

MIRA INFORM REPORT

Report No. :	545971
Report Date :	21.12.2018

IDENTIFICATION DETAILS

Name :	ZYDUS PHARMACEUTICALS (USA) INC
Registered Office :	73, Route 31 North ,Pennington,Nj,0853
Country :	United States
Financials (as on) :	2017 (Summarized)
Date of Incorporation :	18.11.2003
Legal Form :	Corporation
Line of Business :	Subject operates as a generic pharmaceutical company that discovers, develops, manufactures, and markets various healthcare therapies/generic pharmaceutical products to customers
No. of Employees :	31

RATING & COMMENTS

(Mira Inform has adopted New Rating mechanism w.e.f. 23rd January 2017)

MIRA's Rating :

A

Credit Rating	Explanation	Rating Comments
A	Acceptable Risk	Business dealings permissible with moderate risk of default

Status :	Good
Payment Behaviour :	Regular
Litigation :	Exist

NOTES :

Any query related to this report can be made on e-mail : infodept@mirainform.com while quoting report number, name and date.

ECGC Country Risk Classification List

Country Name	Previous Rating (30.06.2018)	Current Rating (30.09.2018)
United States	A1	A1

Risk Category	ECGC Classification
Insignificant	A1
Low Risk	A2
Moderately Low Risk	B1
Moderate Risk	B2
Moderately High Risk	C1
High Risk	C2
Very High Risk	D

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UNITED STATES - ECONOMIC OVERVIEW

The US has the most technologically powerful economy in the world, with a per capita GDP of \$59,500. US firms are at or near the forefront in technological advances, especially in computers, pharmaceuticals, and medical, aerospace, and military equipment; however, their advantage has narrowed since the end of World War II. Based on a comparison of GDP measured at purchasing power parity conversion rates, the US economy in 2014, having stood as the largest in the world for more than a century, slipped into second place behind China, which has more than tripled the US growth rate for each year of the past four decades.

In the US, private individuals and business firms make most of the decisions, and the federal and state governments buy needed goods and services predominantly in the private marketplace. US business firms enjoy greater flexibility than their counterparts in Western Europe and Japan in decisions to expand capital plant, to lay off surplus workers, and to develop new products. At the same time, businesses face higher barriers to enter their rivals' home markets than foreign firms face entering US markets.

Long-term problems for the US include stagnation of wages for lower-income families, inadequate investment in deteriorating infrastructure, rapidly rising medical and pension costs of an aging population, energy shortages, and sizable current account and budget deficits.

The onrush of technology has been a driving factor in the gradual development of a "two-tier" labor market in which those at the bottom lack the education and the professional/technical skills of those at the top and, more and more, fail to get comparable pay raises, health insurance coverage, and other benefits. But the globalization of trade, and especially the rise of low-wage producers such as China, has put additional downward pressure on wages and upward pressure on the return to capital. Since 1975, practically all the gains in household income have gone to the top 20% of households. Since 1996, dividends and capital gains have grown faster than wages or any other category of after-tax income.

Imported oil accounts for more than 50% of US consumption and oil has a major impact on the overall health of the economy. Crude oil prices doubled between 2001 and 2006, the year home prices peaked; higher gasoline prices ate into consumers' budgets and many individuals fell behind in their mortgage payments. Oil prices climbed another 50% between 2006 and 2008, and bank foreclosures more than doubled in the same period. Besides dampening the housing market, soaring oil prices caused a drop in the value of the dollar and a deterioration in the US merchandise trade deficit, which peaked at \$840 billion in 2008. Because the US economy is energy-intensive, falling oil prices since 2013 have alleviated many of the problems the earlier increases had created.

The sub-prime mortgage crisis, falling home prices, investment bank failures, tight credit, and the global economic downturn pushed the US into a recession by mid-2008. GDP contracted until the third quarter of 2009, the deepest and longest downturn since the Great Depression. To help stabilize financial markets, the US Congress established a \$700 billion Troubled Asset Relief Program in October 2008. The government used some of these funds to purchase equity in US banks and industrial corporations, much of which had been returned to the government by early 2011. In January 2009, Congress passed and former President Barack OBAMA signed a bill providing an additional \$787 billion fiscal stimulus to be used over 10 years - two-thirds on additional spending and one-third on tax cuts - to create jobs and to help the economy recover. In 2010 and 2011, the federal budget deficit reached nearly 9% of GDP. In 2012, the Federal Government reduced the growth of spending and the deficit shrank to 7.6% of GDP. US revenues from taxes and other sources are lower, as a percentage of GDP, than those of most other countries.

Wars in Iraq and Afghanistan required major shifts in national resources from civilian to military purposes and contributed to the growth of the budget deficit and public debt. Through FY 2018, the direct costs of the wars will have totaled more than \$1.9 trillion, according to US Government figures.

In March 2010, former President OBAMA signed into law the Patient Protection and Affordable Care Act (ACA), a health insurance reform that was designed to extend coverage to an additional 32 million Americans by 2016,

through private health insurance for the general population and Medicaid for the impoverished. Total spending on healthcare - public plus private - rose from 9.0% of GDP in 1980 to 17.9% in 2010.

In July 2010, the former president signed the DODD-FRANK Wall Street Reform and Consumer Protection Act, a law designed to promote financial stability by protecting consumers from financial abuses, ending taxpayer bailouts of financial firms, dealing with troubled banks that are "too big to fail," and improving accountability and transparency in the financial system - in particular, by requiring certain financial derivatives to be traded in markets that are subject to government regulation and oversight.

The Federal Reserve Board (Fed) announced plans in December 2012 to purchase \$85 billion per month of mortgage-backed and Treasury securities in an effort to hold down long-term interest rates, and to keep short-term rates near zero until unemployment dropped below 6.5% or inflation rose above 2.5%. The Fed ended its purchases during the summer of 2014, after the unemployment rate dropped to 6.2%, inflation stood at 1.7%, and public debt fell below 74% of GDP. In December 2015, the Fed raised its target for the benchmark federal funds rate by 0.25%, the first increase since the recession began. With continued low growth, the Fed opted to raise rates several times since then, and in December 2017, the target rate stood at 1.5%.

In December 2017, Congress passed and President Donald TRUMP signed the Tax Cuts and Jobs Act, which, among its various provisions, reduces the corporate tax rate from 35% to 21%; lowers the individual tax rate for those with the highest incomes from 39.6% to 37%, and by lesser percentages for those at lower income levels; changes many deductions and credits used to calculate taxable income; and eliminates in 2019 the penalty imposed on taxpayers who do not obtain the minimum amount of health insurance required under the ACA. The new taxes took effect on 1 January 2018; the tax cut for corporations are permanent, but those for individuals are scheduled to expire after 2025. The Joint Committee on Taxation (JCT) under the Congressional Budget Office estimates that the new law will reduce tax revenues and increase the federal deficit by about \$1.45 trillion over the 2018-2027 period. This amount would decline if economic growth were to exceed the JCT's estimate.

Source : CIA

STATUTORY INFORMATION

Legal Name	ZYDUS PHARMACEUTICALS (USA) INC.
Trade Name	ZYDUS PHARMACEUTICALS
ID	ID
ID Details	0100915422
Creation Date	2003
Incorporation Date	11/18/2003
Legal Address	Agent: JOSEPH D RENNER Agent/SOP Address: 73, ROUTE 31 NORTH ,PENNINGTON,NJ,08534
Operative Address	73 RTE 31 N PENNINGTON, NJ, 08534-3601 United States
Telephone	(609) 730-1900
Fax	609-730-1998
Legal Form	CORPORATION
E-Mail	NA
Registered In	NEW JERSEY
Website	www.zydususa.com
Contact	Joseph Renner - Director
Staff	31
Activity	SIC Code: 2834, Pharmaceutical Preparations NAICS Code: 325412, Pharmaceutical Preparation Manufacturing

BANKS

Name of Bank	Reported Amount
BANK OF AMERICA, NA	
Description	-

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HISTORY
History

Zybus Pharmaceuticals (USA) Inc was founded in 2003.

DOR Suspension Start

Date:

06-16-2007

DOR Suspension End

Date:

04-29-2008

Key Developments

Sumitomo Dainippon Pharma Co., Ltd. Files Additional Patent Infringement Lawsuit Regarding LATUDA in the United States against Fifteen Companies Feb 24 18

Sumitomo Dainippon Pharma Co. Ltd. filed a patent infringement lawsuit jointly with its U.S. subsidiary, Sunovion Pharmaceuticals Inc. ("Sunovion") on February 23, 2018 in the U.S. District Court for the District of New Jersey against fifteen companies, and related companies regarding their submissions of Abbreviated New Drug applications for generic copies of LATUDA®. The lawsuit alleges infringement of Sumitomo Dainippon Pharma's U.S. Patent No. 9,815,827. The lawsuit is similar to the lawsuits announced in Sumitomo Dainippon Pharma's release issued on February 14, 2018. Sumitomo Dainippon Pharma has granted Sunovion an exclusive license in the United States under the '827 Patent, and Sunovion has been marketing lurasidone HCl tablets in the United States under the brand name LATUDA® since its launch in February 2011. Sumitomo Dainippon Pharma and Sunovion continue to believe that patent portfolio for LATUDA® is very strong, and will continue to vigorously protect patent rights for LATUDA®. The lawsuit will not materially affect Sumitomo Dainippon Pharma's consolidated financial results of the fiscal year ending March 31, 2018. As to the financial impacts for the fiscal year ending March 31, 2019 and thereafter, the company will make announcement as they become available. Fifteen companies are Accord Healthcare Inc., Amneal Pharmaceuticals, LLC, Aurobindo Pharma Ltd., Dr. Reddy's Laboratories Ltd., First Time U.S. Generics, LLC., InvaGen Pharmaceuticals, Inc., Jubilant Generics Ltd., Lupin Ltd., MSN Laboratories Private Ltd., Par Pharmaceutical, Inc., SUN PHARMA GLOBAL FZE, Teva Pharmaceuticals USA, Inc., Torrent

Pharmaceuticals Ltd., Watson Laboratories Inc., Zydus Pharmaceuticals (USA) Inc.

Zydus Pharmaceuticals (USA) Inc. Receives Final Approval from the USFDA for Valacyclovir Tablets USP Dec 30 17

Zydus Pharmaceuticals (USA) Inc. has received the final approval from the USFDA to market Valacyclovir Tablets USP in strengths of 500 mg and 1 gm. The drug is indicated for the treatment of cold sores (herpes labialis), genital herpes, chickenpox and herpes zoster(shingles). It will be manufactured at the group's formulations manufacturing facility at Moraiya, Ahmadabad.

Zydus Pharmaceuticals (USA) Inc. Gets the US Food and Drug Administration Approval for OCD Treatment Drug Dec 29 17

Zydus Pharmaceuticals (USA) Inc. has received final approval from the US health regulator to market Clomipramine Hydrochloride capsules, used to treat obsessive compulsive disorder (OCD). The company has received final approval from the US Food and Drug Administration (USFDA) to market the drug in the strength of 25 mg, 50 mg and 75 mg, Zydus Cadila said in a BSE filing. The company will produce the drug at the group's formulations manufacturing facility at SEZ, Ahmedabad. Clomipramine hydrochloride capsule is used to treat obsessive compulsive disorder, which is characterised by uncontrollable, re-occurring thoughts and behaviours. The company has more than 180 approvals and so far filed over 310 abbreviated new drug applications (ANDAs) since it commenced filings in 2003-04.

Parent Company

Zydus Pharmaceuticals (USA) Inc operates as a subsidiary of:

Cadila Healthcare Limited
Zydus Tower
Satellite Cross Road
Sarkhej-Gandhinagar Highway
Ahmedabad, 380015
India

PRINCIPAL ACTIVITY

General Description

ZyduS Pharmaceuticals (USA) Inc. operates as a generic pharmaceutical company that discovers, develops, manufactures, and markets various healthcare therapies/generic pharmaceutical products to customers in the United States.

Service/Product Description

It offers Valacyclovir Tablets USP in 500 mg and 1 gm, a drug indicated for the treatment of cold sores (herpes labialis), genital herpes, chickenpox, and herpes zoster(shingles); and Clomipramine Hydrochloride capsules in 25 mg, 50 mg, and 75 mg, which is used to treat obsessive compulsive disorder.

Sales

Wholesale

Operations Area

National

Imports From

India

Employees

31 employees

Payments With Suppliers

Regular

BRANDS

Brand

There are not informed brands

Comments

CLIENTS

Name of Client

Country

Comments

There are not informed clients

Comments

The company offers its products to private companies.

SUPPLIERS

Supplier Name

Country

Comments

Cadila Health Care Ltd.

India

-

Comments

-

LOCATION

Headquarters 73 RTE 31 N PENNINGTON, NJ, 08534-3601 United States
Branches No branches were found.

GROUP STRUCTURE AND SUBDIARY COMPANIES

Listed at the stock exchange No

Capital NA

Shareholders (%) Zydus Pharmaceuticals (USA) Inc operates as a subsidiary of:
Cadila Healthcare Limited
Zydus Tower
Satellite Cross Road
Sarkhej-Gandhinagar Highway
Ahmedabad, 380015
India

Management Title: CHIEF EXEC. OFFICER (CEO)
Name: KIKUCHI, MARC T
Address: 73 ROUTE 31 N, PENNINGTON, , , US
Title: PRESIDENT
Name: KEENLEY, MICHAEL G
Address: 73 ROUTE 31 N, PENNINGTON, , , US
Title: TREASURER
Name: YADAVAR, RAVI C
Address: 73 ROUTE 31 N, PENNINGTON, , , US
Title: DIRECTORS
Name: RENNER, JOSEPH D
Address: 73 ROUTE 31 N, PENNINGTON, , , US
Title: DIRECTORS
Name: PATEL, MAHENDRA R
Address: 73 Route 31 N, Pennington, , , US

Subsidiary Companies No subsidiary companies were found.

Related Companies Zydus Wellness Limited
House No. 6 & 7
Sigma Commerce Zone
Near Iskcon Temple
Sarkhej-Gandhinagar Highway
Ahmedabad, 380015
India

Sentynl Therapeutics Inc
265 Santa Helena
Solana Beach, CA 92075-1542
United States

Zydus Healthcare Limited
National Highway 31 A
Majitar, 737136
India

Zydus Pharma Inc
Shinjuku-ku
Tokyo,
Japan

Biochem Pharmaceuticals Industries Limited
Aidun Building
John Castro Lane
Near Metro Adlabs
Mumbai, 400 002
India

FINANCIAL INFORMATION

General Description	The company does not make its financial statements public. The following information has been provided by private sources:
Year/Currency	2017 USD
Sales	466.300.000
Income	5.900.000
Money Flow	Normal

LEGAL FILINGS

Lawsuits	Boehringer Ingelheim Pharmaceuticals Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al Plaintiff: Boehringer Ingelheim Corporation, Boehringer Ingelheim Pharmaceuticals Inc. and Boehringer Ingelheim International GmbH Defendant: Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited
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Case Number: 1:2018cv01763
Filed: November 8, 2018
Court: Delaware District Court
Nature of Suit: Patent - Abbreviated New Drug
Application(ANDA)
Cause of Action: 35:271
Jury Demanded By: None

Anacor Pharmaceuticals, Inc. v. Ascent
Pharmaceuticals, Inc. et al
Plaintiff: Anacor Pharmaceuticals, Inc.
Defendant: Cipla Limited, Perrigo Company plc, Taro
Pharmaceuticals U.S.A., Inc., Aleor Dermaceuticals
Limited, Cipla USA, Inc., Apotex Corp., Apotex Inc.,
Aurobindo Pharma USA, Inc., Ascent Pharmaceuticals,
Inc., Zydus Pharmaceuticals (USA) Inc., Aurobindo
Pharma Limited, Taro Pharmaceutical Industries, Ltd.,
Amneal Pharmaceuticals LLC, Perrigo Pharma
International DAC and Cadila Healthcare Ltd.
Case Number: 1:2018cv01673
Filed: October 25, 2018
Court: Delaware District Court
Nature of Suit: Patent - Abbreviated New Drug
Application(ANDA)
Cause of Action: 35:271
Jury Demanded By: None

VALEANT PHARMACEUTICALS NORTH AMERICA
LLC et al v. ZYDUS PHARMACEUTICALS (USA) INC.
et al
Plaintiff: KAKEN PHARMACEUTICAL CO., LTD., DOW
PHARMACEUTICAL SCIENCES, INC., VALEANT
PHARMACEUTICALS NORTH AMERICA LLC and
VALEANT PHARMACEUTICALS IRELAND LTD.
Defendant: ZYDUS WORLDWIDE DMCC, CADILA
HEALTHCARE LIMITED and ZYDUS
PHARMACEUTICALS (USA) INC.
Case Number: 3:2018cv13635
Filed: September 6, 2018
Court: New Jersey District Court
0 Judge: Lois H Goodman
1 Judge: Peter G Sheridan
Nature of Suit: Patent - Abbreviated New Drug
Application(ANDA)
Cause of Action: 35:271
Jury Demanded By: None

MARION DIAGNOSTIC CENTER, LLC et al v.
MCKEESON CORPORATION et al

Plaintiff: MARION DIAGNOSTIC CENTER, LLC and
MARION HEALTHCARE, LLC
Defendant: HERITAGE PHARMACEUTICALS, INC.,
EMCURE PHARMACEUTICALS, LTD., SANDOZ,
INC., MYLAN PHARMACEUTICALS INC., ASCEND
LABORATORIES, LLC, ZYDUS PHARMACEUTICALS
(USA) INC., TEVA PHARMACEUTICALS, USA, INC.,
UNNAMED DISTRIBUTOR CO-CONSPIRATORS, DR.
REDDY'S LABORATORIES, INC., PAR
PHARMACEUTICAL COMPANIES, INC., APOTEX
CORP., MYLAN INC., CITRON PHARMA, LLC,
MCKEESON CORPORATION, SUN
PHARMACEUTICAL INDUSTRIES, INC., MCKEESON
MEDICAL-SURGICAL, INC., LANNETT COMPANY,
INC., GLENMARK PHARMACEUTICALS, INC., USA,
AUROBINDO PHARMA USA, INC., MAYNE PHARMA
INC., MCKEESON CORPORATION and MCKEESON
MEDICAL-SURGICAL, INC.

Case Number: 2:2018cv04137

Filed: September 25, 2018

Court: Pennsylvania Eastern District Court

Presiding Judge: CYNTHIA M RUFÉ

Nature of Suit: Other Statutes: Anti-Trust

Cause of Action: 15:1

Jury Demanded By: Plaintiff

Bernstein et al v. Actavis Pharma, Inc. et al
Plaintiff: Susan Bernstein and Mark Bernstein
Defendant: KVK-Tech, Inc., Mercy Clinic East
Communities, Actavis Pharma, Inc., Demetrios V.
Polites, D.O. and Zydus Pharmaceuticals (USA), Inc.

Case Number: 1:2018op46037

Filed: September 5, 2018

Court: Ohio Northern District Court

Presiding Judge: Dan Aaron Polster (MDL 2804)

Nature of Suit: Personal Injury: Health

Care/Pharmaceutical Personal Injury Product Liability

Cause of Action: 28:1332

Jury Demanded By: Both

SHIONOGI INC. et al v. ZYDUS PHARMACEUTICALS
(USA) INC.

Plaintiff: SHIONOGI INC. and ANDRX LABS, L.L.C.

Defendant: ZYDUS PHARMACEUTICALS (USA) INC.

Case Number: 3:2018cv12898

Filed: August 16, 2018

Court: New Jersey District Court

0 Judge: Lois H Goodman

Trademarks

1 Judge: Brian R Martinotti
Nature of Suit: Patent - Abbreviated New Drug
Application(ANDA)
Cause of Action: 35:271
Jury Demanded By: None
ZYPHARMA
Chemicals used in pharmaceuticals and cosmetics
Owned by: Zydus Pharmaceuticals (USA) Inc.
Serial Number: 78390103

ZYGENERICS
House mark for a full line of pharmaceutical
preparations
Owned by: Zydus Pharmaceuticals (USA) Inc.
Serial Number: 78496742

ZALDYON
pharmaceutical preparations for treatment of ulcerative
colitis, Pharmaceutical preparations and substances for
the treatment...
Owned by: Zydus Pharmaceuticals (USA) Inc.
Serial Number: 87786107

ADVEGLEE
pharmaceutical preparations and substances for the
treatment of oncological related diseases and disorders
Owned by: Zydus Pharmaceuticals (USA) Inc.
Serial Number: 88139601

TIADYLT
Pharmaceutical preparations for high blood pressure
(hypertension), chest pain (angina) and some types of
irregular heartbeats...
Owned by: Zydus Pharmaceuticals (USA) Inc.
Serial Number: 86960965
No found.

Patents Registered

Renewals

Annual Report Month: NOVEMBER
Last Annual Report
Filed:
09/07/2018
Year: 2018
No records found.

UCC (Uniform Commercial Code)

OFAC Sanctions List Search

The company is not listed in the OFAC list.

SUMMARY

Summary

Founded in 2003, Zydus Pharmaceuticals (USA) Inc is an organization in the Pharmaceutical Preparations Industry headquartered in Pennington, NJ. The company has 31 regular employees and generates an estimated \$466.3 million USD in annual revenue. It operates nationally, mainly importing from India. It is ACTIVE in business with no negative records.

RISK INFORMATION

Debts	Controlled
Payments	Regular
Cash Flow	Normal
State	Active

INTERVIEW

First Name	Whitney
Position	Operator
Comments	She confirmed the name of the company and the address of the headquarters. However, she was reluctant to provide any further information.

FOREIGN EXCHANGE RATES

Currency	Unit	Indian Rupees
US Dollar	1	INR 70.28
UK Pound	1	INR 88.85
Euro	1	INR 80.05
USD	1	INR 70.08

Note : Above are approximate rates obtained from sources believed to be correct

INFORMATION DETAILS

Analysis Done by :	VIVR
Report Prepared by :	KET

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RATING EXPLANATIONS

Credit Rating	Explanation	Rating Comments
A++	Minimum Risk	Business dealings permissible with minimum risk of default
A+	Low Risk	Business dealings permissible with low risk of default
A	Acceptable Risk	Business dealings permissible with moderate risk of default
B	Medium Risk	Business dealings permissible on a regular monitoring basis
C	Medium High Risk	Business dealings permissible preferably on secured basis
D	High Risk	Business dealing not recommended or on secured terms only
NB	New Business	No recommendation can be done due to business in infancy stage
NT	No Trace	No recommendation can be done as the business is not traceable

NB is stated where there is insufficient information to facilitate rating. However, it is not to be considered as unfavourable.

This score serves as a reference to assess SC's credit risk and to set the amount of credit to be extended. It is calculated from a composite of weighted scores obtained from each of the major sections of this report. The assessed factors are as follows:

- Financial condition covering various ratios
- Company background and operations size
- Promoters / Management background
- Payment record
- Litigation against the subject
- Industry scenario / competitor analysis
- Supplier / Customer / Banker review (wherever available)