination spray," as shown below in Figure 7. CIP2064, 9.

Figure 7

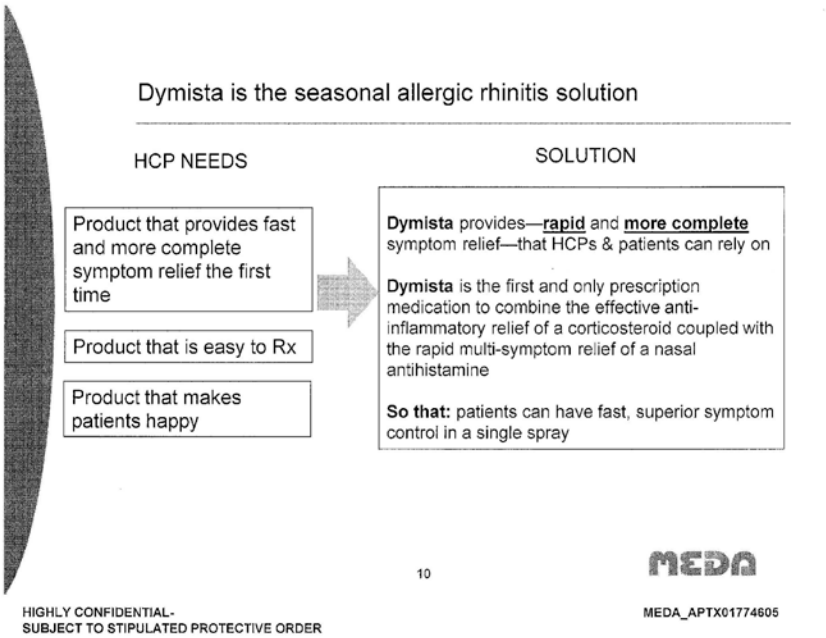


63. As shown in Figure 7, Meda noted that other branded companies are

leaving the space, which Meda viewed as an opportunity for Dymista®. CIP2064, 9. Meda considered Dymista®'s unique benefits as quite attractive.

64. Additionally, the 2012 Dymista® Strategy Plan continued by identifying Dymista® as the solution of seasonal allergic rhinitis. As shown in Figure 8 below, Meda positioned Dymista® to emphasize its "rapid and more complete symptom relief" and emphasized that Dymista® "combine[s] the effective anti-inflammatory relief of a corticosteroid coupled with the rapid multi-symptom relief of a nasal antihistamine" to provide patients "fast, superior symptom control." CIP2064, 11.

Figure 8

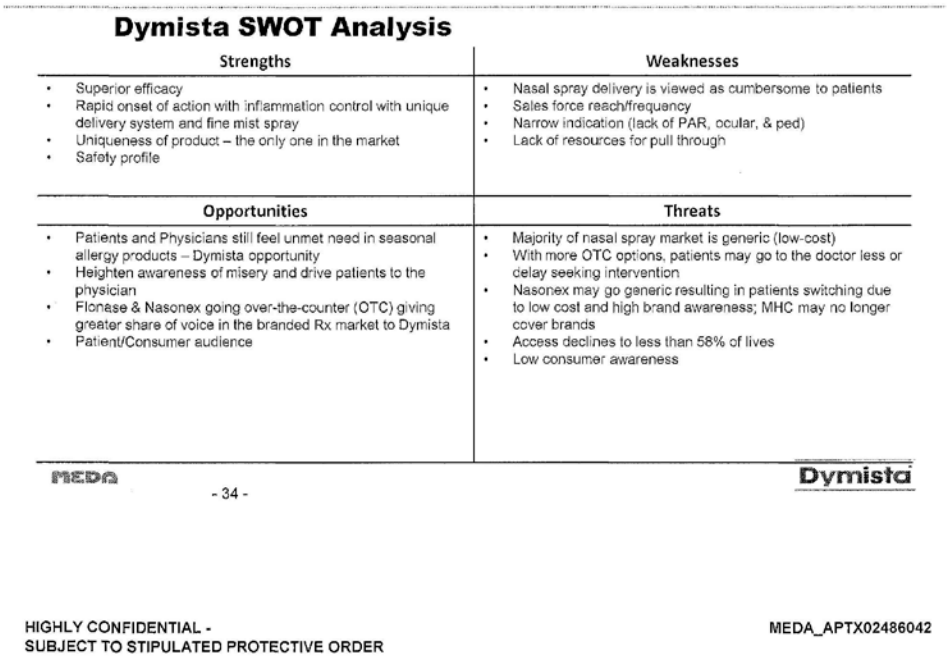


65. As Meda prepared for Dymista®'s commercial launch, the key

differentiating features Meda identified were those that are directly linked to the '620 Patent—namely, 1) a combination spray containing an antihistamine azelastine with a corticosteroid fluticasone, 2) the rapid and more complete relief provided by the azelastine/fluticasone combination, and 3) better efficacy compared with the leading AR treatments provided by the azelastine/fluticasone combination. CIP2064, 9 and 11.

66. After Dymista®'s commercial launch in September of 2012, Meda continued to market Dymista® by informing physicians, patients, and the public about the benefits of the teachings of the '620 Patent. In Figure 9, which is from the 2015 Dymista® Marketing Plan, dated November 14, 2014, Meda identified features made possible by the patented technology as the main strengths of Dymista®, including "[s]uperior efficacy" and the "[r]apid onset of action with inflammation control." CIP2074, 35. Meda also indicated that an important strength of Dymista® was that it was unique in the marketplace as the only combination treatment for AR. CIP2074, 35.

Figure 9



Dymista SWOT Analysis

Strengths	Weaknesses
• Superior efficacy • Rapid onset of action with inflammation control with unique delivery system and fine mist spray • Uniqueness of product – the only one in the market • Safety profile	• Nasal spray delivery is viewed as cumbersome to patients • Sales force reach/frequency • Narrow indication (lack of PAR, ocular, & ped) • Lack of resources for pull through
Opportunities	**Threats**
• Patients and Physicians still feel unmet need in seasonal allergy products – Dymista opportunity • Heighten awareness of misery and drive patients to the physician • Flonase & Nasonex going over-the-counter (OTC) giving greater share of voice in the branded Rx market to Dymista • Patient/Consumer audience	• Majority of nasal spray market is generic (low-cost) • With more OTC options, patients may go to the doctor less or delay seeking intervention • Nasonex may go generic resulting in patients switching due to low cost and high brand awareness; MHC may no longer cover brands • Access declines to less than 58% of lives • Low consumer awareness

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67. Meda viewed the patented benefits as the main features that distinguished Dymista® in a challenging marketplace. In the Strengths, Weaknesses, Opportunities, and Threats ("SWOT") analysis shown above, Meda considered Dymista®'s success to be critically driven by its superior efficacy. CIP2074, 35.

68. And, several Meda advertisements and promotional aids similarly highlighted features of Dymista® that relate to the patented technology, including the 1) combination of the antihistamine azelastine and the corticosteroid fluticasone and rapid symptom relief (CIP2083, 5-7; CIP2084,

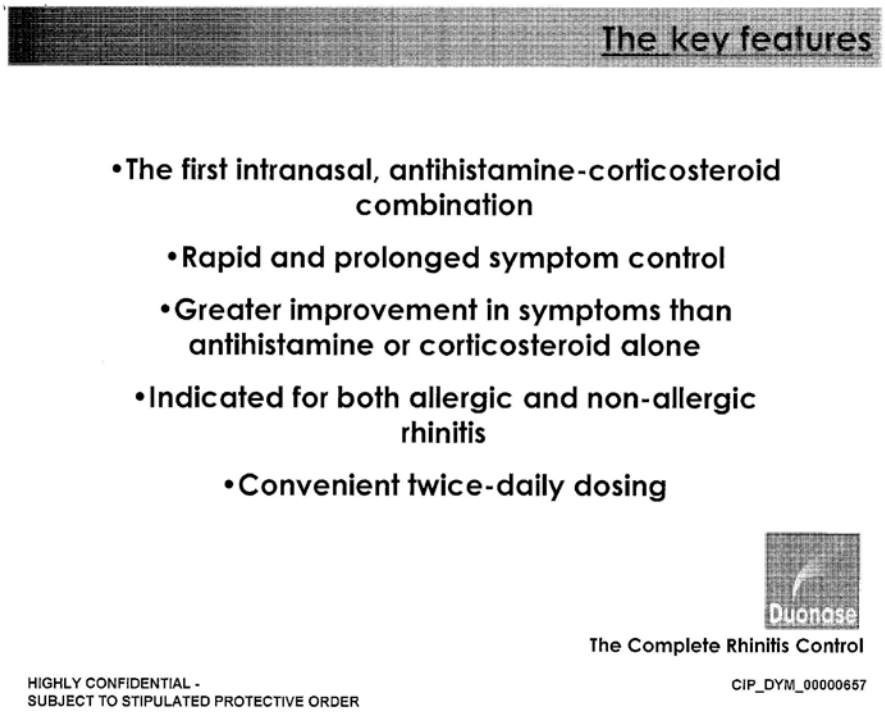
4; CIP2085, 25), 2) superior symptom relief compared to competing AR treatments (CIP2086, 3-4; CIP2084, 5-6; CIP2085, 23 and 33), and 3) sustained symptom relief. CIP2084, 7.

D. Nexus of Patent to Duonase Success

69. As with Dymista®, I understand from both Drs. Smyth and Carr that Duonase and the Imitator Product are embodiments of the entirety of many of the challenged claims. CIP2007, ¶¶64-77; CIP2001, ¶¶142-143, 146-152. In addition, I understand from Drs. Smyth and Carr that Duonase's patented formulation has the same benefits as Dymista®. CIP2007, ¶¶64-77, 83; CIP2001, ¶¶142-143, 146-152.

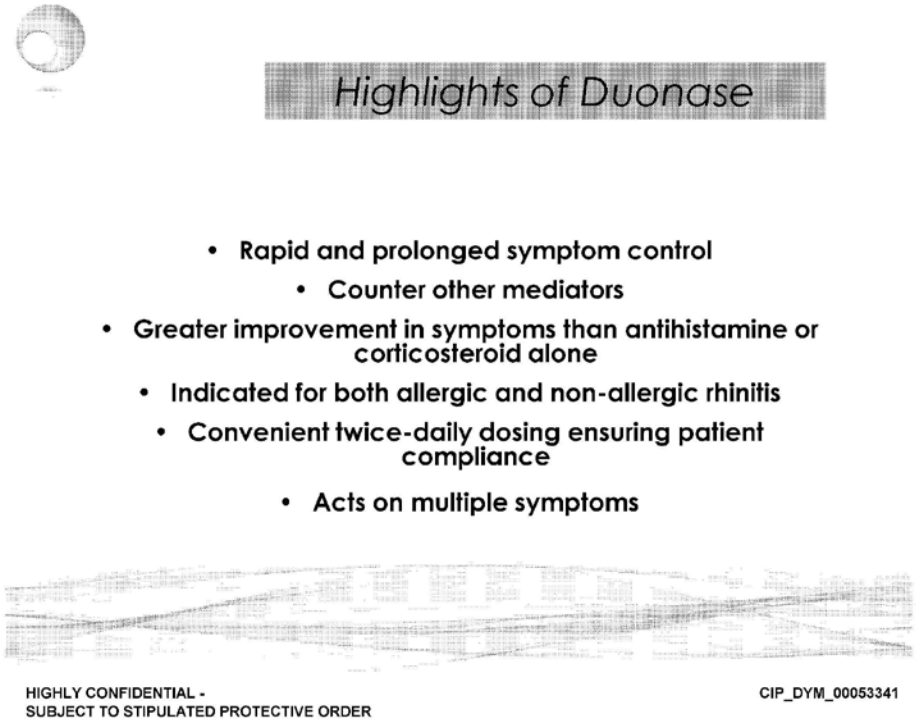
70. The points of emphasis cited by Meda are consistent with the features that were most heavily identified and promoted by Cipla for Duonase, as shown in Cipla's documents. For example, one Cipla marketing document that outlined Duonase's promotional strategy included the following summary of the key features of Duonase, shown in Figure 10. CIP2087, 14.

Figure 10



71. Another Duonase marketing document, entitled "What COMPLETE means to you?", highlighted similar key features of Duonase that correspond to the benefits provided by the patented technology, as shown in Figure 11. CIP2088, 28.

Figure 11



E. Third Party Assessments

72. Beyond Meda and Cipla documents, I also considered what the relevant industry—here physicians, patients, and the larger healthcare industry—viewed as the products' strengths to determine whether those strengths are related to the ’620 Patent.

73. In fact, several industry reports and physician testimonials have highlighted the patented benefits as important to the success of the products.

74. In a September 2015 report, GlobalData identified several strengths of Dymista®, as shown below, including “[d]emonstrated superior efficacy in

clinical trials compared with azelastine, fluticasone, and placebo," "[r]apid onset of action can be effective within minutes, and produces a significant reduction in symptoms within days," "[g]ood safety and tolerability profile should improve patient adherence," and "[t]rial shows improvement over INCS alone, which are currently the gold standard of AR therapy." CIP2053, 133.

75. Furthermore, the GlobalData report selected Dymista® as the branded product with the most growth potential, specifically highlighting the fact that it was the first intranasal combination AR treatment to be approved in the U.S. CIP2053, 208.

76. The GlobalData report also contained quotes from opinion leaders throughout the industry and around the world. For example, a U.S. key opinion leader said, "I think Dymista® is fantastic. I would probably put everyone on it if the insurance would pay," and he noted that compliance is superior with the product. CIP2053, 128.

77. An E.U. opinion leader, addressing the strengths of Dymista®, stated "[w]e now have the nasal antihistamine, azelastine, plus the nasal steroid, fluticasone, in one spray as a [fixed-dose] combination [product], which makes it easier for the patient to be compliant." CIP2053, 128.

78. Other physicians also have recognized the importance of the patented benefits to demand for Dymista®. For example, during a discussion of AR in 2015, a University of Utah physician emphasized that his patients have particularly enjoyed using just one medication instead of two separate ones. CIP2089, 3. Another physician from Family Allergy and Asthma Care of Montana in 2013 wrote that Dymista® "has the advantage of containing 2 very good medications with distinct mechanisms." CIP2090, 1.

79. Dr. Sujeet Rajan had a similar observation, relating to Duonase. In a declaration dated August 16, 2011, Dr. Rajan wrote,

> Duonase[] solves many of the[] long term problems [associated with previous treatments of AR]. Duonase[] provides superior and almost immediate relief from symptoms of AR, so much so that our patient's [sic] compliance and adherence with treatment improves [sic] considerably. Improved compliance and adherence ensures [sic] that my patients not only get fluticasone with the fast-acting azelastine, *but continue to take it* for periods ranging from 2 weeks to 2 months. EX1002, 408-09. (Emphasis in original.)

80. A recent article by four professors of medicine from Europe also emphasized the quality of Dymista® as it relates to the patented benefits. It focused on the importance of simplifying rhinitis treatment, and pointed out,

> [t]he innovation of Dymista® derives from the incorporation of two potent drugs from different medication classes with complementary effects… in a novel, patented formulation and an improved device. CIP2091, 2.

81. The article also noted that the combination of drugs simplifies the treatment protocol and, thus, encourages compliance. CIP2091, 4.

F. Importance of Non-Patented Contributions

82. I understand that the test for commercial success does not require that the patented features be the only reasons for a product's success. Instead, the patented features must be motivating (or important) factors. Accordingly, the existence of other demand drivers does not negate a showing of commercial success. This makes eminent economic sense. Demand for a product, pharmaceutical or not, is driven by a host of factors, not just one. CIP2092, 4. Thus, the existence of other demand drivers does not negate a showing of commercial success. In the present context, several non-patent-related features warrant some consideration.

1. Pricing

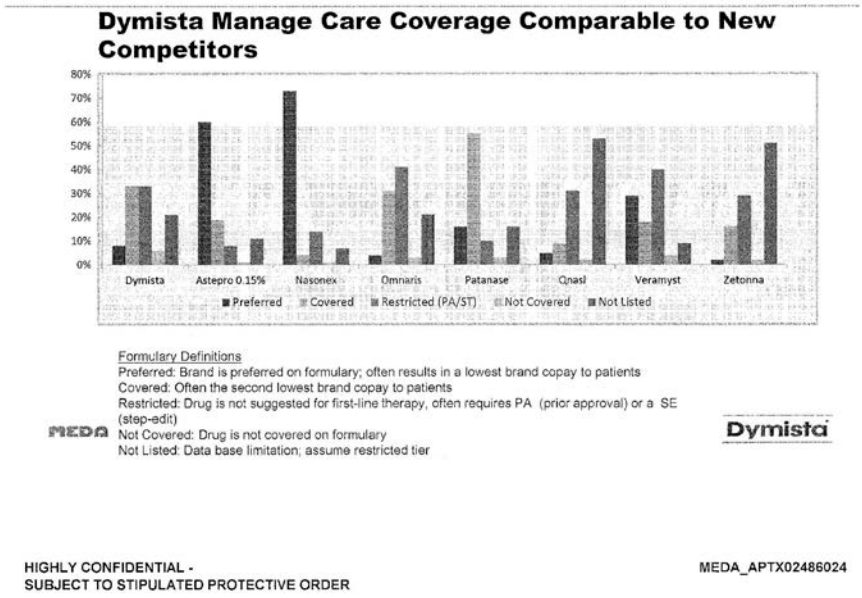
83. As a general matter, low net prices for a branded (or any) drug can encourage usage of the drug. Low pricing, however, does not appear to be a significant contributor to Dymista®'s marketplace success.

84. Formulary status (as determined by insurance carriers) significantly drives relative pricing among AR (or any) drugs in the U.S. Insurance carriers place prescription drugs on formulary tiers, which then dictate the co-payment that patients will be responsible for in order to access the drug. Tier 1 is typically for generic drugs and has the lowest copay; tier 2 is for preferred branded drugs and has a slightly higher copay than tier 1; and lower tiers are typically for non-preferred branded drugs and have the highest copay. CIP2131, 2.

85. Since its launch in September 2012, Dymista® has not enjoyed particularly favorable formulary status (and, therefore, price) among nasal sprays used for the treatment of AR. In Meda's 2015 Dymista® Marketing Plan, from among the 10 largest insurance carriers, Dymista® had tier 2 formulary status in four of the mid-size carriers, had a tier 3 status in another four mid-size carriers, and was blocked (significantly restricting, if not effectively denying, access) by another two carriers, including one of the largest insurance carriers (CSV Caremark). CIP2093, 18.

86. Dymista®'s somewhat-unfavorable formulary status relative to competitive products as of the end of 2014 is illustrated below in Figure 12. CIP2074, 17.

Figure 12



87. This chart shows that branded prescription products Nasonex, Astepro 0.15%, Veramyst, and Patanase all enjoy "Preferred Status" much more frequently than Dymista®, and that Patanase also enjoys a much better position in "Covered Status" compared with Dymista®. In short, Dymista® is the more expensive option on many insurance plans (if it is covered by insurance at all) versus many of Dymista®'s closest competitors.

88. Further, physicians and pharmacists identified cost/co-pay amount and lack of formulary coverage as some of the main disadvantages of Dymista®. CIP2074, 31, and 35-36. And some physicians believe they are unable to prescribe Dymista® as much as they would like due to the current lack of, or

highly restrictive, insurance coverage. CIP2053, 128.

89. Any rebates or discounts Meda may provide effectively lowers the price patients pay for Dymista®. But again, as shown by Meda's 2014 rebates provided to insurance carriers, Meda's rebates provided very little, if any, competitive advantage. CIP2094, 13. In fact, Meda offered CVS Caremark a 58 percent rebate for tier 2 status, but was told by CVS Caremark, "Your rebate was phenomenal; however you still can't replace the Nasonex dollars." CIP2095, 1. Dymista®'s relative pricing is not an advantage in the marketplace.

2. Marketing and Promotion of Dymista®

90. The type and extent of advertising for any product or service varies, depending on the nature of the promoted goods and/or services. Advertising serves many purposes. Informative advertising notifies consumers of a product's existence and its characteristics, while persuasive advertising seeks to create what economists refer to as "spurious product differentiation." CIP2096, 5-6. Recent research on pharmaceutical promotion has found that pharmaceutical promotion is primarily informative with respect to choices among differentiated drugs, but it is persuasive with respect to undifferentiated drugs. CIP2097, 5.

91. Further, prescription drugs, like Dymista®, are "experience goods" that must be tried in order to assess the quality of the product. Promotion for experience goods initially seeks to inform customers of the product's existence and to encourage them to try the product, but following trial, the physician's and consumer's own experience with the product, rather than promotional efforts alone, will dictate future consumption decisions. CIP2098, 11-12 ("Clearly, prescription drugs are predominantly experience goods.… Moreover, since physicians primarily make prescribing decisions, much pharmaceutical marketing is focused on them, with detailers providing information and free samples to physicians to encourage them to experiment with their product.").

92. The primary goal of promotion in the pharmaceutical industry is to encourage physicians and patients to try a drug in order to experience the drug first-hand. Continuing success following the initial experience is likely to reflect the quality of the experience, rather than the impact of marketing efforts themselves.

93. Although Meda actively promoted Dymista®, Meda's documents indicate that Meda's ongoing sales and promotional efforts were not significant drivers of sales. In fact, the "sales force reach/frequency" was

identified as a Weakness for Dymista®, along with "lack of resources for pull through." CIP2074, 35; CIP2064, 9. In addition, third party opinions suggest that the marketing for Dymista® in the U.S. was not as effective as it could have been. GlobalData's SWOT analysis identified a "Threat" to the Dymista® brand that if "a [competing] company with a bigger sales force than Meda enter[s] the race, it could see substantial sales." CIP2053, 133.

94. The GlobalData study also included physician feedback regarding Dymista® and Meda, indicating that Meda's sales and promotional efforts for Dymista® were not a significant driver of sales:

> [a] combination of another corticosteroid and [an] antihistamine — I think it would be competitive…Meda is, as you know, the company that has Dymista[®], and they're a small company. If you put that drug in the hands of Merck, I think you would have seen [it take off much stronger] with their marketing potential… if you took that combination of drug[s], with a large pharma [company], you probably would have something that would be profitable, very much so, over time. …
>
> It's not really brand awareness per se, but I think what it is, is strength in the sales and marketing arena…So, a company with a very large sales force and marketing arm that can reach not only to allergy specialists, like Meda, but also to primary care offices, where the majority of the prescriptions, because of the vast number of

> physicians, are written, yes, I think they would have a greater financial success. CIP2053, 127 and 129.

95. Furthermore, even though the effect of Meda's marketing and promotional efforts may have been limited, Meda's marketing and promotion of Dymista® focused on informing patients of the clinical and therapeutic benefits of Dymista®, including faster symptom relief, more complete symptom relief, and superior symptom relief compared to market leading products, which are covered by the challenged claims. CIP2083, 5-7; CIP2084, 4-7; CIP2085, 25; CIP2086, 3-5; CIP2082, 6-9; CIP2064, 9-11; CIP2074, 35. Because the patented clinical attributes were integral to Dymista®'s marketing message, marketing could not have been effective without these attributes, and therefore, non-patented marketing and promotion alone were not the primary drivers of Dymista®'s success.

3. Reputation of Cipla

96. There is little question that Cipla is one of the oldest and largest pharmaceutical companies in India. In spite of that, it does not appear that its brand recognition is the primary driver of the success of Duonase. In fact, Cipla's reputation does not explain the fact that many of the Imitator Products also have achieved tremendous success in units sold and revenues.

Imitator Products are manufactured by competitor companies of Cipla and could not, and did not, enjoy any benefit from the strength of Cipla's brand.

97. Cipla's reputation has not been a significant driver of the success of Duonase and its Imitator Products.

4. Reformulation of Duonase

98. I understand from counsel that Cipla reformulated Duonase in 2010 to include a sweetening agent to mask the bitter taste of azelastine. However, sales of Duonase indicate that the inclusion of a sweetener and its associated marketing campaign were not primary drivers of Duonase's success. In fact, sales data show strong growth both before and after the rollout of the Duonase reformulation in 2010. The unit sales growth between fiscal years ending 2005 and 2009 generated a CAGR of 26.3 percent, and the growth between fiscal years ending 2010 and 2017 generated a CAGR of 9.4 percent.[5] Tab 10.

99. The same trend can be found in revenues as well, where they (in U.S. dollars) grew at a CAGR of 28.8 percent between fiscal years ending 2005

[5] Calculated as (393,594 / 154,573)^(1/4) - 1 = 26.3%; and (819,338 / 435,695)^(1/7) - 1 = 9.4%.

and 2009, and a CAGR of 9.2 percent between fiscal years ending 2010 and 2017.[6] Tab 9.

100. Even if a portion of Duonase's sales were attributable to use of a sweetener, this would not negate the fact that the patented technology confers the fundamental characteristics to Duonase and its reformulation that differentiate them from other treatment alternatives in the marketplace.

101. The reformulation was not a significant driver of Duonase's success. In fact, growth declined after the reformulation.

G. Revealed Preferences

102. Particularly useful indicators of marketplace success include decisions that have been made with regard to the products in question, such as the decision to commit (and continue to commit) resources to the sale of any product. No company is compelled to pursue or continue such activities, and the decision to continue is an economic/financial choice, as all companies involved have the option to deploy or reallocate their resources to other, presumably higher value, endeavors at any time, if such exist.

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[6] Calculated as ($1,307,689 / $474,970)^(1/4) - 1 = 28.8%; and ($2,588,624 / $1,400,291)^(1/7) - 1 = 9.2%.

103. In the U.S., Apotex Inc. has committed resources to entering the business with a generic version of Dymista®. CIP2017, 3. Apotex's actions are particularly significant because Apotex already markets a commercial azelastine nasal spray and a commercial fluticasone nasal spray. CIP2065, 2 and 9. Apotex must view the combination of these drugs into a single product, like Dymista®, as competitively advantageous. CIP2065, 2 and 9.

104. In India, imitation of Duonase began within 2 years of its launch, and also began after Indian competitors to Cipla had access to Duonase, were able to observe Duonase's performance, and, as I understand from counsel, had access to the patent application that ultimately led to the '620 Patent. Tab 8.

105. The simple fact that companies have decided to commit resources to developing versions of Dymista® and Duonase suggests that all of these companies have viewed Dymista® and Duonase as sufficiently successful in the marketplace such that the marketplace can economically support more versions of the same formulation. If the patented technology were not considered successful, it would make little economic sense for new entrants to choose to launch an imitation Duonase or a new Dymista® product rather than an imitation version of any other branded drug in the marketplace.

H. Cipla-Meda License Agreement

106. Another useful indicator of nexus here is Meda's licensing of this technology for use in the U.S. Meda licensed in the patented technology and contracted with Cipla to obtain rights to Cipla's intellectual property, including the '620 Patent. CIP2049, 5-6, and 28 (identifying PCT/GB03/002557). I understand from Dr. D'Addio that Meda was unable to develop an azelastine/fluticasone combination product without Cipla's patented technology. CIP2003, ¶¶22-28.

107. Meda's action of taking a license reveals that Meda viewed the licensed intellectual property as quite valuable. The Cipla-Meda agreement committed Meda to paying Cipla $1.5 million dollars in licensing fees and milestone payments. Moreover, Meda accepted responsibility for all costs associated with clinical development and regulatory approval for any product resulting from the license. CIP2049, 7-8.

108. The license was Cipla's first business deal with Meda, and Cipla wanted to start the relationship with a level of trust and respect. CIP2021, 292-93. This is consistent with the fact that Meda and Cipla subsequently agreed to a 15 percent royalty, and further supports my opinion that Cipla's licensed intellectual property is quite valuable. CIP2050, 3.

IV. RESPONSE TO ARGENTUM'S PETITION

109. I have reviewed Argentum's petition for *inter partes* review as it relates to commercial success.

110. Argentum did not contend that Dymista® or Duonase are not embodiments of the challenged claims of the '620 Patent.

111. From my review of the petition, Argentum appears to make two arguments that relate to commercial success: 1) the commercial success evidence submitted by Cipla during prosecution of the '620 Patent is "weak and lacks nexus." (Petition, Paper 2, at 58-59) and 2) certain patents (U.S. Patent Nos. 5,164,194 to Hettche (EX1007, "Hettche") and 4,335,121 to Phillipps (EX1009, "Phillipps")) "legally blocked" others from commercializing an azelastine/fluticasone combination product. Pet. 56-58.

112. For the first point, Argentum's contention appears to be that Cipla did not show "significant sales in a relevant market." Pet. 58. In fact, Cipla did present that evidence in the Declaration of Nikhil Chopra, submitted during prosecution. EX1002, 276-83. The "relevant market" used by Mr. Chopra was all azelastine/fluticasone combination products. Table 2 of Mr. Chopra's Declaration shows the Duonase is first in the number of units from among this cohort. EX1002, 279-80. Further, Mr. Chopra's Declaration also shows

in Figure 3 that Duonase represents 55.7 percent of all sales of this same cohort of azelastine/fluticasone combination products. EX1002, 282.

113. As to Argentum's criticism that Mr. Chopra's Declaration failed to present evidence of "what level of sales should have been expected," Mr. Chopra noted, in paragraphs 8 and 9, Duonase established this business, and no competitor has exceeded its success. Tabs 9 and 10.

114. For the point on the alleged blocking patents, it does not appear that the Hettche and Phillipps patents, in fact, prevented any other company from developing and commercializing azelastine/fluticasone combination products in the U.S. before Dymista®.

115. The Hettche patent expired at least a year before, and the Phillipps patent expired years before, Dymista®'s FDA-approval in May 2012. EX1007, 1; EX1009, 1. I understand from counsel that activities necessary for FDA approval fall within a safe harbor from patent infringement liability. As applied here, a competitor was free to develop an azelastine/fluticasone combination product under the safe harbor (before May 2011) and to commercialize that product (after May 2011), beating Dymista® to the marketplace.

116. Further, Argentum cited to no evidence that any entity was actually

blocked by the Hettche and Phillipps patents. In fact, publicly-available evidence shows that competitors were not blocked. At least one competing pharmaceutical company, CyDex, was developing an azelastine/budesonide nasal spray product as early as 2009. CIP2048, 215-216. And, I understand from counsel that CyDex filed patent applications, along with Proctor & Gamble (EX1011) and Warner-Lambert (EX1012), relating to azelastine combination products for treating AR. The fact that these patents were filed before the Hettche patent expired suggests that these companies were not blocked by the Hettche patent or were otherwise dissuaded from developing azelastine products.

V. CONCLUSION

117. Based upon my review of the available evidence, it is my opinion that Dymista® and Duonase (and the Imitator Products) are marketplace successes, and that the success of these products is due, in large part, to the benefits and advantages of the patented inventions. As a result, the claims of the patent at issue have been a commercial success.

118. My opinions may change before hearing if additional information from either party or its experts becomes available.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information and belief.

John C. Jarosz
May 30, 2017

TAB 1

U.S.
ALL ALLERGIC RHINITIS NASAL SPRAYS
IMS NPA DATA
TOTAL PRESCRIPTIONS
2012 – 2017[1]

	2012		2013		2014		2015		2016		2017[1]		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Branded														
Dymista	70,067	0.1%	641,212	1.2%	890,234	1.5%	972,960	1.8%	963,299	1.8%	286,335	1.6%	3,824,107	1.3%
CAGR Since 2013		-		-		38.8%		23.2%		14.5%		-		-
Steroid														
Beconase	5	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	5	0.0%
Beconase AQ	64,172	0.1%	51,669	0.1%	38,854	0.1%	28,867	0.1%	21,596	0.0%	7,139	0.0%	212,297	0.1%
Clarispray Nasal Allergy	0	0.0%	0	0.0%	0	0.0%	0	0.0%	54	0.0%	66	0.0%	120	0.0%
Flonase	77,479	0.2%	62,343	0.1%	38,945	0.1%	13,996	0.0%	2,065	0.0%	235	0.0%	195,063	0.1%
Child Flonase Allergy	0	0.0%	0	0.0%	0	0.0%	0	0.0%	5,471	0.0%	2,974	0.0%	8,445	0.0%
Flonase Sensimist	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	4,481	0.0%	4,481	0.0%
Nasacort	28	0.0%	21	0.0%	91	0.0%	165	0.0%	124	0.0%	25	0.0%	454	0.0%
Nasacort AQ	174,776	0.3%	96,368	0.2%	11,881	0.0%	1,100	0.0%	459	0.0%	74	0.0%	284,658	0.1%
Childrens Nasacort	0	0.0%	0	0.0%	0	0.0%	112	0.0%	2,343	0.0%	1,312	0.0%	3,767	0.0%
Nasalide	5	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	5	0.0%
Nasarel	24	0.0%	30	0.0%	36	0.0%	143	0.0%	85	0.0%	28	0.0%	346	0.0%
Nasonex	8,761,824	17.2%	7,831,691	14.5%	6,832,683	11.7%	4,621,928	8.5%	1,652,443	3.2%	189,805	1.0%	29,890,374	10.3%
Omnaris	353,107	0.7%	258,471	0.5%	162,024	0.3%	87,468	0.2%	54,535	0.1%	13,432	0.1%	929,037	0.3%
Qnasl	126,822	0.2%	372,305	0.7%	477,684	0.8%	474,338	0.9%	428,625	0.8%	121,210	0.7%	2,000,984	0.7%
Qnasl Child	0	0.0%	0	0.0%	0	0.0%	33,915	0.1%	47,280	0.1%	15,570	0.1%	96,765	0.0%
Rhinocort	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Rhinocort Allergy	0	0.0%	0	0.0%	0	0.0%	0	0.0%	12,809	0.0%	5,890	0.0%	18,699	0.0%
Rhinocort Aqua	456,160	0.9%	341,615	0.6%	141,492	0.2%	31,950	0.1%	5,360	0.0%	188	0.0%	976,765	0.3%
Ticanase	0	0.0%	0	0.0%	0	0.0%	0	0.0%	333	0.0%	25	0.0%	358	0.0%
Ticaspray	0	0.0%	0	0.0%	0	0.0%	0	0.0%	73	0.0%	24	0.0%	97	0.0%
Vancenase	30	0.0%	25	0.0%	14	0.0%	0	0.0%	0	0.0%	0	0.0%	69	0.0%
Vancenase AQ 84Mcg	34	0.0%	21	0.0%	11	0.0%	0	0.0%	0	0.0%	0	0.0%	66	0.0%
Veramyst	1,252,469	2.5%	756,760	1.4%	481,581	0.8%	310,370	0.6%	202,982	0.4%	31,423	0.2%	3,035,585	1.1%
Zetonna	40,675	0.1%	212,049	0.4%	124,910	0.2%	62,761	0.1%	37,666	0.1%	8,776	0.0%	486,837	0.2%
Branded Steroid Total	11,307,610	22.2%	9,983,368	18.5%	8,310,206	14.2%	5,667,113	10.4%	2,474,303	4.7%	402,677	2.2%	38,145,277	13.2%
Antihistamine														
Astelin	82,275	0.2%	51,799	0.1%	21,839	0.0%	2,773	0.0%	413	0.0%	51	0.0%	159,150	0.1%
Astepro	1,102,104	2.2%	785,544	1.5%	352,880	0.6%	61,229	0.1%	22,338	0.0%	4,787	0.0%	2,328,882	0.8%
Patanase	764,012	1.5%	661,080	1.2%	512,115	0.9%	96,989	0.2%	66,887	0.1%	21,097	0.1%	2,122,180	0.7%
Branded Antihistamine Total	1,948,391	3.8%	1,498,423	2.8%	886,834	1.5%	160,991	0.3%	89,638	0.2%	25,935	0.1%	4,610,212	1.6%
Branded Total	13,326,068	26.1%	12,123,003	22.4%	10,087,274	17.2%	6,801,064	12.5%	3,527,240	6.7%	714,947	3.9%	46,579,596	16.1%

TAB 1

U.S.
ALL ALLERGIC RHINITIS NASAL SPRAYS
IMS NPA DATA
TOTAL PRESCRIPTIONS
2012 – 2017[1]

	2012		2013		2014		2015		2016		2017[1]		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Generic														
Steroid														
Budesonide	0	0.0%	0	0.0%	134,290	0.2%	348,617	0.6%	166,169	0.3%	4,309	0.0%	653,385	0.2%
Budesonide (OTC)	0	0.0%	0	0.0%	0	0.0%	0	0.0%	29,324	0.1%	21,191	0.1%	50,515	0.0%
Flunisolide	259,049	0.5%	246,491	0.5%	247,880	0.4%	244,111	0.4%	236,052	0.5%	72,491	0.4%	1,306,074	0.5%
Fluticasone Prop (Flonase)	33,638,977	65.9%	37,687,762	69.7%	43,588,428	74.5%	41,897,541	76.8%	40,240,577	76.8%	14,285,193	77.9%	211,338,478	73.2%
Fluticasone Prop (OTC)	0	0.0%	0	0.0%	0	0.0%	0	0.0%	569	0.0%	1,934	0.0%	2,503	0.0%
Mometasone Furoate (Nasonex)	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1,988,850	3.8%	845,339	4.6%	2,834,189	1.0%
Triamcinolone Actn (Nasacort AQ)	1,429,327	2.8%	1,360,854	2.5%	1,019,563	1.7%	577,491	1.1%	65,247	0.1%	21,712	0.1%	4,474,194	1.5%
Triamcn Actn (OTC)	0	0.0%	0	0.0%	0	0.0%	0	0.0%	20,884	0.0%	40,217	0.2%	61,101	0.0%
Generic Steroid Total	35,327,353	69.2%	39,295,107	72.7%	44,990,161	76.9%	43,067,760	79.0%	42,747,672	81.6%	15,292,386	83.4%	220,720,439	76.4%
Antihistamine														
Azelastine Hcl	2,370,912	4.6%	2,660,627	4.9%	3,390,184	5.8%	4,162,787	7.6%	4,681,341	8.9%	1,785,695	9.7%	19,051,546	6.6%
Olopatadine Hcl (Patanase)	0	0.0%	0	0.0%	70,056	0.1%	508,645	0.9%	1,433,622	2.7%	542,806	3.0%	2,555,129	0.9%
Generic Antihistamine Total	2,370,912	4.6%	2,660,627	4.9%	3,460,240	5.9%	4,671,432	8.6%	6,114,963	11.7%	2,328,501	12.7%	21,606,675	7.5%
Generic Total	37,698,265	73.9%	41,955,734	77.6%	48,450,401	82.8%	47,739,192	87.5%	48,862,635	93.3%	17,620,887	96.1%	242,327,114	83.9%
Branded + Generic Total	51,024,333	100.0%	54,078,737	100.0%	58,537,675	100.0%	54,540,256	100.0%	52,389,875	100.0%	18,335,834	100.0%	288,906,710	100.0%

Notes & Sources:
[1] Through April.
CAGR refers to Compound Annual Growth Rate.
National Prescription Audit™ (NPA) data measure demand for prescription drugs, including both what the provider prescribes in the retail setting and what is ultimately dispensed to consumers across four unique channels.
See , https://www.imshealth.com/files/web/IMSH%20Institute/NPA_Data_Brief-.pdf (accessed May 25, 2017).
Percentages based on 'Branded + Generic Total'.
From CIP2132.

TAB 2

U.S.
ALL ALLERGIC RHINITIS NASAL SPRAYS
IMS SMART DATA
REVENUES
2012 – 2016[1]

	2012		2013		2014		2015		2016[1]		Total	
	$	%	$	%	$	%	$	%	$	%	$	%
Branded												
Dymista	$12,155,211	0.5%	$91,849,580	4.2%	$130,225,088	6.2%	$157,477,385	8.8%	$55,912,177	10.3%	$447,619,441	5.0%
CAGR Since 2013		-		-		41.8%		30.9%		-		-
Steroid												
Beconase	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%
Beconase AQ	$10,674,490	0.5%	$10,483,291	0.5%	$7,564,858	0.4%	$7,489,322	0.4%	$2,091,316	0.4%	$38,303,277	0.4%
Flonase	$7,014,507	0.3%	$6,071,072	0.3%	$3,785,377	0.2%	$722,628	0.0%	$12,365	0.0%	$17,605,949	0.2%
Nasacort	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%
Nasacort AQ	$21,617,091	1.0%	$12,391,863	0.6%	$657,850	0.0%	$10,632	0.0%	$0	0.0%	$34,677,436	0.4%
Nasalide	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%
Nasarel	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%
Nasonex	$998,938,933	44.8%	$1,076,204,460	48.9%	$1,145,345,275	54.1%	$970,712,729	54.0%	$241,076,562	44.5%	$4,432,277,959	49.9%
Omnaris	$31,596,825	1.4%	$30,624,624	1.4%	$23,781,144	1.1%	$17,581,106	1.0%	$4,869,446	0.9%	$108,453,145	1.2%
Qnasl	$15,352,420	0.7%	$43,337,307	2.0%	$60,623,046	2.9%	$69,557,074	3.9%	$24,621,389	4.5%	$213,491,236	2.4%
Qnasl Child	$0	0.0%	$0	0.0%	$0	0.0%	$5,600,413	0.3%	$2,569,480	0.5%	$8,169,893	0.1%
Rhinocort Aqua	$60,814,537	2.7%	$53,644,191	2.4%	$22,760,534	1.1%	$6,731,551	0.4%	$1,266,112	0.2%	$145,216,925	1.6%
Ticanase	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%
Vancenase	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%
Vancenase AQ 84Mcg	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%
Veramyst	$130,123,146	5.8%	$86,973,293	3.9%	$60,253,596	2.8%	$51,047,890	2.8%	$15,316,196	2.8%	$343,714,121	3.9%
Zetonna	$5,878,173	0.3%	$24,880,491	1.1%	$18,754,486	0.9%	$13,209,872	0.7%	$3,464,436	0.6%	$66,187,458	0.7%
Branded Steroid Total	$1,282,010,122	57.5%	$1,344,610,592	61.1%	$1,343,526,166	63.5%	$1,142,663,217	63.5%	$295,287,302	54.5%	$5,408,097,399	60.8%
Antihistamine												
Astelin	$12,305,096	0.6%	$8,190,510	0.4%	$1,643,887	0.1%	$19,803	0.0%	$1,775	0.0%	$22,161,071	0.2%
Astepro	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%
Astepro 0.15%	$116,299,984	5.2%	$94,922,554	4.3%	$41,418,962	2.0%	$7,972,121	0.4%	$1,226,370	0.2%	$261,839,991	2.9%
Patanase	$99,176,985	4.4%	$100,997,426	4.6%	$101,815,766	4.8%	$20,389,900	1.1%	$5,405,336	1.0%	$327,785,413	3.7%
Branded Antihistamine Total	$227,782,065	10.2%	$204,110,490	9.3%	$144,878,615	6.8%	$28,381,824	1.6%	$6,633,481	1.2%	$611,786,475	6.9%
Branded Total	$1,521,947,398	68.2%	$1,640,570,662	74.5%	$1,618,629,869	76.5%	$1,328,522,426	73.9%	$357,832,960	66.1%	$6,467,503,315	72.8%

TAB 2

U.S.
ALL ALLERGIC RHINITIS NASAL SPRAYS
IMS SMART DATA
REVENUES
2012 – 2016[1]

	2012		2013		2014		2015		2016[1]		Total	
	$	%	$	%	$	%	$	%	$	%	$	%
Generic												
Steroid												
Budesonide (Rhinocort Aqua)	$0	0.0%	$0	0.0%	$18,316,900	0.9%	$39,829,846	2.2%	$9,794,344	1.8%	$67,941,090	0.8%
Flunisolide	$18,616,183	0.8%	$16,227,135	0.7%	$11,890,331	0.6%	$13,887,541	0.8%	$4,516,350	0.8%	$65,137,540	0.7%
Fluticasone Prop (Flonase)	$472,029,113	21.2%	$359,992,160	16.3%	$269,662,707	12.7%	$212,838,861	11.8%	$67,475,324	12.5%	$1,381,998,165	15.5%
Mometasone Furoate (Nasonex)	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$56,529,243	10.4%	$56,529,243	0.6%
Triamcinolone Actn (Nasacort AQ)	$109,451,528	4.9%	$96,910,587	4.4%	$65,610,956	3.1%	$33,452,634	1.9%	$476,033	0.1%	$305,901,738	3.4%
Generic Steroid Total	$600,096,824	26.9%	$473,129,882	21.5%	$365,480,894	17.3%	$300,008,882	16.7%	$138,791,294	25.6%	$1,877,507,776	21.1%
Antihistamine												
Azelastine Hcl (Astelin)	$108,195,361	4.9%	$88,264,832	4.0%	$73,886,943	3.5%	$57,885,498	3.2%	$16,397,828	3.0%	$344,630,462	3.9%
Azelastine Hcl (Astepro 0.15%)	$0	0.0%	$0	0.0%	$38,332,768	1.8%	$49,682,155	2.8%	$14,142,968	2.6%	$102,157,891	1.1%
Olopatadine Hcl (Patanase)	$0	0.0%	$0	0.0%	$19,555,850	0.9%	$62,616,541	3.5%	$14,551,108	2.7%	$96,723,499	1.1%
Generic Antihistamine Total	$108,195,361	4.9%	$88,264,832	4.0%	$131,775,561	6.2%	$170,184,194	9.5%	$45,091,904	8.3%	$543,511,852	6.1%
Generic Total	$708,292,185	31.8%	$561,394,714	25.5%	$497,256,455	23.5%	$470,193,076	26.1%	$183,883,198	33.9%	$2,421,019,628	27.2%
Branded + Generic Total	$2,230,239,583	100.0%	$2,201,965,376	100.0%	$2,115,886,324	100.0%	$1,798,715,502	100.0%	$541,716,158	100.0%	$8,888,522,943	100.0%

Notes & Sources:
[1] Through April.
CAGR refers to Compound Annual Growth Rate.
IMS Health SMART Solutions integrates key pharmaceutical insights including supply and sales volumes from IMS' National Sales Perspectives™ (NSP) audit and demand and consumption data from their National Prescription Audit™. *See* , https://www.imshealth.com/files/web/Global/Market%20Insights/SMART%20Solutions/SMART-MVP-Solutions-Brochure.pdf (accessed May 18, 2017).
Percentages based on 'Branded + Generic Total'.
From CIP2062.

TAB 3

U.S.
BRANDED ALLERGIC RHINITIS NASAL SPRAYS
IMS NPA DATA
TOTAL PRESCRIPTIONS
2012 – 2017[1]

	2012		2013		2014		2015		2016		2017[1]		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Dymista	70,067	0.5%	641,212	5.3%	890,234	8.8%	972,960	14.3%	963,299	27.3%	286,335	40.0%	3,824,107	8.2%
Steroid														
Beconase	5	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	5	0.0%
Beconase AQ	64,172	0.5%	51,669	0.4%	38,854	0.4%	28,867	0.4%	21,596	0.6%	7,139	1.0%	212,297	0.5%
Clarispray Nasal Allergy	0	0.0%	0	0.0%	0	0.0%	0	0.0%	54	0.0%	66	0.0%	120	0.0%
Flonase	77,479	0.6%	62,343	0.5%	38,945	0.4%	13,996	0.2%	2,065	0.1%	235	0.0%	195,063	0.4%
Child Flonase Allergy	0	0.0%	0	0.0%	0	0.0%	0	0.0%	5,471	0.2%	2,974	0.4%	8,445	0.0%
Flonase Sensimist	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	4,481	0.6%	4,481	0.0%
Nasacort	28	0.0%	21	0.0%	91	0.0%	165	0.0%	124	0.0%	25	0.0%	454	0.0%
Nasacort AQ	174,776	1.3%	96,368	0.8%	11,881	0.1%	1,100	0.0%	459	0.0%	74	0.0%	284,658	0.6%
Childrens Nasacort	0	0.0%	0	0.0%	0	0.0%	112	0.0%	2,343	0.1%	1,312	0.2%	3,767	0.0%
Nasalide	5	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	5	0.0%
Nasarel	24	0.0%	30	0.0%	36	0.0%	143	0.0%	85	0.0%	28	0.0%	346	0.0%
Nasonex	8,761,824	65.7%	7,831,691	64.6%	6,832,683	67.7%	4,621,928	68.0%	1,652,443	46.8%	189,805	26.5%	29,890,374	64.2%
Omnaris	353,107	2.6%	258,471	2.1%	162,024	1.6%	87,468	1.3%	54,535	1.5%	13,432	1.9%	929,037	2.0%
Qnasl	126,822	1.0%	372,305	3.1%	477,684	4.7%	474,338	7.0%	428,625	12.2%	121,210	17.0%	2,000,984	4.3%
Qnasl Child	0	0.0%	0	0.0%	0	0.0%	33,915	0.5%	47,280	1.3%	15,570	2.2%	96,765	0.2%
Rhinocort	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Rhinocort Allergy	0	0.0%	0	0.0%	0	0.0%	0	0.0%	12,809	0.4%	5,890	0.8%	18,699	0.0%
Rhinocort Aqua	456,160	3.4%	341,615	2.8%	141,492	1.4%	31,950	0.5%	5,360	0.2%	188	0.0%	976,765	2.1%
Ticanase	0	0.0%	0	0.0%	0	0.0%	0	0.0%	333	0.0%	25	0.0%	358	0.0%
Ticaspray	0	0.0%	0	0.0%	0	0.0%	0	0.0%	73	0.0%	24	0.0%	97	0.0%
Vancenase	30	0.0%	25	0.0%	14	0.0%	0	0.0%	0	0.0%	0	0.0%	69	0.0%
Vancenase AQ 84Mcg	34	0.0%	21	0.0%	11	0.0%	0	0.0%	0	0.0%	0	0.0%	66	0.0%
Veramyst	1,252,469	9.4%	756,760	6.2%	481,581	4.8%	310,370	4.6%	202,982	5.8%	31,423	4.4%	3,035,585	6.5%
Zetonna	40,675	0.3%	212,049	1.7%	124,910	1.2%	62,761	0.9%	37,666	1.1%	8,776	1.2%	486,837	1.0%
Steroid Total	11,307,610	84.9%	9,983,368	82.4%	8,310,206	82.4%	5,667,113	83.3%	2,474,303	70.1%	402,677	56.3%	38,145,277	81.9%
Antihistamine														
Astelin	82,275	0.6%	51,799	0.4%	21,839	0.2%	2,773	0.0%	413	0.0%	51	0.0%	159,150	0.3%
Astepro	1,102,104	8.3%	785,544	6.5%	352,880	3.5%	61,229	0.9%	22,338	0.6%	4,787	0.7%	2,328,882	5.0%
Patanase	764,012	5.7%	661,080	5.5%	512,115	5.1%	96,989	1.4%	66,887	1.9%	21,097	3.0%	2,122,180	4.6%
Antihistamine Total	1,948,391	14.6%	1,498,423	12.4%	886,834	8.8%	160,991	2.4%	89,638	2.5%	25,935	3.6%	4,610,212	9.9%
Steroid + Antihistamine Total	13,326,068	100.0%	12,123,003	100.0%	10,087,274	100.0%	6,801,064	100.0%	3,527,240	100.0%	714,947	100.0%	46,579,596	100.0%

Notes & Sources:
[1] Through April.
National Prescription Audit™ (NPA) data measure demand for prescription drugs, including both what the provider prescribes in the retail setting and what is ultimately dispensed to consumers across four unique channels. *See* , https://www.imshealth.com/files/web/IMSH%20Institute/NPA_Data_Brief-.pdf (accessed May 25, 2017).
Percentages based on 'Steroid + Antihistamine Total'.
From CIP2132.

TAB 4

U.S.
BRANDED ALLERGIC RHINITIS NASAL SPRAYS
IMS SMART DATA
REVENUES
2012 – 2016[1]

	2012		2013		2014		2015		2016[1]		Total	
	$	%	$	%	$	%	$	%	$	%	$	%
Dymista	$12,155,211	0.8%	$91,849,580	5.6%	$130,225,088	8.0%	$157,477,385	11.9%	$55,912,177	15.6%	$447,619,441	6.9%
Steroid												
Beconase	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%
Beconase AQ	$10,674,490	0.7%	$10,483,291	0.6%	$7,564,858	0.5%	$7,489,322	0.6%	$2,091,316	0.6%	$38,303,277	0.6%
Flonase	$7,014,507	0.5%	$6,071,072	0.4%	$3,785,377	0.2%	$722,628	0.1%	$12,365	0.0%	$17,605,949	0.3%
Nasacort	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%
Nasacort AQ	$21,617,091	1.4%	$12,391,863	0.8%	$657,850	0.0%	$10,632	0.0%	$0	0.0%	$34,677,436	0.5%
Nasalide	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%
Nasarel	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%
Nasonex	$998,938,933	65.6%	$1,076,204,460	65.6%	$1,145,345,275	70.8%	$970,712,729	73.1%	$241,076,562	67.4%	$4,432,277,959	68.5%
Omnaris	$31,596,825	2.1%	$30,624,624	1.9%	$23,781,144	1.5%	$17,581,106	1.3%	$4,869,446	1.4%	$108,453,145	1.7%
Qnasl	$15,352,420	1.0%	$43,337,307	2.6%	$60,623,046	3.7%	$69,557,074	5.2%	$24,621,389	6.9%	$213,491,236	3.3%
Qnasl Child	$0	0.0%	$0	0.0%	$0	0.0%	$5,600,413	0.4%	$2,569,480	0.7%	$8,169,893	0.1%
Rhinocort Aqua	$60,814,537	4.0%	$53,644,191	3.3%	$22,760,534	1.4%	$6,731,551	0.5%	$1,266,112	0.4%	$145,216,925	2.2%
Ticanase	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%
Vancenase	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%
Vancenase AQ 84Mcg	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%
Veramyst	$130,123,146	8.5%	$86,973,293	5.3%	$60,253,596	3.7%	$51,047,890	3.8%	$15,316,196	4.3%	$343,714,121	5.3%
Zetonna	$5,878,173	0.4%	$24,880,491	1.5%	$18,754,486	1.2%	$13,209,872	1.0%	$3,464,436	1.0%	$66,187,458	1.0%
Steroid Total	$1,282,010,122	84.2%	$1,344,610,592	82.0%	$1,343,526,166	83.0%	$1,142,663,217	86.0%	$295,287,302	82.5%	$5,408,097,399	83.6%
Antihistamine												
Astelin	$12,305,096	0.8%	$8,190,510	0.5%	$1,643,887	0.1%	$19,803	0.0%	$1,775	0.0%	$22,161,071	0.3%
Astepro	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%
Astepro 0.15%	$116,299,984	7.6%	$94,922,554	5.8%	$41,418,962	2.6%	$7,972,121	0.6%	$1,226,370	0.3%	$261,839,991	4.0%
Patanase	$99,176,985	6.5%	$100,997,426	6.2%	$101,815,766	6.3%	$20,389,900	1.5%	$5,405,336	1.5%	$327,785,413	5.1%
Antihistamine Total	$227,782,065	15.0%	$204,110,490	12.4%	$144,878,615	9.0%	$28,381,824	2.1%	$6,633,481	1.9%	$611,786,475	9.5%
Steroid + Antihistamine Total	$1,521,947,398	100.0%	$1,640,570,662	100.0%	$1,618,629,869	100.0%	$1,328,522,426	100.0%	$357,832,960	100.0%	$6,467,503,315	100.0%

Notes & Sources:
[1] Through April.
IMS Health SMART Solutions integrates key pharmaceutical insights including supply and sales volumes from IMS' National Sales Perspectives™ (NSP) audit and demand and consumption data from their National Prescription Audit™. *See* , https://www.imshealth.com/files/web/Global/Market%20Insights/SMART%20Solutions/SMART-MVP-Solutions-Brochure.pdf (accessed May 18, 2017).
Percentages based on 'Steroid + Antihistamine Total'.
From CIP2062.

TAB 5

INDIA
ALLERGIC RHINITIS NASAL SPRAYS
IMS TSA DATA
REVENUES (INR)
2010 – 2017

	Year Ending December 31						Year Ending March 31										Total	
	2010		2011		2012		2013		2014		2015		2016		2017			
	₹	%	₹	%	₹	%	₹	%	₹	%	₹	%	₹	%	₹	%	₹	%
Fluticasone																		
Flomist	₹72,715,195	13.0%	₹83,509,330	11.2%	₹92,454,968	10.3%	₹94,201,228	10.0%	₹108,139,872	9.4%	₹127,157,328	9.3%	₹149,576,213	9.3%	₹156,617,780	8.6%	₹884,371,914	9.7%
Fluticone-Ft	₹27,425,226	4.9%	₹41,767,565	5.6%	₹53,473,890	5.9%	₹52,617,406	5.6%	₹62,330,869	5.4%	₹75,106,346	5.5%	₹95,925,861	6.0%	₹120,067,426	6.6%	₹528,714,589	5.8%
Avamys	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹4,355,161	0.5%	₹43,500,573	3.8%	₹66,935,876	4.9%	₹91,276,386	5.7%	₹122,344,159	6.7%	₹328,412,155	3.6%
Flixonase	₹66,833,805	11.9%	₹69,936,533	9.4%	₹67,439,939	7.5%	₹65,808,127	7.0%	₹57,531,095	5.0%	₹53,568,182	3.9%	₹56,986,337	3.5%	₹56,810,048	3.1%	₹494,914,066	5.4%
Flutiflo	₹26,351,802	4.7%	₹30,865,143	4.2%	₹34,616,559	3.8%	₹35,751,585	3.8%	₹38,380,523	3.3%	₹46,169,427	3.4%	₹50,000,126	3.1%	₹57,433,584	3.2%	₹319,568,749	3.5%
Furamist	₹17,644,188	3.2%	₹20,732,970	2.8%	₹25,380,232	2.8%	₹26,787,470	2.8%	₹36,157,849	3.2%	₹54,573,262	4.0%	₹67,341,316	4.2%	₹76,575,857	4.2%	₹325,193,144	3.6%
Fluticone	₹34,866,275	6.2%	₹42,681,267	5.7%	₹46,935,856	5.2%	₹44,043,384	4.7%	₹37,519,897	3.3%	₹31,852,232	2.3%	₹32,974,633	2.0%	₹38,297,991	2.1%	₹309,171,535	3.4%
Ennhale	₹0	0.0%	₹8,246,836	1.1%	₹17,595,539	2.0%	₹19,129,812	2.0%	₹25,530,540	2.2%	₹32,779,446	2.4%	₹35,029,447	2.2%	₹32,519,436	1.8%	₹170,831,056	1.9%
Floresp	₹0	0.0%	₹0	0.0%	₹6,864,303	0.8%	₹11,589,528	1.2%	₹20,722,946	1.8%	₹27,121,272	2.0%	₹26,680,302	1.7%	₹37,934,461	2.1%	₹130,912,812	1.4%
Alerflo	₹0	0.0%	₹0	0.0%	₹10,287,927	1.1%	₹12,173,707	1.3%	₹20,248,273	1.8%	₹24,865,529	1.8%	₹25,871,089	1.6%	₹25,518,975	1.4%	₹118,965,500	1.3%
Flublock	₹0	0.0%	₹0	0.0%	₹4,341,532	0.5%	₹7,770,882	0.8%	₹15,892,455	1.4%	₹19,378,541	1.4%	₹20,850,035	1.3%	₹17,677,531	1.0%	₹85,910,976	0.9%
Nazomac-F	₹3,450,420	0.6%	₹11,549,964	1.6%	₹15,575,595	1.7%	₹15,793,953	1.7%	₹14,439,106	1.3%	₹20,873,146	1.5%	₹23,436,915	1.5%	₹23,943,561	1.3%	₹129,062,660	1.4%
Efnase	₹7,914,565	1.4%	₹12,562,985	1.7%	₹14,740,713	1.6%	₹14,228,190	1.5%	₹13,135,983	1.1%	₹12,184,579	0.9%	₹10,719,715	0.7%	₹8,195,527	0.4%	₹93,682,257	1.0%
Mezaflo	₹11,382,490	2.0%	₹16,541,330	2.2%	₹18,001,380	2.0%	₹17,959,618	1.9%	₹18,435,049	1.6%	₹7,171,406	0.5%	₹2,152,721	0.1%	₹2,766,239	0.2%	₹94,410,233	1.0%
Nezaflo	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹35,348	0.0%	₹12,508,489	0.9%	₹7,248,098	0.5%	₹11,342,924	0.6%	₹31,134,859	0.3%
Freeair	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹12,840,543	0.9%	₹25,271,588	1.6%	₹26,293,597	1.4%	₹64,405,728	0.7%
Nasocom	₹8,038,101	1.4%	₹9,812,531	1.3%	₹7,064,448	0.8%	₹6,728,883	0.7%	₹6,756,158	0.6%	₹7,779,694	0.6%	₹8,088,432	0.5%	₹7,173,875	0.4%	₹61,442,122	0.7%
Ezicas	₹3,166,870	0.6%	₹7,294,875	1.0%	₹7,158,506	0.8%	₹6,688,791	0.7%	₹4,933,746	0.4%	₹7,619,726	0.6%	₹10,484,127	0.7%	₹11,958,674	0.7%	₹59,305,315	0.7%
Ezicas-F	₹392,792	0.1%	₹3,396,415	0.5%	₹4,717,351	0.5%	₹4,409,748	0.5%	₹3,123,462	0.3%	₹5,309,550	0.4%	₹8,968,755	0.6%	₹11,614,729	0.6%	₹41,932,802	0.5%
Flutirest	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹2,231,578	0.2%	₹1,178,574	0.1%	₹747,017	0.0%	₹41,286	0.0%	₹4,198,455	0.0%
Rhinofit	₹752,299	0.1%	₹555,381	0.1%	₹377,114	0.0%	₹367,853	0.0%	₹978,797	0.1%	₹526,187	0.0%	₹946,899	0.1%	₹2,106,274	0.1%	₹6,610,804	0.1%
Furaspray	₹272,718	0.0%	₹2,290,408	0.3%	₹2,891,928	0.3%	₹2,725,659	0.3%	₹1,281,333	0.1%	₹209,774	0.0%	₹449,648	0.0%	₹525,897	0.0%	₹10,647,365	0.1%
Otrivin-C	₹3,921,768	0.7%	₹424,183	0.1%	₹370,204	0.0%	₹324,494	0.0%	₹401,551	0.0%	₹78,423	0.0%	₹0	0.0%	₹0	0.0%	₹5,520,623	0.1%
Fivasa	₹8,991,281	1.6%	₹7,955,703	1.1%	₹5,629,485	0.6%	₹5,074,521	0.5%	₹2,140,104	0.2%	₹72,864	0.0%	₹46,300	0.0%	₹59,580	0.0%	₹29,969,838	0.3%
Flutispray	₹0	0.0%	₹25,168	0.0%	₹10,218	0.0%	₹4,542	0.0%	₹946	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹40,874	0.0%
Nasicure	₹637,964	0.1%	₹616,829	0.1%	₹0	0.0%	₹0	0.0%	₹7,135	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹1,261,928	0.0%
Flutiflo-Ft	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹8,756,706	0.8%	₹21,201,581	1.6%	₹35,896,174	2.2%	₹44,878,619	2.5%	₹110,733,080	1.2%
Odnase	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹14,857,930	0.8%	₹14,857,930	0.2%
Nazobic	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹30,698,527	1.9%	₹7,982,485	0.4%	₹38,681,012	0.4%
Flocare	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹1,366,109	0.1%	₹2,006,004	0.1%	₹3,372,113	0.0%
FFNS	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹688,100	0.0%	₹688,100	0.0%
Flutivio	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹18,530	0.0%	₹18,530	0.0%
Total Fluticasone	₹294,757,759	52.7%	₹370,765,416	49.9%	₹435,927,687	48.3%	₹448,534,542	47.7%	₹542,611,894	47.3%	₹669,061,977	49.0%	₹819,032,770	50.9%	₹918,251,079	50.4%	₹4,498,943,124	49.5%

TAB 5

INDIA
ALLERGIC RHINITIS NASAL SPRAYS
IMS TSA DATA
REVENUES (INR)
2010 – 2017

	Year Ending December 31						Year Ending March 31										Total	
	2010		2011		2012		2013		2014		2015		2016		2017			
	₹	%	₹	%	₹	%	₹	%	₹	%	₹	%	₹	%	₹	%	₹	%
Azelastine + Fluticasone																		
Imitator Products																		
Duonase	₹76,678,138	13.7%	₹99,907,104	13.4%	₹106,353,223	11.8%	₹109,580,098	11.7%	₹134,984,011	11.8%	₹153,813,468	11.3%	₹175,920,535	10.9%	₹201,464,383	11.1%	₹1,058,700,960	11.6%
Azeflo	₹26,732,772	4.8%	₹34,140,544	4.6%	₹38,343,362	4.3%	₹40,181,250	4.3%	₹50,656,957	4.4%	₹60,367,609	4.4%	₹69,323,923	4.3%	₹91,643,888	5.0%	₹411,390,305	4.5%
Combinase-AQ	₹25,775,103	4.6%	₹30,654,975	4.1%	₹32,206,035	3.6%	₹30,829,676	3.3%	₹36,019,793	3.1%	₹35,825,617	2.6%	₹41,406,278	2.6%	₹43,304,748	2.4%	₹276,022,225	3.0%
Nazomac-AF	₹577,978	0.1%	₹13,553,908	1.8%	₹21,757,915	2.4%	₹22,428,602	2.4%	₹26,767,013	2.3%	₹36,657,475	2.7%	₹43,529,686	2.7%	₹47,955,278	2.6%	₹213,227,855	2.3%
Floresp-AZ	₹0	0.0%	₹0	0.0%	₹11,888,871	1.3%	₹16,005,701	1.7%	₹19,065,597	1.7%	₹18,376,313	1.3%	₹22,176,758	1.4%	₹29,871,242	1.6%	₹117,384,482	1.3%
Ezicas-AZ	₹2,871,394	0.5%	₹7,846,991	1.1%	₹7,847,360	0.9%	₹7,203,856	0.8%	₹7,444,225	0.6%	₹11,660,392	0.9%	₹17,239,351	1.1%	₹23,854,302	1.3%	₹85,967,871	0.9%
Nasocom-AZ	₹1,636,938	0.3%	₹4,394,135	0.6%	₹4,101,388	0.5%	₹4,105,530	0.4%	₹3,786,353	0.3%	₹8,064,263	0.6%	₹11,631,670	0.7%	₹12,620,070	0.7%	₹50,340,347	0.6%
Total Imitator Products	₹134,272,323	24.0%	₹190,497,657	25.6%	₹222,498,154	24.7%	₹230,334,713	24.5%	₹278,723,949	24.3%	₹324,765,137	23.8%	₹381,228,201	23.7%	₹450,713,911	24.7%	₹2,213,034,045	24.3%
Other Azelastine + Fluticasone																		
Furamist-AZ	₹11,336,217	2.0%	₹19,119,553	2.6%	₹22,291,920	2.5%	₹23,482,534	2.5%	₹30,175,239	2.6%	₹38,840,123	2.8%	₹47,553,638	3.0%	₹54,159,965	3.0%	₹246,959,189	2.7%
Nezalast	₹10,635,003	1.9%	₹11,776,930	1.6%	₹12,249,396	1.4%	₹12,561,627	1.3%	₹14,489,580	1.3%	₹14,377,445	1.1%	₹6,652,118	0.4%	₹10,801,120	0.6%	₹93,543,219	1.0%
Flublock-AZ	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹7,405,071	0.6%	₹13,299,292	1.0%	₹14,602,908	0.9%	₹15,108,475	0.8%	₹50,415,746	0.6%
Azenate	₹357,881	0.1%	₹451,810	0.1%	₹490,315	0.1%	₹583,598	0.1%	₹827,117	0.1%	₹1,680,480	0.1%	₹2,236,541	0.1%	₹2,982,415	0.2%	₹9,610,157	0.1%
Flutirest AZ	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹1,545	0.0%	₹723,933	0.1%	₹655,237	0.0%	₹64,443	0.0%	₹1,445,158	0.0%
Flutiair-AZ	₹0	0.0%	₹0	0.0%	₹331,527	0.0%	₹415,119	0.0%	₹87,062	0.0%	₹72,079	0.0%	₹70,189	0.0%	₹18,297	0.0%	₹994,273	0.0%
Fivasa-AZ	₹1,442,222	0.3%	₹4,238,090	0.6%	₹4,155,138	0.5%	₹4,035,271	0.4%	₹2,138,701	0.2%	₹50,425	0.0%	₹35,693	0.0%	₹45,861	0.0%	₹16,141,401	0.2%
Duospray	₹0	0.0%	₹226,844	0.0%	₹274,816	0.0%	₹253,108	0.0%	₹8,884	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹763,652	0.0%
Sarnase	₹104,092	0.0%	₹5,670	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹109,762	0.0%
Combinase-Ft	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹7,009,703	0.4%	₹16,816,332	0.9%	₹23,826,035	0.3%
Total Other Azelastine + Fluticasone	₹23,875,415	4.3%	₹35,818,897	4.8%	₹39,793,112	4.4%	₹41,331,257	4.4%	₹55,133,199	4.8%	₹69,043,777	5.1%	₹78,816,027	4.9%	₹99,996,908	5.5%	₹443,808,592	4.9%
Total Azelastine + Fluticasone	₹158,147,738	28.3%	₹226,316,554	30.4%	₹262,291,266	29.1%	₹271,665,970	28.9%	₹333,857,148	29.1%	₹393,808,914	28.8%	₹460,044,228	28.6%	₹550,710,819	30.2%	₹2,656,842,637	29.2%
Mometasone																		
Nasonex	₹0	0.0%	₹28,315,778	3.8%	₹77,040,449	8.5%	₹89,107,308	9.5%	₹123,046,197	10.7%	₹124,707,830	9.1%	₹121,499,218	7.6%	₹102,588,996	5.6%	₹666,305,776	7.3%
Metaspray	₹44,264,308	7.9%	₹47,756,839	6.4%	₹51,544,850	5.7%	₹54,290,505	5.8%	₹58,418,724	5.1%	₹78,951,890	5.8%	₹97,914,162	6.1%	₹111,364,542	6.1%	₹544,505,820	6.0%
Momeflo	₹18,077,004	3.2%	₹22,743,679	3.1%	₹27,757,734	3.1%	₹28,800,657	3.1%	₹32,847,979	2.9%	₹39,076,324	2.9%	₹46,058,920	2.9%	₹62,592,694	3.4%	₹277,954,991	3.1%
Metatop	₹18,890,022	3.4%	₹22,312,726	3.0%	₹24,080,068	2.7%	₹24,090,334	2.6%	₹28,972,817	2.5%	₹25,862,295	1.9%	₹33,257,055	2.1%	₹41,905,783	2.3%	₹219,371,100	2.4%
Aquamet	₹13,510,947	2.4%	₹14,965,950	2.0%	₹13,145,207	1.5%	₹13,054,635	1.4%	₹12,368,455	1.1%	₹12,317,757	0.9%	₹7,749,010	0.5%	₹6,517,027	0.4%	₹93,628,988	1.0%
Nazomac-M	₹0	0.0%	₹4,039,095	0.5%	₹6,539,445	0.7%	₹6,902,637	0.7%	₹6,211,646	0.5%	₹10,695,155	0.8%	₹13,769,297	0.9%	₹14,984,617	0.8%	₹63,141,892	0.7%
Esynos	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹3,138,926	0.3%	₹5,828,078	0.4%	₹3,759,889	0.2%	₹152,830	0.0%	₹12,879,723	0.1%
Momenta	₹1,264,865	0.2%	₹2,674,195	0.4%	₹2,788,578	0.3%	₹2,809,860	0.3%	₹3,281,271	0.3%	₹3,810,243	0.3%	₹3,481,316	0.2%	₹4,431,672	0.2%	₹24,542,000	0.3%
Rhine-M	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹1,599,941	0.1%	₹1,691,479	0.1%	₹1,483,286	0.1%	₹1,729,393	0.1%	₹6,504,099	0.1%
Eziwin	₹0	0.0%	₹0	0.0%	₹632,130	0.1%	₹854,621	0.1%	₹1,177,463	0.1%	₹64,103	0.0%	₹0	0.0%	₹431,693	0.0%	₹3,160,010	0.0%
M-Spray	₹10,688,803	1.9%	₹3,663,507	0.5%	₹43,392	0.0%	₹11,558	0.0%	₹2,224	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹14,409,484	0.2%
Sensonase	₹1,413	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹1,413	0.0%
Respizen	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹3,338,764	0.2%	₹3,338,764	0.0%
Ezispray	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹537,401	0.0%	₹3,270,707	0.2%	₹3,808,108	0.0%
Vioson	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹0	0.0%	₹10,712	0.0%	₹10,712	0.0%
Total Mometasone	₹106,697,362	19.1%	₹146,471,769	19.7%	₹203,571,853	22.6%	₹219,922,115	23.4%	₹271,065,643	23.6%	₹303,005,154	22.2%	₹329,509,554	20.5%	₹353,319,430	19.4%	₹1,933,562,880	21.3%
Total AR Nasal Sprays	₹559,602,859	100.0%	₹743,553,739	100.0%	₹901,790,806	100.0%	₹940,122,627	100.0%	₹1,147,534,685	100.0%	₹1,365,876,045	100.0%	₹1,608,586,552	100.0%	₹1,822,281,328	100.0%	₹9,089,348,641	100.0%

Notes & Sources:
Data for 2010 through 2012 reflect 12-month period ending December 31 of each respective year. Data for 2013 through 2017 reflect 12-month period ending March 31 of each respective year.
IMS TSA (Total Sales Audit) data include hospital, doctor, and retail channel sales. *See*, http://medicinman.net/2016/10/ims-health-market-reflection-report-for-september-2016/ (accessed May 9, 2017).
Percentages based on 'Total AR Nasal Sprays'.
Data for 2010 through 2012 from CIP2123. Data for 2013 through 2017 from CIP2124.

TAB 6

INDIA
ALLERGIC RHINITIS NASAL SPRAYS
IMS TSA DATA
REVENUES (USD)
2010 – 2017

	Year Ending December 31						Year Ending March 31										Total	
	2010		2011		2012		2013		2014		2015		2016		2017			
	$	%	$	%	$	%	$	%	$	%	$	%	$	%	$	%	$	%
Fluticasone																		
Flomist	$1,535,762	13.0%	$1,833,481	11.2%	$1,935,905	10.3%	$1,730,901	10.0%	$1,790,886	9.4%	$2,081,002	9.3%	$2,287,044	9.3%	$2,336,185	8.6%	$15,531,166	9.9%
Fluticone-Ft	$579,227	4.9%	$917,024	5.6%	$1,119,684	5.9%	$966,819	5.6%	$1,032,251	5.4%	$1,229,158	5.5%	$1,466,722	6.0%	$1,790,983	6.6%	$9,101,867	5.8%
Avamys	$0	0.0%	$0	0.0%	$0	0.0%	$80,024	0.5%	$720,406	3.8%	$1,095,444	4.9%	$1,395,631	5.7%	$1,824,944	6.7%	$5,116,447	3.2%
Flixonase	$1,411,545	11.9%	$1,535,485	9.4%	$1,412,118	7.5%	$1,209,192	7.0%	$952,763	5.0%	$876,674	3.9%	$871,330	3.5%	$847,406	3.1%	$9,116,512	5.8%
Flutiflo	$556,556	4.7%	$677,657	4.2%	$724,833	3.8%	$656,918	3.8%	$635,613	3.3%	$755,589	3.4%	$764,510	3.1%	$856,707	3.2%	$5,628,382	3.6%
Furamist	$372,649	3.2%	$455,201	2.8%	$531,434	2.8%	$492,206	2.8%	$598,804	3.2%	$893,123	4.0%	$1,029,660	4.2%	$1,142,242	4.2%	$5,515,318	3.5%
Fluticone	$736,384	6.2%	$937,084	5.7%	$982,785	5.2%	$809,275	4.7%	$621,361	3.3%	$521,280	2.3%	$504,187	2.0%	$571,271	2.1%	$5,683,628	3.6%
Ennhale	$0	0.0%	$181,063	1.1%	$368,431	2.0%	$351,501	2.0%	$422,807	2.2%	$536,454	2.4%	$535,606	2.2%	$485,075	1.8%	$2,880,937	1.8%
Floresp	$0	0.0%	$0	0.0%	$143,731	0.8%	$212,952	1.2%	$343,189	1.8%	$443,855	2.0%	$407,946	1.7%	$565,848	2.1%	$2,117,522	1.3%
Alerflo	$0	0.0%	$0	0.0%	$215,418	1.1%	$223,686	1.3%	$335,328	1.8%	$406,939	1.8%	$395,573	1.6%	$380,653	1.4%	$1,957,597	1.2%
Flublock	$0	0.0%	$0	0.0%	$90,907	0.5%	$142,786	0.8%	$263,192	1.4%	$317,141	1.4%	$318,800	1.3%	$263,686	1.0%	$1,396,513	0.9%
Nazomac-F	$72,874	0.6%	$253,584	1.6%	$326,136	1.7%	$290,206	1.7%	$239,124	1.3%	$341,601	1.5%	$358,354	1.5%	$357,154	1.3%	$2,239,032	1.4%
Efnase	$167,157	1.4%	$275,825	1.7%	$308,654	1.6%	$261,436	1.5%	$217,543	1.1%	$199,408	0.9%	$163,906	0.7%	$122,248	0.4%	$1,716,178	1.1%
Mezaflo	$240,401	2.0%	$363,172	2.2%	$376,929	2.0%	$329,999	1.9%	$305,300	1.6%	$117,364	0.5%	$32,915	0.1%	$41,263	0.2%	$1,807,342	1.1%
Nezaflo	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$585	0.0%	$204,709	0.9%	$110,825	0.5%	$169,196	0.6%	$485,315	0.3%
Freeair	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$210,143	0.9%	$386,407	1.6%	$392,208	1.4%	$988,757	0.6%
Nasocom	$169,767	1.4%	$215,438	1.3%	$147,922	0.8%	$123,640	0.7%	$111,888	0.6%	$127,319	0.6%	$123,673	0.5%	$107,009	0.4%	$1,126,655	0.7%
Ezicas	$66,885	0.6%	$160,162	1.0%	$149,891	0.8%	$122,903	0.7%	$81,707	0.4%	$124,701	0.6%	$160,304	0.7%	$178,381	0.7%	$1,044,935	0.7%
Ezicas-F	$8,296	0.1%	$74,570	0.5%	$98,776	0.5%	$81,027	0.5%	$51,727	0.3%	$86,894	0.4%	$137,134	0.6%	$173,251	0.6%	$711,674	0.5%
Flutirest	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$36,957	0.2%	$19,288	0.1%	$11,422	0.0%	$616	0.0%	$68,283	0.0%
Rhinofit	$15,889	0.1%	$12,194	0.1%	$7,896	0.0%	$6,759	0.0%	$16,210	0.1%	$8,611	0.0%	$14,478	0.1%	$31,418	0.1%	$113,455	0.1%
Furaspray	$5,760	0.0%	$50,287	0.3%	$60,554	0.3%	$50,083	0.3%	$21,220	0.1%	$3,433	0.0%	$6,875	0.0%	$7,845	0.0%	$206,056	0.1%
Otrivin-C	$82,829	0.7%	$9,313	0.1%	$7,752	0.0%	$5,962	0.0%	$6,650	0.0%	$1,283	0.0%	$0	0.0%	$0	0.0%	$113,789	0.1%
Fivasa	$189,898	1.6%	$174,671	1.1%	$117,875	0.6%	$93,242	0.5%	$35,442	0.2%	$1,192	0.0%	$708	0.0%	$889	0.0%	$613,917	0.4%
Flutispray	$0	0.0%	$553	0.0%	$214	0.0%	$83	0.0%	$16	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$866	0.0%
Nasicure	$13,474	0.1%	$13,543	0.1%	$0	0.0%	$0	0.0%	$118	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$27,135	0.0%
Flutiflo-Ft	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$145,018	0.8%	$346,976	1.6%	$548,858	2.2%	$669,431	2.5%	$1,710,283	1.1%
Odnase	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$221,628	0.8%	$221,628	0.1%
Nazobic	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$469,385	1.9%	$119,071	0.4%	$588,456	0.4%
Flocare	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$20,888	0.1%	$29,923	0.1%	$50,811	0.0%
FFNS	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$10,264	0.0%	$10,264	0.0%
Flutivio	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$276	0.0%	$276	0.0%
Total Fluticasone	$6,225,352	52.7%	$8,140,304	49.9%	$9,127,844	48.3%	$8,241,599	47.7%	$8,986,104	47.3%	$10,949,580	49.0%	$12,523,142	50.9%	$13,697,069	50.4%	$77,890,995	49.5%

TAB 6

INDIA
ALLERGIC RHINITIS NASAL SPRAYS
IMS TSA DATA
REVENUES (USD)
2010 – 2017

	Year Ending December 31						Year Ending March 31										Total	
	2010		2011		2012		2013		2014		2015		2016		2017			
	$	%	$	%	$	%	$	%	$	%	$	%	$	%	$	%	$	%
Azelastine + Fluticasone																		
Imitator Products																		
Duonase	$1,619,460	13.7%	$2,193,501	13.4%	$2,226,919	11.8%	$2,013,480	11.7%	$2,235,447	11.8%	$2,517,245	11.3%	$2,689,853	10.9%	$3,005,138	11.1%	$18,501,044	11.8%
Azeflo	$564,602	4.8%	$749,569	4.6%	$802,868	4.3%	$738,310	4.3%	$838,921	4.4%	$987,950	4.4%	$1,059,974	4.3%	$1,367,004	5.0%	$7,109,199	4.5%
Combinase-AQ	$544,376	4.6%	$673,042	4.1%	$674,359	3.6%	$566,480	3.3%	$596,518	3.1%	$586,307	2.6%	$633,109	2.6%	$645,954	2.4%	$4,920,144	3.1%
Nazomac-AF	$12,207	0.1%	$297,582	1.8%	$455,587	2.4%	$412,114	2.4%	$443,284	2.3%	$599,920	2.7%	$665,576	2.7%	$715,324	2.6%	$3,601,594	2.3%
Floresp-AZ	$0	0.0%	$0	0.0%	$248,940	1.3%	$294,097	1.7%	$315,742	1.7%	$300,739	1.3%	$339,086	1.4%	$445,574	1.6%	$1,944,177	1.2%
Ezicas-AZ	$60,645	0.5%	$172,284	1.1%	$164,315	0.9%	$132,367	0.8%	$123,283	0.6%	$190,829	0.9%	$263,592	1.1%	$355,822	1.3%	$1,463,137	0.9%
Nasocom-AZ	$34,573	0.3%	$96,475	0.6%	$85,879	0.5%	$75,437	0.4%	$62,705	0.3%	$131,976	0.6%	$177,850	0.7%	$188,247	0.7%	$853,142	0.5%
Total Imitator Products	$2,835,862	24.0%	$4,182,453	25.6%	$4,658,866	24.7%	$4,232,286	24.5%	$4,615,900	24.3%	$5,314,967	23.8%	$5,829,040	23.7%	$6,723,063	24.7%	$38,392,436	24.4%
Other Azelastine + Fluticasone																		
Furamist-AZ	$239,424	2.0%	$419,778	2.6%	$466,768	2.5%	$431,480	2.5%	$499,727	2.6%	$635,641	2.8%	$727,103	3.0%	$807,876	3.0%	$4,227,795	2.7%
Nezalast	$224,614	1.9%	$258,567	1.6%	$256,489	1.4%	$230,814	1.3%	$239,959	1.3%	$235,295	1.1%	$101,712	0.4%	$161,115	0.6%	$1,708,565	1.1%
Flublock-AZ	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$122,634	0.6%	$217,650	1.0%	$223,281	0.9%	$225,365	0.8%	$788,931	0.5%
Azenate	$7,559	0.1%	$9,920	0.1%	$10,267	0.1%	$10,723	0.1%	$13,698	0.1%	$27,502	0.1%	$34,197	0.1%	$44,487	0.2%	$158,352	0.1%
Flutirest AZ	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$26	0.0%	$11,848	0.1%	$10,019	0.0%	$961	0.0%	$22,853	0.0%
Flutiair-AZ	$0	0.0%	$0	0.0%	$6,942	0.0%	$7,628	0.0%	$1,442	0.0%	$1,180	0.0%	$1,073	0.0%	$273	0.0%	$18,537	0.0%
Fivasa-AZ	$30,460	0.3%	$93,049	0.6%	$87,004	0.5%	$74,146	0.4%	$35,419	0.2%	$825	0.0%	$546	0.0%	$684	0.0%	$322,133	0.2%
Duospray	$0	0.0%	$4,980	0.0%	$5,754	0.0%	$4,651	0.0%	$147	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$15,533	0.0%
Sarnase	$2,198	0.0%	$124	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$2,323	0.0%
Combinase-Ft	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$107,179	0.4%	$250,840	0.9%	$358,020	0.2%
Total Other Azelastine + Fluticasone	$504,254	4.3%	$786,418	4.8%	$833,224	4.4%	$759,441	4.4%	$913,052	4.8%	$1,129,941	5.1%	$1,205,110	4.9%	$1,491,601	5.5%	$7,623,041	4.8%
Total Azelastine + Fluticasone	$3,340,117	28.3%	$4,968,871	30.4%	$5,492,089	29.1%	$4,991,727	28.9%	$5,528,952	29.1%	$6,444,907	28.8%	$7,034,150	28.6%	$8,214,664	30.2%	$46,015,478	29.2%
Mometasone																		
Nasonex	$0	0.0%	$621,684	3.8%	$1,613,142	8.5%	$1,637,302	9.5%	$2,037,747	10.7%	$2,040,915	9.1%	$1,857,743	7.6%	$1,530,266	5.6%	$11,338,799	7.2%
Metaspray	$934,872	7.9%	$1,048,521	6.4%	$1,079,292	5.7%	$997,561	5.8%	$967,463	5.1%	$1,292,093	5.8%	$1,497,123	6.1%	$1,661,166	6.1%	$9,478,091	6.0%
Momeflo	$381,790	3.2%	$499,347	3.1%	$581,216	3.1%	$529,198	3.1%	$543,990	2.9%	$639,506	2.9%	$704,248	2.9%	$933,662	3.4%	$4,812,958	3.1%
Metatop	$398,962	3.4%	$489,885	3.0%	$504,210	2.7%	$442,648	2.6%	$479,814	2.5%	$423,251	1.9%	$508,506	2.1%	$625,087	2.3%	$3,872,362	2.5%
Aquamet	$285,354	2.4%	$328,583	2.0%	$275,246	1.5%	$239,872	1.4%	$204,832	1.1%	$201,587	0.9%	$118,484	0.5%	$97,211	0.4%	$1,751,170	1.1%
Nazomac-M	$0	0.0%	$88,680	0.5%	$136,929	0.7%	$126,833	0.7%	$102,870	0.5%	$175,032	0.8%	$210,535	0.9%	$223,518	0.8%	$1,064,396	0.7%
Esynos	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$51,983	0.3%	$95,380	0.4%	$57,489	0.2%	$2,280	0.0%	$207,132	0.1%
Momenta	$26,714	0.2%	$58,713	0.4%	$58,390	0.3%	$51,630	0.3%	$54,341	0.3%	$62,357	0.3%	$53,230	0.2%	$66,105	0.2%	$431,479	0.3%
Rhine-M	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$26,496	0.1%	$27,682	0.1%	$22,680	0.1%	$25,796	0.1%	$102,654	0.1%
Eziwin	$0	0.0%	$0	0.0%	$13,236	0.1%	$15,703	0.1%	$19,500	0.1%	$1,049	0.0%	$0	0.0%	$6,439	0.0%	$55,928	0.0%
M-Spray	$225,750	1.9%	$80,434	0.5%	$909	0.0%	$212	0.0%	$37	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$307,342	0.2%
Sensonase	$30	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$30	0.0%
Respizen	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$49,803	0.2%	$49,803	0.0%
Ezispray	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$8,217	0.0%	$48,787	0.2%	$57,004	0.0%
Vioson	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$0	0.0%	$160	0.0%	$160	0.0%
Total Mometasone	$2,253,473	19.1%	$3,215,847	19.7%	$4,262,570	22.6%	$4,040,959	23.4%	$4,489,072	23.6%	$4,958,852	22.2%	$5,038,254	20.5%	$5,270,280	19.4%	$33,529,307	21.3%
Total AR Nasal Sprays	$11,818,941	100.0%	$16,325,023	100.0%	$18,882,503	100.0%	$17,274,285	100.0%	$19,004,128	100.0%	$22,353,340	100.0%	$24,595,546	100.0%	$27,182,014	100.0%	$157,435,780	100.0%

Notes & Sources:
Data for 2010 through 2012 reflect 12-month period ending December 31 of each respective year. Data for 2013 through 2017 reflect 12-month period ending March 31 of each respective year.
IMS TSA (Total Sales Audit) data include hospital, doctor, and retail channel sales. *See* , http://medicinman.net/2016/10/ims-health-market-reflection-report-for-september-2016/ (accessed May 9, 2017).
Percentages based on 'Total AR Nasal Sprays'.
INR converted to USD using annual average exchange rate from Bloomberg.
Data for 2010 through 2012 from CIP2123. Data for 2013 through 2017 from CIP2124.

TAB 7

INDIA
ALLERGIC RHINITIS NASAL SPRAYS
IMS TSA DATA
UNITS
2010 – 2017

	Year Ending December 31						Year Ending March 31										Total	
	2010		2011		2012		2013		2014		2015		2016		2017			
	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Fluticasone																		
Flomist	585,121	16.0%	670,986	14.3%	719,051	13.3%	721,975	12.9%	791,101	12.3%	848,343	11.6%	914,309	11.3%	895,488	10.3%	6,146,374	12.3%
Fluticone-Ft	157,354	4.3%	238,041	5.1%	287,819	5.3%	283,209	5.1%	314,096	4.9%	360,889	4.9%	432,146	5.3%	530,591	6.1%	2,604,145	5.2%
Avamys	0	0.0%	0	0.0%	0	0.0%	18,370	0.3%	192,532	3.0%	302,932	4.1%	413,090	5.1%	529,165	6.1%	1,456,089	2.9%
Flixonase	230,374	6.3%	240,493	5.1%	227,017	4.2%	221,524	4.0%	191,440	3.0%	170,514	2.3%	178,128	2.2%	177,610	2.0%	1,637,100	3.3%
Flutiflo	218,195	6.0%	254,789	5.4%	284,332	5.2%	292,364	5.2%	297,304	4.6%	345,008	4.7%	343,596	4.2%	363,819	4.2%	2,399,407	4.8%
Furamist	94,948	2.6%	111,648	2.4%	137,592	2.5%	145,221	2.6%	186,696	2.9%	268,490	3.7%	301,695	3.7%	325,590	3.7%	1,571,880	3.1%
Fluticone	237,450	6.5%	264,470	5.6%	269,174	5.0%	252,586	4.5%	214,011	3.3%	180,763	2.5%	176,673	2.2%	192,176	2.2%	1,787,303	3.6%
Ennhale	0	0.0%	41,706	0.9%	95,919	1.8%	104,493	1.9%	139,618	2.2%	170,647	2.3%	167,189	2.1%	147,811	1.7%	867,383	1.7%
Floresp	0	0.0%	0	0.0%	30,508	0.6%	51,509	0.9%	92,102	1.4%	120,539	1.6%	118,579	1.5%	167,994	1.9%	581,231	1.2%
Alerflo	0	0.0%	0	0.0%	50,540	0.9%	59,804	1.1%	105,713	1.6%	129,819	1.8%	127,501	1.6%	118,638	1.4%	592,015	1.2%
Flublock	0	0.0%	0	0.0%	23,274	0.4%	41,658	0.7%	85,196	1.3%	103,187	1.4%	101,688	1.3%	80,025	0.9%	435,028	0.9%
Nazomac-F	29,745	0.8%	98,832	2.1%	126,082	2.3%	128,053	2.3%	117,210	1.8%	145,890	2.0%	157,718	1.9%	151,619	1.7%	955,149	1.9%
Efnase	52,522	1.4%	82,483	1.8%	96,781	1.8%	93,416	1.7%	79,641	1.2%	67,979	0.9%	59,366	0.7%	45,387	0.5%	577,575	1.2%
Mezaflo	81,710	2.2%	118,041	2.5%	124,577	2.3%	124,288	2.2%	124,152	1.9%	46,154	0.6%	13,773	0.2%	17,245	0.2%	649,940	1.3%
Nezaflo	0	0.0%	0	0.0%	0	0.0%	0	0.0%	213	0.0%	79,108	1.1%	46,373	0.6%	70,026	0.8%	195,720	0.4%
Freeair	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	64,145	0.9%	125,508	1.5%	123,729	1.4%	313,382	0.6%
Nasocom	62,891	1.7%	76,307	1.6%	52,100	1.0%	48,669	0.9%	46,872	0.7%	51,728	0.7%	48,425	0.6%	42,030	0.5%	429,022	0.9%
Ezicas	21,405	0.6%	49,122	1.0%	46,507	0.9%	43,556	0.8%	31,089	0.5%	45,292	0.6%	60,219	0.7%	64,606	0.7%	361,796	0.7%
Ezicas-F	2,002	0.1%	17,403	0.4%	25,477	0.5%	23,862	0.4%	16,933	0.3%	27,901	0.4%	44,674	0.6%	55,672	0.6%	213,924	0.4%
Flutirest	0	0.0%	0	0.0%	0	0.0%	0	0.0%	11,374	0.2%	6,007	0.1%	3,598	0.0%	185	0.0%	21,164	0.0%
Rhinofit	5,849	0.2%	4,318	0.1%	2,932	0.1%	2,860	0.1%	7,610	0.1%	4,091	0.1%	7,362	0.1%	16,188	0.2%	51,210	0.1%
Furaspray	1,390	0.0%	11,761	0.2%	15,690	0.3%	14,776	0.3%	6,934	0.1%	1,126	0.0%	2,302	0.0%	2,851	0.0%	56,830	0.1%
Otrivin-C	24,105	0.7%	2,614	0.1%	2,292	0.0%	2,009	0.0%	2,566	0.0%	490	0.0%	0	0.0%	0	0.0%	34,076	0.1%
Fivasa	51,591	1.4%	45,785	1.0%	31,796	0.6%	28,006	0.5%	11,602	0.2%	395	0.0%	251	0.0%	323	0.0%	169,749	0.3%
Flutispray	0	0.0%	133	0.0%	54	0.0%	24	0.0%	5	0.0%	0	0.0%	0	0.0%	0	0.0%	216	0.0%
Nasicure	4,739	0.1%	4,582	0.1%	0	0.0%	0	0.0%	53	0.0%	0	0.0%	0	0.0%	0	0.0%	9,374	0.0%
Flutiflo-Ft	0	0.0%	0	0.0%	0	0.0%	0	0.0%	43,162	0.7%	104,503	1.4%	176,933	2.2%	205,331	2.4%	529,929	1.1%
Odnase	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	65,773	0.8%	65,773	0.1%
Nazobic	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	138,007	1.7%	36,128	0.4%	174,135	0.3%
Flocare	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	7,961	0.1%	11,690	0.1%	19,651	0.0%
FFNS	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	3,042	0.0%	3,042	0.0%
Flutivio	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	128	0.0%	128	0.0%
Total Fluticasone	1,861,391	50.9%	2,333,514	49.6%	2,649,514	48.8%	2,702,232	48.4%	3,109,225	48.4%	3,645,940	49.8%	4,167,064	51.3%	4,440,860	50.9%	24,909,740	49.9%

TAB 7

INDIA
ALLERGIC RHINITIS NASAL SPRAYS
IMS TSA DATA
UNITS
2010 – 2017

	Year Ending December 31						Year Ending March 31										Total	
	2010		2011		2012		2013		2014		2015		2016		2017			
	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Azelastine + Fluticasone																		
Imitator Products																		
Duonase	492,503	13.5%	623,768	13.2%	661,336	12.2%	671,867	12.0%	779,174	12.1%	848,256	11.6%	937,462	11.6%	943,817	10.8%	5,958,183	11.9%
Azeflo	184,581	5.0%	235,063	5.0%	262,626	4.8%	274,089	4.9%	326,640	5.1%	378,789	5.2%	401,980	5.0%	503,187	5.8%	2,566,955	5.1%
Combinase-AQ	170,099	4.6%	202,303	4.3%	212,539	3.9%	203,456	3.6%	197,201	3.1%	183,418	2.5%	197,507	2.4%	204,582	2.3%	1,571,105	3.1%
Nazomac-AF	3,807	0.1%	89,256	1.9%	143,783	2.7%	148,458	2.7%	173,146	2.7%	207,989	2.8%	239,056	2.9%	250,489	2.9%	1,255,984	2.5%
Floresp-AZ	0	0.0%	0	0.0%	60,435	1.1%	81,876	1.5%	99,300	1.5%	95,710	1.3%	115,504	1.4%	154,883	1.8%	607,708	1.2%
Ezicas-AZ	18,722	0.5%	50,902	1.1%	48,911	0.9%	45,009	0.8%	45,636	0.7%	64,543	0.9%	92,352	1.1%	119,080	1.4%	485,155	1.0%
Nasocom-AZ	10,775	0.3%	28,515	0.6%	25,147	0.5%	24,688	0.4%	22,507	0.4%	43,815	0.6%	58,348	0.7%	60,835	0.7%	274,630	0.5%
Total Imitator Products	880,487	24.1%	1,229,807	26.1%	1,414,777	26.1%	1,449,443	26.0%	1,643,604	25.6%	1,822,520	24.9%	2,042,209	25.2%	2,236,873	25.7%	12,719,720	25.5%
Other Azelastine + Fluticasone																		
Furamist-AZ	47,816	1.3%	80,646	1.7%	94,027	1.7%	99,049	1.8%	145,157	2.3%	171,170	2.3%	189,223	2.3%	204,336	2.3%	1,031,424	2.1%
Nezalast	69,257	1.9%	76,815	1.6%	76,621	1.4%	78,574	1.4%	87,870	1.4%	82,062	1.1%	37,893	0.5%	59,029	0.7%	568,121	1.1%
Flublock-AZ	0	0.0%	0	0.0%	0	0.0%	0	0.0%	42,244	0.7%	74,122	1.0%	77,403	1.0%	77,405	0.9%	271,174	0.5%
Azenate	2,327	0.1%	2,903	0.1%	3,124	0.1%	3,669	0.1%	5,151	0.1%	10,503	0.1%	13,182	0.2%	16,136	0.2%	56,995	0.1%
Flutirest AZ	0	0.0%	0	0.0%	0	0.0%	0	0.0%	7	0.0%	3,349	0.0%	3,152	0.0%	310	0.0%	6,818	0.0%
Flutiair-AZ	0	0.0%	0	0.0%	2,102	0.0%	2,632	0.0%	552	0.0%	457	0.0%	445	0.0%	116	0.0%	6,304	0.0%
Fivasa-AZ	7,085	0.2%	20,926	0.4%	20,648	0.4%	19,671	0.4%	10,306	0.2%	243	0.0%	172	0.0%	221	0.0%	79,272	0.2%
Duospray	0	0.0%	1,391	0.0%	1,698	0.0%	1,565	0.0%	55	0.0%	0	0.0%	0	0.0%	0	0.0%	4,709	0.0%
Sarnase	716	0.0%	39	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	755	0.0%
Combinase-Ft	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	30,278	0.4%	73,070	0.8%	103,348	0.2%
Total Other Azelastine + Fluticasone	127,201	3.5%	182,720	3.9%	198,220	3.7%	205,160	3.7%	291,342	4.5%	341,906	4.7%	351,748	4.3%	430,623	4.9%	2,128,920	4.3%
Total Azelastine + Fluticasone	1,007,688	27.5%	1,412,527	30.0%	1,612,997	29.7%	1,654,603	29.7%	1,934,946	30.1%	2,164,426	29.5%	2,393,957	29.5%	2,667,496	30.6%	14,848,640	29.7%
Mometasone																		
Nasonex	0	0.0%	93,075	2.0%	254,217	4.7%	294,035	5.3%	406,026	6.3%	411,509	5.6%	372,484	4.6%	291,923	3.3%	2,123,269	4.3%
Metaspray	334,681	9.1%	362,221	7.7%	369,721	6.8%	380,122	6.8%	385,352	6.0%	466,325	6.4%	532,331	6.6%	568,600	6.5%	3,399,353	6.8%
Momeflo	140,081	3.8%	175,503	3.7%	212,690	3.9%	220,182	3.9%	237,886	3.7%	272,932	3.7%	295,401	3.6%	366,296	4.2%	1,920,971	3.8%
Metatop	136,331	3.7%	161,033	3.4%	173,788	3.2%	173,862	3.1%	168,638	2.6%	151,215	2.1%	172,512	2.1%	193,680	2.2%	1,331,059	2.7%
Aquamet	83,173	2.3%	91,413	1.9%	79,166	1.5%	78,616	1.4%	73,844	1.1%	69,331	0.9%	41,641	0.5%	34,020	0.4%	551,204	1.1%
Nazomac-M	0	0.0%	32,534	0.7%	50,914	0.9%	53,143	1.0%	47,457	0.7%	70,337	1.0%	85,687	1.1%	85,088	1.0%	425,160	0.9%
Esynos	0	0.0%	0	0.0%	0	0.0%	0	0.0%	22,290	0.3%	39,736	0.5%	25,635	0.3%	1,042	0.0%	88,703	0.2%
Momenta	8,552	0.2%	17,052	0.4%	17,557	0.3%	17,691	0.3%	20,659	0.3%	21,329	0.3%	17,430	0.2%	20,869	0.2%	141,139	0.3%
Rhine-M	0	0.0%	0	0.0%	0	0.0%	0	0.0%	11,000	0.2%	11,442	0.2%	9,663	0.1%	11,030	0.1%	43,135	0.1%
Eziwin	0	0.0%	0	0.0%	3,452	0.1%	4,667	0.1%	6,430	0.1%	360	0.0%	0	0.0%	2,503	0.0%	17,412	0.0%
M-Spray	86,514	2.4%	29,650	0.6%	341	0.0%	92	0.0%	18	0.0%	0	0.0%	0	0.0%	0	0.0%	116,615	0.2%
Sensonase	9	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	9	0.0%
Respizen	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	19,556	0.2%	19,556	0.0%
Ezispray	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	2,391	0.0%	14,552	0.2%	16,943	0.0%
Vioson	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	74	0.0%	74	0.0%
Total Mometasone	789,341	21.6%	962,481	20.4%	1,161,846	21.4%	1,222,410	21.9%	1,379,600	21.5%	1,514,516	20.7%	1,555,175	19.2%	1,609,233	18.5%	10,194,602	20.4%
Total AR Nasal Sprays	3,658,420	100.0%	4,708,522	100.0%	5,424,357	100.0%	5,579,245	100.0%	6,423,771	100.0%	7,324,882	100.0%	8,116,196	100.0%	8,717,589	100.0%	49,952,982	100.0%

Notes & Sources:
Data for 2010 through 2012 reflect 12-month period ending December 31 of each respective year. Data for 2013 through 2017 reflect 12-month period ending March 31 of each respective year.
IMS TSA (Total Sales Audit) data include hospital, doctor, and retail channel sales. *See* , http://medicinman.net/2016/10/ims-health-market-reflection-report-for-september-2016/ (accessed May 9, 2017).
Percentages based on 'Total AR Nasal Sprays'.
Data for 2010 through 2012 from CIP2123. Data for 2013 through 2017 from CIP2124.

TAB 8

INDIA
IMITATOR PRODUCTS
LAUNCH DATES

Product	Company	Launch Date
Duonase	Cipla	Apr-2004
Combinase-AQ	Zydus Cadila	Oct-2005
Azeflo	Lupin	Jun-2006
Ezicas-AZ	Intas	Apr-2010
Nasocom-AZ	Drl	Jun-2010
Nazomac-AF	Macleods	Dec-2010
Floresp-AZ	Emcure	Mar-2012

Notes & Sources:

I understand that these products represent proper comparators based on testing that establishes that each of these products meets all claim limitations of the challenged claims. *See also* , CIP2126.

TAB 9

INDIA
IMITATOR PRODUCTS
IMS SSA DATA
REVENUES
2005 – 2017

	2005			2006			2007			2008			2009		
Product	₹	$	%	₹	$	%	₹	$	%	₹	$	%	₹	$	%
Duonase	₹21,396,093	$474,970	100.0%	₹32,792,135	$741,948	96.4%	₹37,713,728	$832,951	81.7%	₹50,635,355	$1,249,846	69.6%	₹58,556,518	$1,307,689	68.2%
Azeflo	₹0	$0	0.0%	₹0	$0	0.0%	₹2,314,451	$51,117	5.0%	₹10,100,950	$249,324	13.9%	₹14,432,622	$322,310	16.8%
Nazomac-AF	₹0	$0	0.0%	₹0	$0	0.0%	₹0	$0	0.0%	₹0	$0	0.0%	₹0	$0	0.0%
Combinase-AQ	₹0	$0	0.0%	₹1,211,947	$27,421	3.6%	₹6,148,823	$135,804	13.3%	₹12,066,119	$297,831	16.6%	₹12,897,092	$288,019	15.0%
Floresp-AZ	₹0	$0	0.0%	₹0	$0	0.0%	₹0	$0	0.0%	₹0	$0	0.0%	₹0	$0	0.0%
Ezicas-AZ	₹0	$0	0.0%	₹0	$0	0.0%	₹0	$0	0.0%	₹0	$0	0.0%	₹0	$0	0.0%
Nasocom-AZ	₹0	$0	0.0%	₹0	$0	0.0%	₹0	$0	0.0%	₹0	$0	0.0%	₹0	$0	0.0%
Total	₹21,396,093	$474,970	100.0%	₹34,004,082	$769,369	100.0%	₹46,177,002	$1,019,872	100.0%	₹72,802,424	$1,797,002	100.0%	₹85,886,232	$1,918,018	100.0%

	2010			2011			2012			2013			2014		
Product	₹	$	%	₹	$	%	₹	$	%	₹	$	%	₹	$	%
Duonase	₹66,943,041	$1,400,291	62.7%	₹79,547,616	$1,744,795	61.3%	₹88,152,242	$1,864,149	53.2%	₹95,047,000	$1,757,784	48.8%	₹117,880,025	$1,969,668	49.4%
Azeflo	₹18,546,944	$387,959	17.4%	₹22,993,596	$504,341	17.7%	₹29,069,930	$614,740	17.5%	₹32,889,814	$608,259	16.9%	₹42,692,000	$713,344	17.9%
Nazomac-AF	₹0	$0	0.0%	₹0	$0	0.0%	₹13,010,644	$275,135	7.8%	₹19,476,866	$360,202	10.0%	₹22,708,623	$379,440	9.5%
Combinase-AQ	₹21,306,629	$445,685	20.0%	₹21,996,856	$482,478	17.0%	₹24,854,709	$525,601	15.0%	₹25,534,919	$472,239	13.1%	₹30,006,119	$501,375	12.6%
Floresp-AZ	₹0	$0	0.0%	₹0	$0	0.0%	₹0	$0	0.0%	₹12,225,704	$226,100	6.3%	₹15,940,797	$266,356	6.7%
Ezicas-AZ	₹0	$0	0.0%	₹3,107,430	$68,158	2.4%	₹6,968,929	$147,371	4.2%	₹6,336,255	$117,182	3.3%	₹6,214,213	$103,834	2.6%
Nasocom-AZ	₹0	$0	0.0%	₹2,068,087	$45,361	1.6%	₹3,701,001	$78,265	2.2%	₹3,436,442	$63,553	1.8%	₹3,257,941	$54,437	1.4%
Total	₹106,796,614	$2,233,935	100.0%	₹129,713,585	$2,845,134	100.0%	₹165,757,455	$3,505,261	100.0%	₹194,947,000	$3,605,318	100.0%	₹238,699,718	$3,988,455	100.0%

	2015			2016			2017			CAGR 2005 - 2017 ($)
Product	₹	$	%	₹	$	%	₹	$	%	%
Duonase	₹132,165,813	$2,167,329	47.3%	₹147,207,776	$2,264,111	45.1%	₹173,796,648	$2,588,624	44.5%	15.2%
Azeflo	₹52,581,586	$862,262	18.8%	₹60,186,837	$925,696	18.4%	₹78,519,844	$1,169,518	20.1%	-
Nazomac-AF	₹30,572,194	$501,340	10.9%	₹37,565,518	$577,772	11.5%	₹42,214,730	$628,770	10.8%	-
Combinase-AQ	₹31,261,830	$512,649	11.2%	₹36,857,057	$566,875	11.3%	₹37,722,257	$561,856	9.7%	-
Floresp-AZ	₹16,628,927	$272,690	6.0%	₹20,087,609	$308,955	6.2%	₹26,735,900	$398,219	6.9%	-
Ezicas-AZ	₹9,625,790	$157,849	3.4%	₹14,938,080	$229,753	4.6%	₹20,421,430	$304,168	5.2%	-
Nasocom-AZ	₹6,466,429	$106,040	2.3%	₹9,483,475	$145,859	2.9%	₹10,733,663	$159,873	2.8%	-
Total	₹279,302,569	$4,580,160	100.0%	₹326,326,352	$5,019,022	100.0%	₹390,144,472	$5,811,028	100.0%	23.2%

Notes & Sources:
Data for each year represents the 12-month cumulative period ending in February. For example, data for 2016 goes from March 2015 through February 2016.
INR converted to USD using annual average exchange rate for each 12-month cumulative period from Bloomberg.
CAGR refers to Compound Annual Growth Rate.
IMS SSA (Secondary Sales Audit) data include retail channel sales from local pharmacy retailers. *See* , http://medicinman.net/2016/10/ims-health-market-reflection-report-for-september-2016/ (accessed May 9, 2017).
From CIP2126. *See also* , Tab 8.

TAB 10

INDIA
IMITATOR PRODUCTS
IMS SSA DATA
UNITS
2005 – 2017

	2005		2006		2007		2008		2009	
Product	#	%	#	%	#	%	#	%	#	%
Duonase	154,573	100.0%	235,103	96.4%	257,012	81.1%	344,806	69.3%	393,594	68.5%
Azeflo	0	0.0%	0	0.0%	15,263	4.8%	65,860	13.2%	93,906	16.3%
Nazomac-AF	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Combinase-AQ	0	0.0%	8,802	3.6%	44,657	14.1%	86,576	17.4%	87,432	15.2%
Floresp-AZ	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Ezicas-AZ	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Nasocom-AZ	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Total	154,573	100.0%	243,905	100.0%	316,932	100.0%	497,242	100.0%	574,932	100.0%

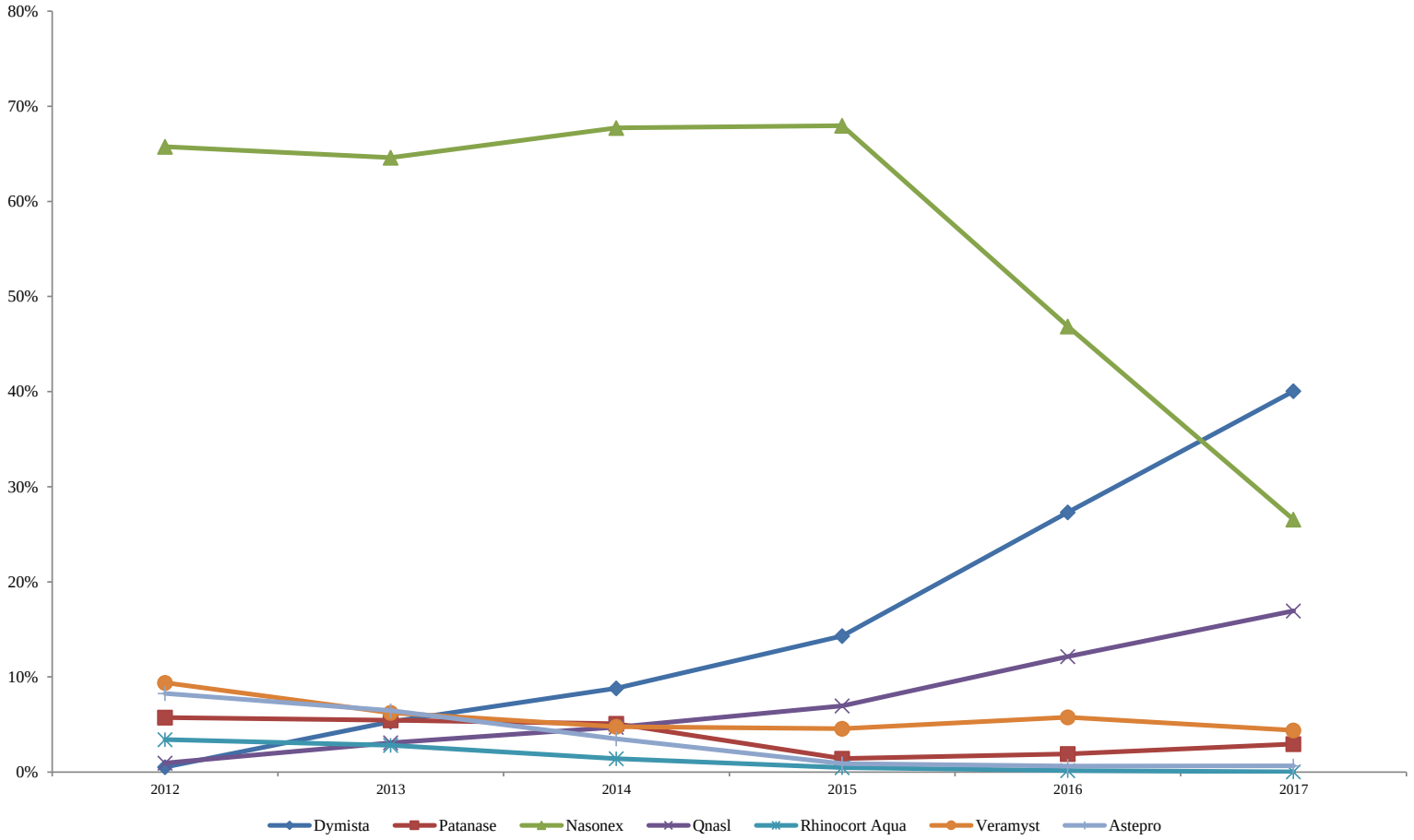
	2010		2011		2012		2013		2014	
Product	#	%	#	%	#	%	#	%	#	%
Duonase	435,695	61.8%	506,695	60.0%	551,045	51.5%	586,731	47.6%	680,444	48.2%
Azeflo	126,725	18.0%	158,765	18.8%	200,151	18.7%	224,638	18.2%	276,623	19.6%
Nazomac-AF	0	0.0%	0	0.0%	85,654	8.0%	128,848	10.5%	148,063	10.5%
Combinase-AQ	142,529	20.2%	145,165	17.2%	164,025	15.3%	168,514	13.7%	166,955	11.8%
Floresp-AZ	0	0.0%	0	0.0%	0	0.0%	62,644	5.1%	83,025	5.9%
Ezicas-AZ	0	0.0%	20,261	2.4%	44,825	4.2%	39,554	3.2%	38,334	2.7%
Nasocom-AZ	0	0.0%	13,613	1.6%	23,945	2.2%	20,793	1.7%	19,366	1.4%
Total	704,949	100.0%	844,499	100.0%	1,069,645	100.0%	1,231,722	100.0%	1,412,810	100.0%

	2015		2016		2017		CAGR 2005 - 2017
Product	#	%	#	%	#	%	%
Duonase	732,434	46.6%	790,271	45.0%	819,338	42.1%	14.9%
Azeflo	329,934	21.0%	351,438	20.0%	432,454	22.2%	-
Nazomac-AF	174,611	11.1%	206,302	11.7%	222,056	11.4%	-
Combinase-AQ	160,550	10.2%	176,698	10.1%	178,205	9.2%	-
Floresp-AZ	86,609	5.5%	104,623	6.0%	138,676	7.1%	-
Ezicas-AZ	53,619	3.4%	80,024	4.6%	102,558	5.3%	-
Nasocom-AZ	35,481	2.3%	47,572	2.7%	52,044	2.7%	-
Total	1,573,238	100.0%	1,756,928	100.0%	1,945,331	100.0%	23.5%

Notes & Sources:
Data for each year represents the 12-month cumulative period ending in February. For example, data for 2016 goes from March 2015 through February 2016.
CAGR refers to Compound Annual Growth Rate.
IMS SSA (Secondary Sales Audit) data include retail channel sales from local pharmacy retailers. *See* ,
http://medicinman.net/2016/10/ims-health-market-reflection-report-for-september-2016/ (accessed May 9, 2017).
From CIP2126. *See also* , Tab 8.

TAB 11

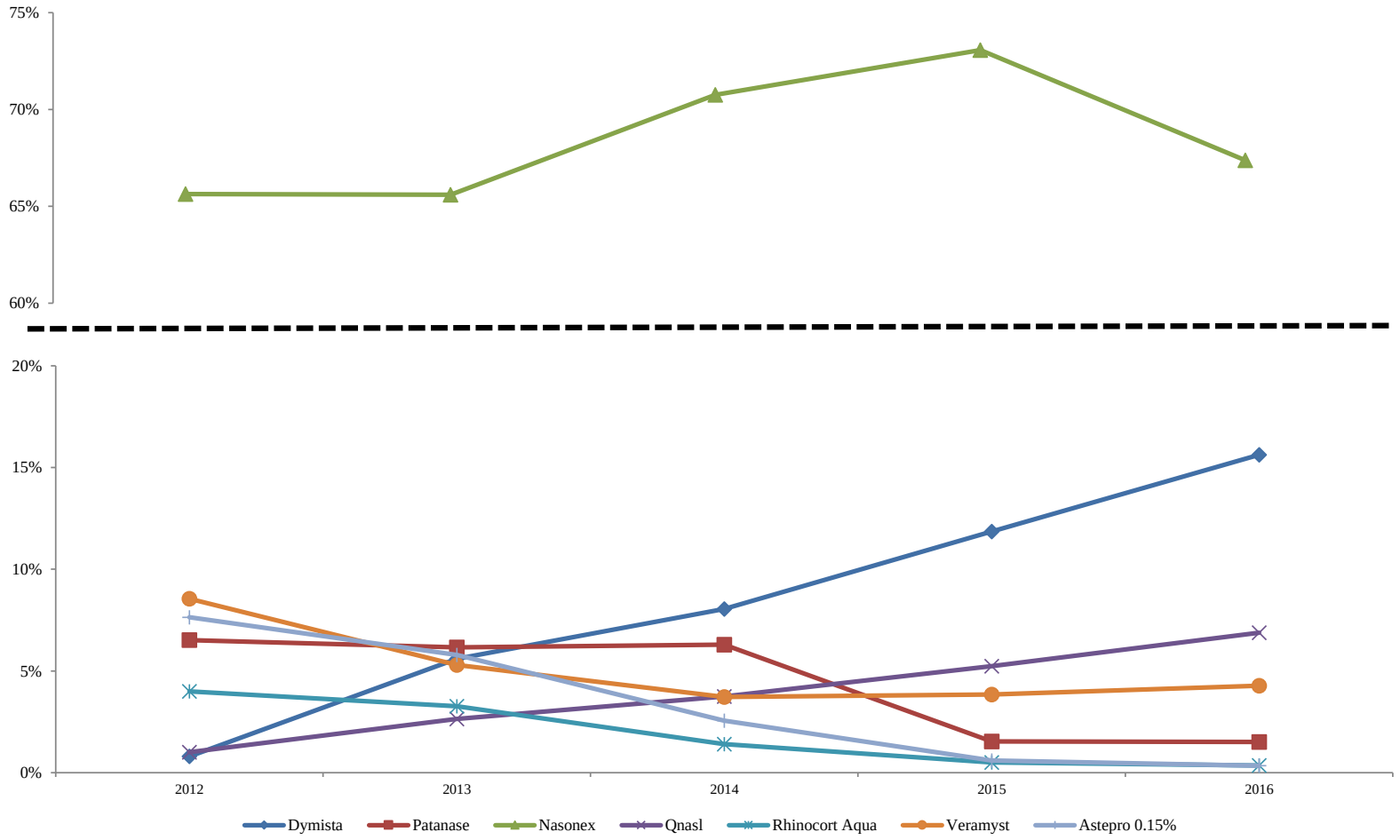
U.S.
SHARE OF BRANDED ALLERGIC RHINITIS NASAL SPRAYS
TOTAL PRESCRIPTIONS
2012 – 2017[1]



Notes & Sources:
[1] Through April.
Branded nasal sprays with a maximum share of less than 3% not shown.
From Tab 3.

TAB 12

U.S.
SHARE OF BRANDED ALLERGIC RHINITIS NASAL SPRAYS
REVENUES
2012 – 2016[1]



Notes & Sources:
[1] Through April.
Branded nasal sprays with a maximum share of less than 3% not shown.
From Tab 4.