# IMPAX Laboratories, Inc.

# IMPAX Laboratories, Inc. (IPXL.PK)

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To the extent any statements made in this presentation contain information that is not historical, these statements are forward-looking in nature and express the beliefs and expectations of management. Such statements are based on management's current expectations and are subject to a number of known and unknown risks and uncertainties that could cause IMPAX's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to, possible adverse effects resulting from the delisting of and suspension of trading in IMPAX's stock, the SEC proceeding to determine whether to suspend or revoke the registration of IMPAX's securities under section 12 of the Securities Exchange Act, IMPAX's delay in filing its periodic reports subsequent to its Form 10-Q for the third quarter of 2004, the time that will be required to complete the filing of IMPAX's delinquent periodic reports, IMPAX's ability to obtain sufficient capital to fund its operations, the difficulty of predicting FDA filings and approvals, consumer acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, IMPAX's ability to successfully develop and commercialize pharmaceutical products, IMPAX's reliance on key strategic alliances, the uncertainty of patent litigation, the availability of raw materials, the regulatory environment, dependence on patent and other protection for innovative products, exposure to product liability claims, fluctuations in operating results and other risks detailed from time to time in IMPAX's filings with the Securities and Exchange Commission. Forward-looking statements speak only as to the date on which they are made, and IMPAX undertakes no obligation to update publicly or revise any forward-looking statement, regardless of whether new information becomes available, future developments occur or otherwise.

**Note: All product sales data included herein are derived from data published by Wolters Kluwer Health for the 12 months ending February 28, 2007, except for the veterinary product Carprofen, which are derived from data published by Market Dynamics for the 12 months ending December 31, 2004.**



# Company Overview

- Technology based specialty pharmaceutical company
- Applying oral drug delivery technology and formulation expertise to the development of generic and branded pharmaceutical products
- Experienced senior management team
- Strong product portfolio
- Brand strategy offers potential long-term growth opportunities

# Product Portfolio

- Approximately 112 generic products approved, pending or under development - targeting over $30 billion in US product sales
  - 37 Approved applications
  - 22 Applications pending at FDA
    - 5 ANDAs with Tentative Approval
  - Approximately 53 more under development
    - Additional products and/or strengths
- Additionally, 1 NDA for a brand product is pending and three additional brand products are under development

# R&D Highlights

- 2006 - Received 6 approvals from FDA

  Final Approvals for generic versions of:

  - Salagen
  - Colestid Granules
  - Colestid Tablets
  - Urecholine
  - Ditropan XL 15mg
  - Wellbutrin XL 300mg

# Commercial Highlights

- 2006 - Launched 6 new products
  - Includes generic versions of:
    - Salagen 5, 7.5mg
    - Colestid Granules
    - Lofibra 67,134,200mg
    - ProAmatine 10mg
    - Ditropan XL 15mg
    - Wellbutrin XL 300mg

# R&D Highlights

- 2007 - Received 1 approval from FDA

  Final Approval for generic version of:

  Corzide

# Commercial Highlights

- 2007 – Launched 2 new products
  - Includes generic versions of:

    Colestid Tablets

    Urecholine 5,10,25,50 mg

# Drug Delivery Capabilities

- Multiple delivery vehicles
- Applying new and existing drug delivery technologies to create new product opportunities
  (19 approved ANDAs utilize our drug delivery technologies)
- Developing and patenting new concepts and oral controlled release technologies
- Approximately 120 employees in our R&D effort

# Development Strategy

- **Target limited competition environment**
  - Generic
    - Controlled Release – large, rapidly growing market
    - Specialty – technically challenging projects, barriers to entry, or other selected market opportunities
  - Brand
    - Targeting drugs used in treating CNS disorders
    - Focusing on improved versions of marketed compounds
      - Lower cost – much smaller R&D investment compared to NCEs
      - Lower risk of development – compounds previously shown to be safe and effective

# Development Strategy

- Outsourced Development
  - Selected Generic Projects
    - 20 development projects outsourced
    - Utilizing 6 off-shore companies
    - Out of the 20 projects, 7 have been submitted
  - Provides
    - Lower cost of development
    - Increased development capacity

# Generic Projects

# Generic Projects

## Current Status

| Group | Specialty | | Controlled Release | | Total | |
|---|---|---|---|---|---|---|
| Category | Qty | Market* | Qty | Market* | Qty | Market* |
| Pending at FDA | 11 | $835 | 11 | $7,016 | 22 | $7,851 |
| Under Development | 14 | $3,126 | 39 | $16,176 | 53 | $19,302 |
| **Total** | **25** | **$3,961** | **50** | **$23,192** | **75** | **$27,153** |

*US Market size, millions of US$

# Generic Projects

## Paragraph IV Filing Summary (24 total)

| IMPAX Project | Generic of* | Est. Filing Order** | Initial Filing |
|---|---|---|---|
| Omeprazole 10,20,40mg DR | Prilosec (AZN) | 5th of 10 total | 4Q99 |
| Bupropion 100,150mg ER | Wellbutrin SR (GSK) | 3rd of 5 total | 2Q00 |
| Bupropion 150mg ER | Zyban (GSK) | 2nd of 4 total | 2Q00 |
| Fenofibrate 67,134,200mg | Lofibra (Gate/Teva) | 2nd of 2 total | 2Q00 |
| Loratadine & PSE 10/240mg ER | Claritin-D 24 hr (SGP) | 2nd of 3 total | 3Q00 |
| Loratadine 10mg ODT | Claritin Reditab (SGP) | 3rd of 3 total | 4Q00 |
| Loratadine & PSE 5/120mg ER | Claritin-D 12 hr (SGP) | 1st of 2 total | 4Q00 |
| Metformin 500mg ER | Glucophage XR (BMS) | 2nd of 15 total | 3Q01[1] |
| Fexofenadine & PSE 60/120mg ER | Allegra-D (AVE) | 2nd of 5 total | 4Q01 |
| Oxycodone 80mg ER | OxyContin (PUR) | 3rd of 6 total | 4Q01 |
| Oxycodone 10,20&40mg ER | OxyContin (PUR) | 3rd of 6 total | 2Q02 |
| Fenofibrate 54,160mg | Tricor Tablet (ABT) | 2nd of 4 total | 3Q02 |

*Trademarks referenced are the property of their respective owners. **Estimation based on publicly available data.
Note [1]:Paragraph IV cert. & notice filed 4Q02. Products in Teal are marketed. White background means TA/FA rec'd.

# Generic Projects

## Paragraph IV Filing Summary

| IMPAX Project | Generic of* | Est. Filing Order** | Initial Filing |
|---|---|---|---|
| Methylphenidate 18,27,36&54mg ER | Concerta (Alza/JNJ) | 1st of 2 total | 4Q02[2] |
| Carbidopa/Levodopa ER | Sinemet CR (BMS) | 2nd of 4 total | 4Q02 |
| Carprofen 25,75 &100mg (Vet) | Rimadyl (Pfizer) | 1st | 4Q02 |
| Bupropion 200mg ER | Wellbutrin SR (GSK) | 1st of 2 total | 1Q03 |
| Oxybutynin 5,10,15mg ER | Ditropan XL (Alza/JNJ) | 2nd of 2 total[3] | 2Q03 |
| Amphetamine 5,10,15,20,25&30mg ER | Adderall XR (Shire) | 2nd of 5 total | 3Q03 |
| Metformin 750mg ER | Glucophage XR (BMS) | 5th of 10 total | 4Q03 |
| Bupropion 150&300mg ER | Wellbutrin XL (GSK) | 3rd of 4 total | 4Q04 |
| Colestipol 1gm | Colestid Tablet (Pfizer) | 1st | 4Q04[2] |
| Venlafaxine 37.5,75&150 mg ER | Effexor XR (Wyeth) | 2nd of 3 total | 4Q05 |
| Undisclosed | | | 4Q06 |
| Undisclosed | | | 1Q07 |

*Trademarks referenced are the property of their respective owners. **Estimation based on publicly available data.
Note [2]--Paragraph IV certification and notice filed 3Q05. Note [3]--First to file on 15 mg strength.

# Generic Projects

## Paragraph IV Litigation Status Summary (24 total filed)

| Litigation Resolved or Not Sued (18 projects) | |
|---|---|
| Bupropion 100,150mg ER (W) | Methylphenidate 18,27,36&54mg ER |
| Bupropion 150mg ER (Z) | Carbidopa/Levodopa ER |
| Fenofibrate 67,134,200mg Caps | Carprofen 25,75,100mg |
| Loratadine & PSE 10/240mg ER 24hr | Bupropion 200mg ER |
| Loratadine 10mg ODT | Oxybutynin 5,10&15mg ER |
| Loratadine & PSE 5/120mg ER 12hr | SE Amphetamine 5,10,15,20,25&30mg ER |
| Metformin 500mg ER | Metformin 750mg ER |
| Fenofibrate 54 &160mg Tabs | Colestipol 1gm Tabs |
| Bupropion 150 & 300mg ER (XL) | Undisclosed |

# Generic Projects

## Paragraph IV Litigation Status Summary (24 total filed)

| Project | Litigation Status |
|---|---|
| Omeprazole 10, 20 & 40mg DR | Trial completed June 2006; awaiting decision. |
| Fexofenadine & PSE ER | No trial date scheduled. |
| Oxycodone 80mg ER | Settled March 30, 2007. |
| Oxycodone 10, 20 & 40mg ER | |
| Venlafaxine 37.5, 75, 150 mg ER | Discovery stage. Trial 1H2007. |
| Undisclosed | Not yet sued. |

# Commercial Strategy

## *Strategic Alliances for Generic Projects*

- **Teva**
  - Signed June 2001
  - First product shipped 1Q 2004
  - 12 Rx products, 11 filed to date, 11 disclosed
- **Dava/Purdue**
  - Signed November 2005
  - First product shipped 4Q 2005
  - 1 Rx product, 4 Strengths, Oxycodone HCl ER Tablets; 10, 20, 40 & 80 mg
  - Signed patent settlement with Purdue Pharmaceuticals in March 2007 which granted IMPAX a full release and ability to sell a limited amount of product for a limited amount of time
  - Amended terms of Dava agreement that better reflects the changes in the marketplace (e.g. larger share of profits to IMPAX in exchange for relieving DAVA of all future appointment fees)

# Brand Projects

# Brand Projects

- Targeting improved versions of existing chemical entities
  - Reduced risk and expense associated with development as compared to NCE development.
  - Reduced time of development as compared to NCE development
- Utilize development and drug delivery expertise
  - Improve patient compliance and outcomes

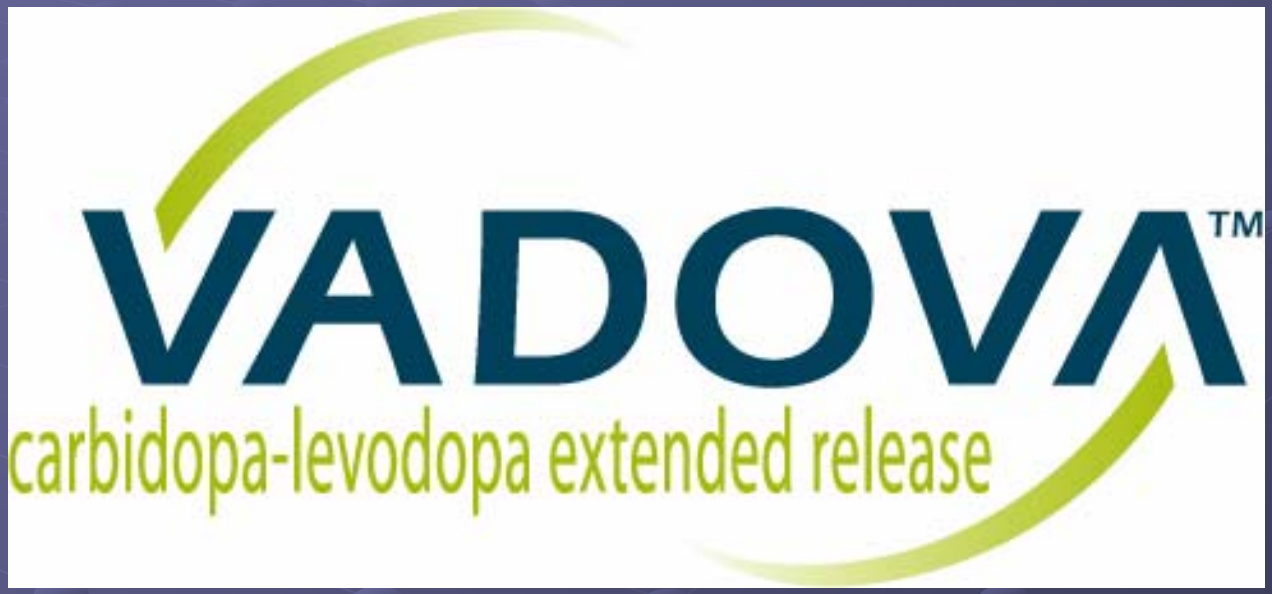
# Brand Projects

- Focus on Central Nervous System (CNS) drugs
  - Rapidly growing therapeutic area
  - Focus on CNS disease states, including movement disorders such as Parkinson's disease.
  - These movement disorders are frequently treated by the approximately 8,300 practicing neurologists, of which about 3,500 write the majority of prescriptions.
  - This group can be addressed by the small existing sales force by adding these products to the current effort for Carbatrol.

# Brand Projects

- Despite being the standard for treating Parkinson's Disease, existing levodopa therapy does not meet certain needs:
  - Delayed or unpredictable "on"
  - Motor fluctuation and dyskinesias
  - Pill burden
  - True delivery of continuous dopaminergic stimulation

# Brand Projects




- VADOVA™ (carbidopa-levodopa) is formulated with the goal of meeting one of these unmet needs by allowing a reduction in pill burden.

# Brand Projects

- The effective date of acceptance of the VADOVA NDA by FDA was May 3, 2005.
- “Non-approvable” letter received from FDA March 3, 2006.
- An Amendment was filed on January 18, 2007 addressing the concerns raised in the Agency’s non-approvable letter of March 2006.
- US and foreign patent applications filed.

# Commercial Strategy

## *Strategic Alliances for Branded Projects*

- **Carbatrol ® (Shire)**
  - Signed January 2006
  - Promoted Product: Carbatrol® (carbamazepine extended release)
  - Payments of $40 million to be received over three years to provide promotional services
  - Target audience – Neurologists
  - Impax Pharmaceuticals Sales Force formed and detailing of Carbatrol launched – July 2006

# Significant Milestones

| Milestone | 2000/ 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 (YTD) |
|---|---|---|---|---|---|---|---|
| **Applications Filed** | **16** | **8** | **8** | **6** | **10** | **6** | **2** |
| • PPG IV filings | 9 | 5 | 4 | 1 | 3* | 1 | 1 |
| • IND filings | 0 | 0 | 2 | 1 | 0 | 0 | 0 |
| • NDA filings | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| **Approvals (Total)** | **3** | **8** | **9** | **11** | **6** | **6** | **1** |
| • Tentative approval | 0 | 5 | 2 | 2 | 1 | 1 | 0 |

*Includes amendments to two previously filed applications—not included in 2005 applications filed

Filing Goal 2007: 8-10 with focus on modified-release products

# Financials

| | Mar-06 | Jun-06 (1) | Sep-06 | Dec-06 | Mar-07 |
|---|---|---|---|---|---|
| | | (in thousands and unaudited) | | | |
| Cash and Investments | 41,438 | 30,695 | 27,353 | 29,092 | 46,648 |
| Senior Debt | 5,369 | 5,342 | 5,316 | 5,430 | 5,375 |
| Convertible & Subordinated Debt | 75,000 | 75,000 | 75,000 | 75,000 | 75,000 |
| Subordinated Settlement Obligation | | 11,000 | 11,000 | 11,000 | 10,616 |
| Total Senior and Subordinated Debt | 80,369 | 91,342 | 91,316 | 91,430 | 90,991 |
| Less Current Maturities | 110 | 110 | 970 | 1,830 | 1,829 |
| Long-Term | 80,259 | 91,232 | 90,346 | 89,600 | 89,161 |
| Capital Expenditures | 4,822 (3 Months) | 12,886 (6 Months) | 17,820 (9 Months) | 20,793 (12 Months) | 6,269 (3 Months) |

(1) Settlement of Solvay litigation reached 2Q 2006 for $23 million of which $12 million was paid immediately.

# Highlights

- Experienced management with strong industry knowledge and technical expertise
- Broad base of drug delivery technology, formulation and development expertise
- Strong product portfolio
- Branded product strategy offers potential additional long-term growth opportunities

Thank you for your interest in

IMPAX Laboratories, Inc.