

# **ZS Pharma Inc**

# **CORTELLIS COMPANY DETAILED PIPELINE REPORT**

A comprehensive coverage of the the company's drug pipeline portfolio including detailed product records.

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### ABOUT CORTELLIS COMPANY DETAILED PIPELINE REPORT

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### **GLOSSARY**

#### **Number of Drugs in Active Development**

Number of drugs associated with the company or subsidiary that are currently in active development, i.e. the development status for the drug(s) is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended.

#### **Number of Inactive Drugs**

Number of drugs associated with the company or subsidiary that are currently classified as inactive, i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.

#### **Number of Patents as Owner**

Number of patents associated with the company where the company is listed as owner; i.e. the relationship type (or way the patent refers to the company) is: Patent Assignee/Owner, Patent owner (not assignee), Licensee for development and marketing, Licensee – marketing only (Distributor), Patent assignee of family member, Inferred assignee.

#### **Number of Patents as Third Party**

Number of patents associated with the company where the company is listed as third party; i.e. the relationship type (or way the patent refers to the company) is: Patent assignee (not owner), Ex-Licensee for development and marketing, Ex-Licensee marketing only (Distributor), Customer of technology, Ex-Customer of technology, Patent opponent or infringer, Affiliate organization of inventor, Owner of underlying technology.

#### Patents summary table

This table represents a summary of the core patent coverage for this company covering Therapeutic EP, US and WO patents since 1990 only.

#### **Number of Deals**

A count of deals where the company or one of its subsidiaries is the primary company.

#### **Key Indications**

Displays top ten key indications for the company and its subsidiaries based on frequency (indications occurring with high and identical frequency are always included, and this may result in more than ten Key Indications being listed). Includes both indications associated with patents where the company is patent owner and indications associated with drugs in active development. A drug is classified as 'active' if it features on a row (or rows) in the current development status table where the status is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended.

#### **Key Target-based Actions**

Displays top ten key target-based actions for the company and its subsidiaries based on frequency (actions occurring with high and identical frequency are always included, and this may result in more than ten Key Target-based Actions being listed). Includes both target-based actions associated with patents where the company patent owner and target-based actions associated with drugs in active development. A drug is classified as 'active' if it features on a row (or rows) in the current development status table where the status is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended. A target-based action is one that is associated with a target.

#### **Key Technologies**

Displays top ten key technologies for the company and its subsidiaries based on frequency (technologies occurring with high and identical frequency are always included, and this may result in more than ten Key Technologies being listed). Includes both key technologies associated with patents where the company relationship is patent owner and key technologies associated with drugs in active development. A drug is classified as 'active' if it features on a row (or rows) in the current development status table where the status is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended.

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## **ZS Pharma Inc**

### **COMPANY OVERVIEW**

| Company Name                             | ZS Pharma Inc  |
|--|--|
| Parent Company Name                      | ZS Pharma Inc  |
| Website                                  | http://www.zspharma.com/   |
| Country                                  | US   |
| Number of Drugs in Active<br>Development | 1  |
| Number of Inactive Drugs                 | 0  |
| Number of Patents as Owner               | 4  |
| Number of Patents as Third Party         | 0  |
| Number of Deals                          | 0  |
| Key Indications                          | Hyperkalemia,Hyperphosphatemia,Hyperammonemia,Bladder disease,End stage renal disease,Heart disease  |
| Key Target-based Actions                 |  |
| Key Technologies                         | Oral absorption enhancer, Oral formulation, Small molecule therapeutic, Crystalline form, Microparticle formulation, Tablet formulation, Capsule formulation, Formulation powder |

## **COMPANY PROFILE**

#### **SUMMARY**

ZS Pharma Inc, a private specialty pharmaceutical company, founded in 2008 is focused on the development and commercialization of oral sorbent technology in therapeutic areas of kidney and liver disease.

#### **FINANCIAL**

In July 2014, ZS Pharma secured a debt facility of up to \$20 million with MidCap Financial. At that time, the company had drawn \$10 million, under the agreement.

In June 2014, the company priced its IPO of 5,944,444 shares of its common stock at \$18 per share that begun trading on the NASDAQ Global Market under the symbol 'ZSPH'. The underwriters were granted a 30-day option to purchase an additional 891,667 shares of common stock. At that time, the offering was expected to close on or about June 23, 2014. Later that month, the company raised approximately \$112 million through the IPO of 6,836,111 shares of common stock and additional shares allotted. At that time, the offering was closed.

In March 2014, ZS Pharma raised \$55 million in a series D financing round.

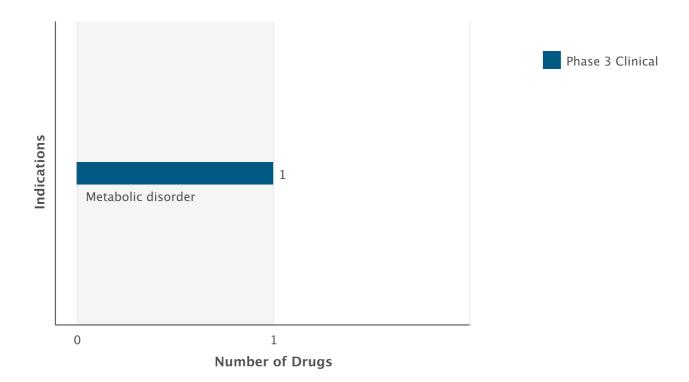
In October 2012, ZS pharma raised \$46 million in a series C financing round.

# PRODUCT PORTFOLIO SUMMARY

### **DRUGS**

# Drugs by Indication

Active Drugs by Indication Chart

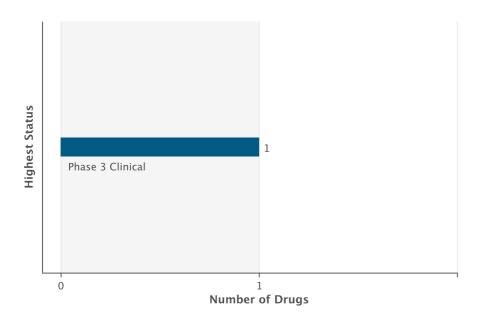


# Drugs by Indication Table

| Indication         | Active | Inactive | Total |
|--------------------|--------|----------|-------|
| Metabolic disorder | 1      | 0        | 1     |

### **Drugs by Highest Status**

Active Drugs by Highest Status Chart



# Drugs by Highest Status Table

| Development Status | Number of Drugs |
|--------------------|-----------------|
| Phase 3 Clinical   | 1               |

### **CLINICAL TRIALS**

# Trials by Condition Studied

| Condition Studied     | Ongoing | All |
|-----------------------|---------|-----|
| Metabolic disorder    | 1       | 6   |
| Genitourinary disease | 0       | 1   |

# Trials by Phase

| Phase   | Ongoing | All |
|---------|---------|-----|
| Phase 4 | 0       | 1   |
| Phase 3 | 1       | 4   |
| Phase 2 | 0       | 1   |

### **Phase Definitions**

### Phase 3 Clinical

Includes Phase 3, Phase 3b, Phase 3a, Phase 2/3 (where enrolment count is 300 or over)



#### Phase 2 Clinical

Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

# Phase 1 Clinical

Includes Phase 1, Phase 1, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

### **PATENTS** \*

| Indication             | As Owner | As Third Party | Total |
|------------------------|----------|----------------|-------|
| Cardiovascular disease | 1        | 0              | 1     |
| Genitourinary disease  | 1        | 0              | 1     |
| Metabolic disorder     | 5        | 0              | 5     |

<sup>\*</sup> This table represents a summary of the core patent coverage for this company covering Therapeutic EP, US and WO patents since 1990 only.

### PRODUCT PORTFOLIO DRUG PIPELINE DETAIL

PLEASE NOTE: Highest status refers to highest development of that drug for one of the active companies

## sodium zirconium cyclosilicate

#### sodium zirconium cyclosilicate SNAPSHOT

| Drug Name            | sodium zirconium cyclosilicate                                       |
|----------------------|--|
| Key Synonyms         | sodium zirconium cyclosilicate                                       |
| Originator Company   | ZS Pharma Inc  |
| Active Companies     | ZS Pharma Inc  |
| Inactive Companies   |  |
| Highest Status       | Phase 3 Clinical   |
| Active Indications   | Hyperkalemia;Hyperammonemia;Hyperphosphatemia                        |
| Target-based Actions |  |
| Other Actions        | Nitrogen metabolism modulator;Potassium metabolism modulator         |
| Technologies         | Oral formulation;Oral absorption enhancer;Small molecule therapeutic |
| Last Change Date     | 16-Dec-2014  |

#### sodium zirconium cyclosilicate DEVELOPMENT PROFILE

#### **SUMMARY**

ZS Pharma is developing sodium zirconium cyclosilicate (ZS-9, zirconium silicate), an oral sorbent cation exchanger and potassium absorbing agent, developed using the company's ZrSi technology, for the potential treatment of acute and chronic hyperkalemia and investigating it for the potential treatment of hyperammonemia and hyperphosphatemia. In March 2013, a phase III trial was initiated in the US and Australia. In March 2014, the company initiated an additional phase III trial. In June 2014, another phase III trial was initiated in the US. By November 2014, two phase III trials were completed. In November 2014, phase III results were published. By July 2011, the company was planning to seek regulatory approval for the treatment of additional indications including hyperammonemia and hyperphosphatemia following US approval.

#### sodium zirconium cyclosilicate DEVELOPMENT STATUS

### **CURRENT DEVELOPMENT STATUS**

| Company       | Indication     | Country   | <b>Development Status</b> | Date        |
|---------------|----------------|-----------|---------------------------|-------------|
| ZS Pharma Inc | Hyperkalemia   | Australia | Phase 3 Clinical          | 13-Mar-2013 |
| ZS Pharma Inc | Hyperkalemia   | US        | Phase 3 Clinical          | 13-Mar-2013 |
| ZS Pharma Inc | Hyperammonemia | US        | Discovery                 | 31-Jul-2010 |



| Company       | Indication        | Country      | Development Status | Date        |
|---------------|-------------------|--------------|--------------------|-------------|
| ZS Pharma Inc | Hyperkalemia      | Europe       | Discovery          | 11-Jun-2014 |
| ZS Pharma Inc | Hyperkalemia      | South Africa | Discovery          | 11-Jun-2014 |
| ZS Pharma Inc | Hyperphosphatemia | US           | Discovery          | 31-Jul-2011 |

### sodium zirconium cyclosilicate DRUG NAMES

| Names  | Туре          |
|--|---------------|
| ZS-9   | Research Code |
| zirconium silicate (hyperkalemia), ZS Pharma                 |               |
| sodium zirconium cyclosilicate                               | USAN          |
| cation exhange agent (oral sorbent, hyperkalemia), ZS Pharma |               |

### sodium zirconium cyclosilicate CLINICAL TRIALS

### Trials by Phase and Condition Studied

|              | se 4<br>nical |              | se 3<br>nical |              | se 2<br>nical |              | se 1<br>nical |              | ase<br>ecified | То           | tal |
|--------------|---------------|--------------|---------------|--------------|---------------|--------------|---------------|--------------|----------------|--------------|-----|
| On-<br>going | All            | On-<br>going | All |
| Hyperkal     | emia          |              |               |              |               |              |               |              |                |              |     |
| 0            | 0             | 0            | 2             | 0            | 0             | 0            | 0             | 0            | 0              | 0            | 2   |

# Total Trials by Phase and Status

| Phase 4<br>Clinical       |     | Phase 3<br>Clinical |     | Phase 2<br>Clinical |     | Phase 1<br>Clinical |     | Phase<br>Unspecified |     | Total        |     |
|---------------------------|-----|---------------------|-----|---------------------|-----|---------------------|-----|----------------------|-----|--------------|-----|
| On-<br>going              | All | On-<br>going        | All | On-<br>going        | All | On-<br>going        | All | On-<br>going         | All | On-<br>going | All |
| Total by Phase and Status |     |                     |     |                     |     |                     |     |                      |     |              |     |
| 0                         | 0   | 0                   | 2   | 0                   | 0   | 0                   | 0   | 0                    | 0   | 0            | 2   |

#### **Phase Definitions**

### Phase 3 Clinical

Includes Phase 3, Phase 3b, Phase 3a, Phase 2/3 (where enrolment count is 300 or over)

#### Phase 2 Clinical

Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

## Phase 1 Clinical

Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

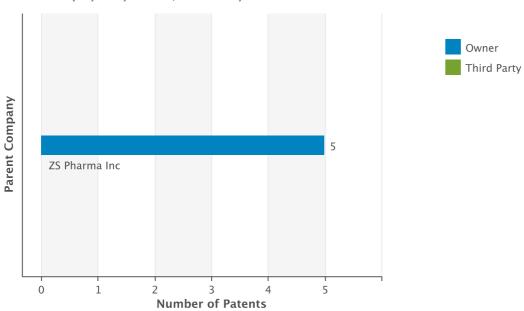


# sodium zirconium cyclosilicate DEALS AND PATENTS

### **PATENTS**

# **Patents by Parent Company Chart**

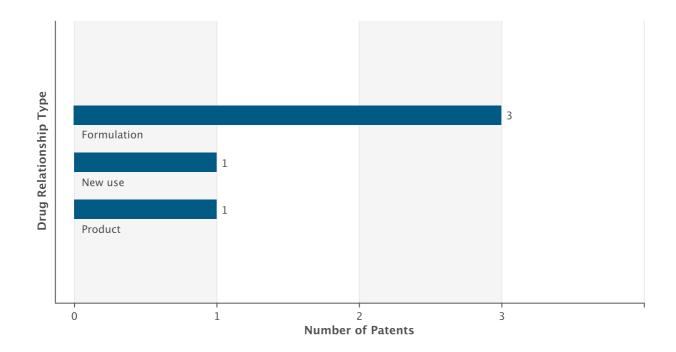
Chart displayed by Owner/Third Party



### **Patents by Parent Company Table**

| Company Name  | As Owner | As Third Party | Total |
|---------------|----------|----------------|-------|
| ZS Pharma Inc | 5        | 0              | 5     |

# **Patents by Drug Relationship Type Chart**



# **Patents by Drug Relationship Type Table**

| Drug Relationship |   |
|-------------------|---|
| Formulation       | 3 |
| Product           | 1 |
| New use           | 1 |

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