Summer Placement
In
Astellas Pharma India Limited
(May 14-July 14, 2012)

A Report on

# Feasibility analysis of launching Urology portfolio in India

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Post-graduate Programme in Pharmaceutical Management
2011-2013

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Dated: 9th Jul 2012

To Whomsoever it may concern

This is to certify that Mr Shashank Srivastava has successfully completed his summer internship for the project titled: **Feasibility Analysis of Launching Urology Portfolio in India**

The training commenced on 14th May 2012 and was completed on 6th Jul 2012 during the course of which his performance was found to be satisfactory and we wish him all the success in his future endeavours.

Best Regards

Isamu Sakurai

Managing Director

Astellas india Private Limited

Astellas Pharma India Private Limited
Mumbai

## Acknowledgement

This report bears the imprint of many people, right from the experienced staff of Astellas Pharma India private ltd whose support and guidance helped me to successfully complete my internship in this esteemed organization.

I express my sincere gratitude to **Mr. Isamu Sakurai**(Managing director) without whose consent I would have never got the opportunity to undertake this project in Astellas pharma India private ltd

I am indebted for the rich guidance, knowledge and suggestions provided by my mentor **Dr. Nandita Katiyar**(Product manager) who in spite of her busy schedule took sincere efforts and illustrated the Marketing Concept, with her vast knowledge in the field, which helped me in carrying out my internship.

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Last but not least I wish to avail myself of this opportunity, express a sense of gratitude and love to my friends and my beloved parents for their manual support, strength, help and for everything.

## 1.0 Executive summary

This project aims to assess the feasibility of launching two Overactive bladder drugs namely VESIcare and YM178 in the Indian market. The project was started on 14th of May, 2012 after knowing all the relevant information about the OAB market and drugs available, under the guidance of Dr. Nandita Katiyar(Product manager).The first part of my project involves the study of OAB market and designing a marketing mix for the drugs Vesicare and YM178 . For this external data such as IMS and Cmarc data and internal market research data was used. This study also involves forecasting sales for Vesicare and YM178 for a span of ten years i.e. from 2013-2022, thus assessing the feasibility of launching these drugs in the Indian market. Conditional forecasting was used to forecast sales for both the drugs and indicators such as NPV, Breakeven sales and payback period were used to assess the feasibility of the project.

## 2.0 Introduction

### 2.1 Introduction to the study

- **Major objectives:** To assess the feasibility of launching VESIcare and YM178 in Urology segment, in Indian market.

- **Sub-objectives**
  - To do a situation analysis thereby analyzing the current OAB market in India.
  - To develop a marketing mix strategy for VESIcare and YM178.
  - To do Segmentation, Targeting and positioning analysis.
  - To forecast sales for both the drugs for a period of ten years.

- **Research methodology**
  - Secondary research
  - Method of Data collection: Secondary data such as IMS and Cmarc and internal market research report.
  - Method of Data Analysis: Microsoft excel

## 2.2 Overview of the Industry

The demand for pharmaceutical products in India is significant and is driven by low drug penetration, rising middle-class & disposable income, increased government & private spending on healthcare infrastructure, increasing medical insurance penetration etc. The Indian pharmaceutical industry is growing at about 8 to 9 percent annually according to "A Brief Report Pharmaceutical Industry in India," published in January 2011. The Pharmaceutical industry in India meets around 70% of the country's demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals and injectables. There are approximately 250 large units and about 8000 Small Scale Units, which form the core of the pharmaceutical industry in India (including 5 Central Public Sector Units).

India's pharmaceutical market grew at 15.7 per cent during December 2011. Globally, India ranks third in terms of manufacturing pharma products by volume. According to McKinsey, the Pharmaceutical Market is ranked 14th in the world. By 2015 it is expected to reach top 10 in the world beating Brazil, Mexico, South Korea and Turkey. More importantly, the incremental market growth of US$ 14billion over the next decade is likely to be the third largest among all markets. The US and China are expected to add US$ 200bn and US$ 23bn respectively.

McKinsey & Company's report, "India Pharma 2020: Propelling access and acceptance, realizing true potential," predicted that the Indian pharmaceuticals market will grow to US$55 billion in 2020; and if aggressive growth strategies are implemented, it has further potential to reach US$70 billion by 2020. While, Market Research firm Cygnus' report forecasts that the Indian bulk drug industry will expand at an annual growth rate of 21 percent to reach $16.91 billion by 2014. The report also noted that India ranks third in terms of volume among the top 15 drug manufacturing countries. Further, McKinsey reports Healthcare grew from 4 per cent of average household income in 1995 to 7 per cent in 2005 and is expected to grow to 13 per cent by 2025.

India tops the world in exporting generic medicines worth US$ 11 billion. The Indian generic drug market is to grow at a CAGR of around 17 per cent between 2010-11 and 2012-13.

The demand for pharmaceutical products in India is significant and is driven by many factors like low drug penetration, rising middle-class & disposable income, increased government & private spending on healthcare infrastructure, increasing medical insurance penetration, changing demographic pattern and rise in chronic lifestyle-related diseases; adoption of product patents, and aggressive market penetration driven by the relatively smaller companies.

### 2.3 Organization profile

**Astellas Pharma Inc.** is a Japanese pharmaceutical company, formed on 1 April 2005 from the merger of Yamanouchi Pharmaceutical Co., Ltd.and Fujisawa Pharmaceutical Co., Ltd.

The company mainly engages in the pharmaceuticals and related products business with franchise areas in urology, immunology (transplantation), dermatology, cardiology, and infectious disease. Priority areas for R&D are infectious diseases, diabetes, gastrointestinal diseases, oncology, and diseases of the central nervous system. The Company operates in two business segments. The Pharmaceuticals and Related Products segment is engaged in the development, manufacture and sale of its pharmaceuticals to both domestic and overseas markets including Japan, North America, Europe and Asia.

The other segment is engaged in the real estate business. Key brands include Prograf, Vesicare, Protopic, Harnal and Funguard. The company's headquarters are in Tokyo, with research centers in Tsukuba and Osaka. Clinical development is centred in Deerfield, Illinois and Leiderdorp, Netherlands. Combined revenues of the two pre-merger companies were $7.9 billion in 2004. Worldwide the company employs about 17,000 people.

On June 9, 2010, Astellas acquired OSI Pharmaceuticals for $4.0 billion. In July 2010, the Company established a subsidiary in Brazil and India. The company currently markets immunosuppressant drugs Advagraf and Prograf in India.

### 3.0 Objective

- **Major objectives:** To assess the feasibility of launching VESIcare and YM178 in Urology segment, in Indian market.

- **Sub-objectives**
  - To do a situation analysis thereby analyzing the current OAB market in India.
  - To develop a marketing mix strategy for VESIcare and YM178.
  - To do Segmentation, Targeting and positioning analysis.
  - To forecast sales for both the drugs for a period of ten years.

## 4.0 ANALYSIS

### 4.1 Introduction to OAB:

**Over**active bladder is defined by the International incontinence society as “ medical condition characterized by symptoms of urinary urgency, with or without urge incontinence, usually with urinary frequency and nocturia, in the absence of pathological or metabolic conditions that might explain these symptoms.” Symptoms of OAB are caused by the overactivity of the detrusor muscle, which controls the urinary bladder.

OAB is characterized by following symptoms, with urgency as pivotal symptom:

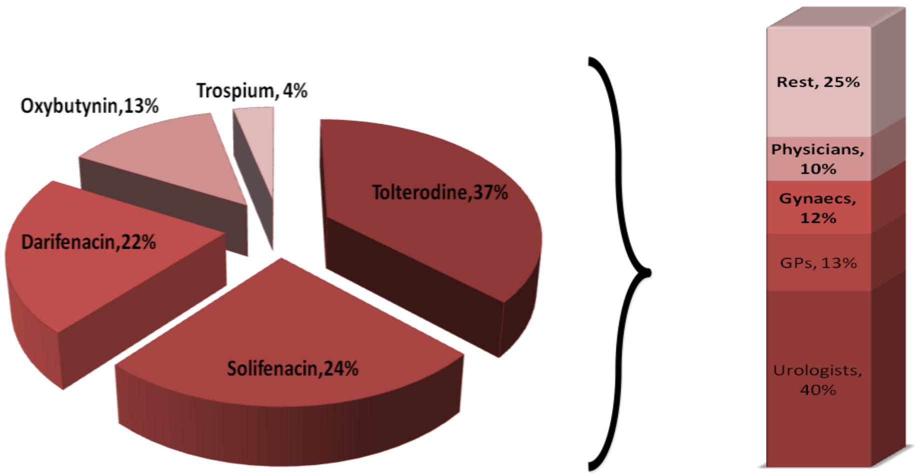
- Urgency:  the complaint of sudden, compelling desire to urinate that is difficult to defer.
- Urge incontinence: the complaint of involuntary leakage accompanied by or immediately proceeded by urgency.
- Frequency: the complaint of voiding too often during the day
- Nocturia: the complaint of waking at night one or more times to void

**Prevalence of OAB:**

More than 33 million Americans suffer from OAB, compared with approximately 17 millionwho have urinary incontinence. The National Overactive Bladder Evaluation (NOBLE)  Program reported that overall prevalence of OAB was similar between men (16%)and women (16.9%) age 18 years or older and that the prevalence of symptoms varied by gender and age. A European study also reported that the overall prevalence of OAB symptoms in individuals 40 years or older was 16.6%.

### 4.2 OAB market analysis

OAB Market is highly fragmented dominated by 5 molecules shown below and is estimated to be around INR 419.3 million for 2011 with a growth of 36% with 5 years CAGR of 24%. Expected growth in OAB market is above 20% y-o-y for the next 10 years primarily due to higher ratio of elderly population and increased affordability.




Source: IMS data MAT 2011

Prescribers for OAB comprise of General practitioners, Physicians, Gynaecologists and Urologists which make the largest share of prescribers.

Solifenacin has been available in Indian market since 2006 and currently enjoys a market share of 24% valued at 102 million. Darifenacin was introduced in Indian market in 2008. Currently it enjoys 22% market share among the OAB molecules valued at 90.4 million. Ranbaxy is the current market leader for both Solifenacin and Darifenacin. CAGR for the period 2008-11 for Solifenacin and Darifenacin is 49.4% and 106.8% respectively.

Market share for both Tolterodine and Oxybutynin are declining. Trospium has been showing a stunted growth.

Urologists contribute 40% of OAB business** (210 mINR)* however 65% of solifenacin business is contributed by urologists** (60.68 mINR)*.

* IMS DATA MAT DEC 2011
**CMARC OCT 2011

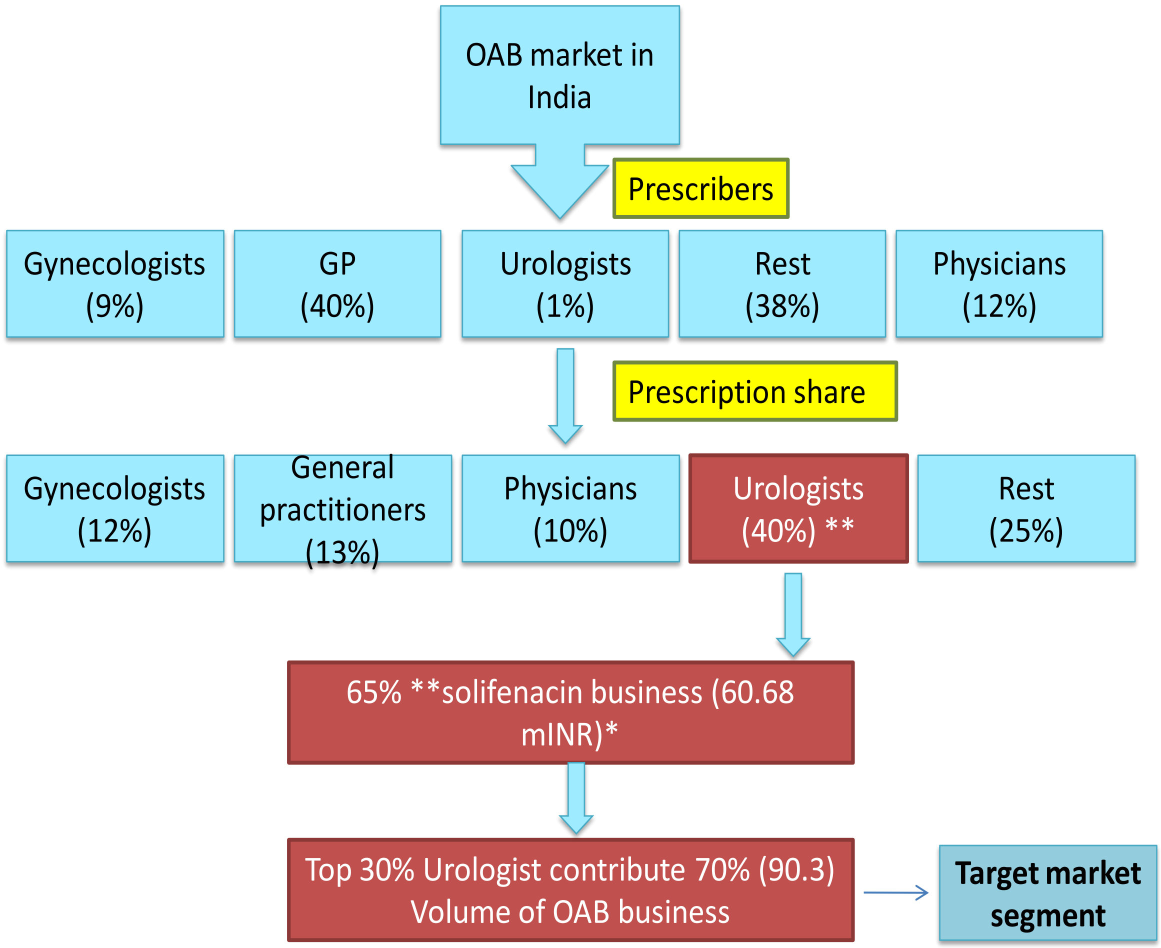
### 4.3 Competitors Scenario:

Major competitors in OAB market are Ranbaxy, Dr.Reddy's, Cipla and Sun Pharma. Ranbaxy is the current market leader in solifenacin market enjoying 15% market share. Soliten is Ranbaxy's blockbuster brand in solifenacin market and enjoys 70% market share in Solifenacin market. Dr. Reddy's solifenacin brand Bispec enjoys a market share of 4%. Major Darifenacin brands in OAB market are Ranbaxy's Dariten OD, launched in 2008, having market share 7% and Sun pharma's Darilong having market share 5% in Darifenacin category.

| Molecule | No. of generic Brands | Brand | SKU | Company | Launch Year | Market Share MAT Dec 2011 |
|---|---|---|---|---|---|---|
| **Solifenacin** | **5** | **Soliten** | 5mg, 10mg & 2mg | Ranbaxy | Aug 2006 | **15%** |
| | | **Bispec** | 5 mg,10 mg | DRL | Apr 2009 | **4%** |
| **Darifenacin** | **6** | **Dariten OD** | 7.5mg,15mg | Ranbaxy | Mar 2008 | **7%** |
| | | **Darilong** | 7.5mg,15mg | Sun Pharma | Sept 2008 | **5%** |
| **Tolterodine** | **10** | **Roliten** | 1 mg, 2mg, 2 mg SR& 4mg SR | Ranbaxy | Sept 2002 | **16%** |
| | | **Terol** | 1 mg, 2mg, 2 mg SR& 4mg SR | Cipla | Dec 2003 | **14%** |

- Market Shares shown are for the category

**5.0 Segmentation and Targeting:**




* IMS DATA MAT DEC 2011
**CMARC OCT 2011

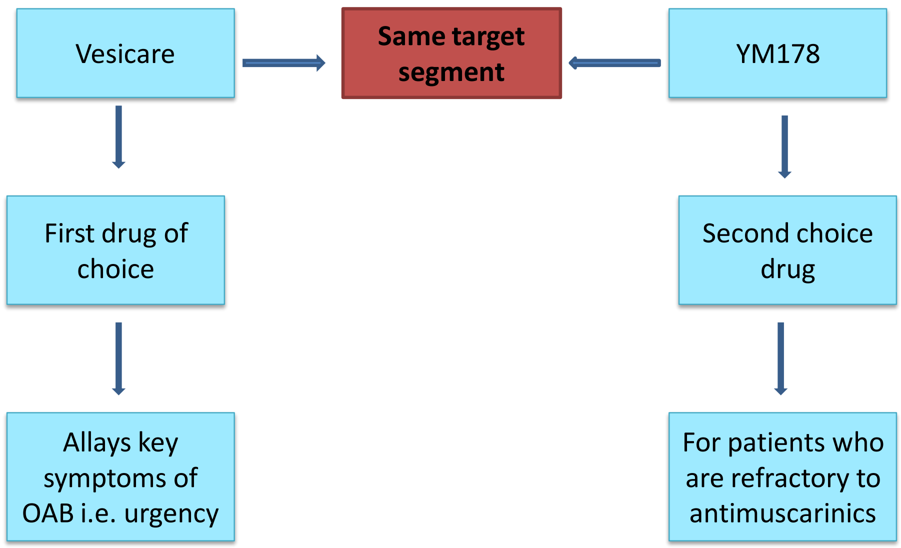
- Target market segment should be Urologists since they contribute maximum in prescription of solifenacin market.
- These Urologists should be covered in four categories of hospitals namely :
    - Large corporate hospitals
    - Corporate hospitals
    - Government hospitals
    - Private hospitals

**Targeting plan:**

| Hospital category | No. of hospitals | No. of urologists | AID Coverage | Total Doctors covered |
|---|---|---|---|---|
| **Large corporate hospitals** | 37 | 74 | 100% | 74 |
| **Corporate hospitals** | 186 | 372 | 100% | 372 |
| **Government hospitals** | 99 | 297 | 5% | 15 |
| **Private hospitals** | 548 | 548 | 80% | 439 |
| **Total** | | 1291 | | 900 |

**6.0 Positioning**

- Both Vesicare and Mirabegron will be promoted to the same customer segment since we are targeting only the top of pyramid in OAB market.
- Vesicare will be targeted as Drug of first choice with positioning of "Vesicare reduces the key symptom of OAB i.e. Urgency".
- Mirabegron will be promoted as the second line drug when anti-muscarinics fail or patient cannot tolerate antimuscarinic side effects.



**7.0 Marketing mix:**

**Product:**

**Vesicare:**

- Vesicare will be marketed in two dosage strengths of 5mg and 10 mg. Product packaging will be monocartons for both strengths with 10 tablets per blister.

- **Core product :**
    - Allays symptoms of OAB
- **Actual product :**
    - Scientific inputs
    - Affordable pricing
    - Originator
    - Product quality
- **Augmented product :**
    - Patient awareness
    - OAB conference
    - OAB camps

**YM178:**

- YM178 will be marketed in 50mg strength in monocartons with 10 tablets per blister.

- **Core product :**
    - Allays symptoms of OAB
- **Actual product :**
    - Scientific inputs
    - Global launch
    - First to be available in India
    - Product quality
- **Augmented product :**
    - Patient awareness
    - OAB conference
    - OAB camps
    - Novel therapy category
    - Improved efficacy and side effect profile

**Pricing:**

Pricing strategy adopted for both Vesicare and YM178 is competitor pricing. Internal market research data shows 80% affordability if Vesicare is priced at a premium of 20% over market leader. Many innovator molecules have been launched at a premium over the market leader in the segment. Moreover, new mechanism of action and first to be launched in beta blocker segment gives YM178 an advantage to be priced at a premium.

- Vesicare priced at a premium of 20% over current market leader.
- YM178 priced at a premium of 70% over Vesicare.

| | |
|---|---|
| Vesicare 5 mg | 230 |
| Vesicare10 mg | 330 |
| Ranbaxy's Soliten 5mg (Market Leader) | 192.48 |
| Ranbaxy's Soliten 10mg (Market Leader) | 274.9 |
| Price premium for Vesicare 5mg over Soliten 5mg | 20% |
| Price premium for Vesicare 10mg over Soliten 10mg | 20% |
| YM178 50 mg | 560 |
| Price premium for YM178 50 mg over Vesicare 10mg | 70% |

**Place:**

Point of purchase of Vesicare and YM178 would be retail pharmacies. Supply chain

Manufacturer ⟶ Stockists ⟶ Distributors ⟶ Retailers

**Promotion:**

Promotion for both the drugs could be done through following mediums:

**Advertising:**

- Patient brochures and pamphlets
- OAB awareness standees at Incontinence clinics
- Corporate film + OAB film at hospital waiting rooms
- Standees in Incontinence Clinics

**Personal selling:**

- Through Medical Representatives
  - Promotional inputs
  - Case studies
  - Clinical studies

**Sales promotion:**

- Physicians' samples
- Discount schemes

**Online marketing:**

- Through webcasts
- Websites educating patient and doctors about OAB.

**Event marketing:**

- Seminars/Symposia
- International conferences
    - Congress of ICS/IUGA
    - APUC
    - Congress of EUA
- National Events
  - USICON- sponsored lectures
    - Role of Vesicare(solifenacin) in OAB
    - Vesicare (solifenacin) in elderly patients

## 7.0 Forecasting

Forecasting was done using conditional forecasting method taking into consideration the scenario where top 30% Urologist are targeted with a sales force of 18 MR.

Profit and loss account of the forecast is given below:

| | 2012-13 | 2013-14 | 2014-15 | 2015-16 | 2016-17 | 2017-18 | 2018-19 | 2019-20 | 2020-21 | 2021-22 | 2022-23 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Vesicare sales in millions | | 7.07 | 7.77 | 9.56 | 10.85 | 13.46 | 15.30 | 19.12 | 23.90 | 29.88 | 37.35 |
| Mir sales in millions | | | 18.24 | 29.27 | 48.00 | 66.96 | 92.25 | 115.32 | 144.15 | 180.18 | 225.23 |
| **Net Sales in millions** | | **7.07** | **26.01** | **38.83** | **58.85** | **80.42** | **107.55** | **134.44** | **168.05** | **210.06** | **262.58** |
| Cost of Goods sold in millions | | 2.14 | 8.48 | 12.72 | 19.40 | 26.56 | 35.61 | 44.51 | 55.64 | 69.55 | 86.94 |
| Gross Profit in millions | | 4.93 | 17.54 | 26.11 | 39.45 | 53.86 | 71.94 | 89.93 | 112.41 | 140.51 | 175.64 |
| Gross Profit Margin | | 69.78% | 67.42% | 67.24% | 67.03% | 66.98% | 66.89% | 66.89% | 66.89% | 66.89% | 66.89% |
| Total Expenses | | 28.65 | 39.59 | 40.81 | 36.00 | 34.96 | 37.45 | 40.18 | 43.20 | 46.53 | 50.24 |
| Promotional Expenses in millions | | 19.9 | 29.8 | 29.6 | 23.2 | 20.1 | 20.2 | 20.1 | 19.7 | 19.0 | 18.0 |
| Payroll | | 8.7 | 9.8 | 11.2 | 12.8 | 14.8 | 17.2 | 20.1 | 23.5 | 27.5 | 32.3 |
| **Net Profit** | | **-23.72** | **-22.05** | **-14.70** | **3.45** | **18.90** | **34.49** | **49.74** | **69.21** | **93.98** | **125.40** |
| **Net Profit at Discounted rate** | | **-23.72** | **-20.23** | **-12.37** | **2.67** | **13.39** | **22.42** | **29.66** | **37.86** | **47.16** | **57.74** |

| | |
|---|---|
| **Net Present Value at discount rate of 10%** | **Rs. 156.12** |
| **Breakeven point** | **2017-18** |

- Targeting top 30% Urologist with a sales force of 18 MR, revenues generated in first year INR 7.07 million and a combines sales of INR 25.31 million in the first year of YM178 launch.
- Net present value at discounted rate of 10% is INR 156.12 million.

## 8.0 Conclusion and recommendations

- Self promotion seems to be the best option for the launch of Vesicare and YM178 in India.
- Positioning plays a crucial role since both the drugs are for treatment of same symptoms and target segment. Vesicare positioned as first choice of drug for treatment of Urgency and YM178 as drug of choice for patients who are refractory to antimuscarinics.
- Proper Segmentation and Targeting is important since the market is highly fragmented with many speciality prescribing the drug. Only top-of-the Pyramid Urologists targeted which is 30%(900 Urologists)
- Promotion with a new field force of 18 will reach out to 900 Urologists who contribute 70% of OAB business.
- The revenue of INR 7.07 million in first year of Vesicare launch and combined revenues of INR 26.01 million in the first year of YM178 launch.