



# Athenex – Where there's smoke...

Athenex's revenue generating business is a house of cards, muddled with further ties to large scale frauds, fabricated management credentials, and photoshopped offices.



**October 23, 2019** – This follow up report focuses specifically on **Athenex's Polymed subsidiary**, which accounts for a large portion of Athenex's revenues and capital expenditure:

- Our investigations have found ties between Polymed and its management team's **ties to the largest taxol smuggling ring in history Hande Yunnan, resulting in 50 arrests and 32 imprisonments. Major perpetrators and shareholders of this scheme now work for Athenex.**
- Polymed appears to continue sourcing its taxol from Hande Yunnan, despite the fact that our investigations show Hande Yunnan no longer produce taxol.
- Further inspection of Polymed's management show inconsistencies in prior executive roles, specifically of William Zuo. **Zuo was also the US liaison of bringing smuggled taxol to the USA.**
- A deep dive into Chinese regulatory notes from the Ministry of Emergency Management, coupled with Polymed's history of objectionable site inspections by Chinese regulators and the FDA, lead us to believe that **Polymed's manufacturing facility suspension was anything but voluntary.** In any event, Athenex's manufacturing facility does not manufacture anything.
- Viceroy dismantles **photoshopped Polymed advertisements for its facilities and expose chemical manufacturing facilities we believe are non-existent or outsourced.**

Athenex, Inc.		
Exchange		NASDAQ
Ticker		ATNX
Shares Outstanding	m	77.3
Share Price*	US\$	11.50
<b>Market Cap</b>	<b>US\$m</b>	<b>888.9</b>
Net Cash	US\$m	78.7
NCI	US\$m	11.7
<b>EV</b>	<b>US\$m</b>	<b>798.5</b>
NTA	US\$m	131.6
Licensing Revenue	US\$m	87.2
Revenue Multiple	X	1.0
<b>Viceroy Valuation</b>	<b>US\$m</b>	<b>218.8</b>
<b>Viceroy Price Target</b>	<b>US\$</b>	<b>2.83</b>
Downside	%	-75%
* As at close of market - Oct 22, 2019		
NB: LTM/balance from Jun 30, 2019		

Viceroy remains short Athenex with high conviction. The quantum of red flags uncovered within the business and management team surpass any other company we have previously analyzed purely within data sourced from the public domain.

**We reiterate our target price of \$2.83, now representing a 75% downside, and will continue to keep investors informed through further reporting.**

We conclude that Athenex exists to abuse capital markets and enrich its management through **related party transactions and licensing deals, rather than bring revolutionary drugs into the market.** This activity is masqueraded through overpromise in both its flagship drug, Oraxol, and its purported "supply-chain" businesses, such as Polymed.

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*Athenex is a perfect storm of investor deception, insider enrichment and clinical trial risks. Investors should demand a full investigation of the issues discussed within this report: we are confident there is more to this story given how much was available purely through the public domain.*

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Athenex's operational and R&D cash-burn rate is over US\$100m a year – the company would be lucky to survive until HY 2020 without needing a further cash injection from investors. Even if Athenex scrapped its R&D completely, the company's revenue streams operate at a substantial loss.

**Accordingly, we believe our valuation of \$2.83 is optimistic, and will be realized in the short term. We do not see a future for the company in its current state.** Viceroy's preliminary report on Athenex can be found in the below link:

<https://viceroyresearch.org/2019/10/22/athenex-too-little-too-late/>



### **Attention: Whistleblowers**

Viceroy encourage any parties with information pertaining to misconduct within Athenex, its affiliates or any other entity to file a report with the appropriate regulatory body.

We also understand first-hand the retaliation whistleblowers sometimes face for championing these issues. Where possible, Viceroy is happy act as intermediaries in providing information to regulators and reporting information in the public interest in order to protect the identities of whistleblowers.

You can contact the Viceroy team via email on [viceroy@viceroyresearch.com](mailto:viceroy@viceroyresearch.com).

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## 1. Polymed & Yunnan Hande

This one is something of a rabbit hole.

Athenex subsidiary Polymed therapeutics appears to source its Taxol and other raw API from Hande Yunnan Biotechnology Co.

Hande Yunnan Biotechnology Co. Ltd. Was previously the second largest taxol supplier in the world, until the company was raided by Chinese authorities for illegally harvesting yew bark (the source of taxol), resulting in 50 arrests and 32 imprisonments, and setting a precedent against illegal harvesting which has resulted in hundreds of arrests since<sup>1</sup>.

Polymed founder William Wei Zuo was the director of a US Yunnan Hande subsidiary as far back as 1995 implying his involvement in the smuggling and illegal sale of Taxol – in fact, Hande’s US distributor and Polymed even shared the same offices.

Wu Xiaojing, the American investor in Hande Yunnan and sister of its imprisoned Chairman at the time of its impropriety, continues to run alongside Zuo for Hande’s USA distributor, which now appears to operate as a subsidiary of Polymed. Her Facebook shows she is indeed an employee of Athenex.

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*More recent documents show Hande Yunnan continues to supply Athenex’s taxol.*

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On the ground checks at Yunnan Hande’s one remaining operating subsidiary show no evidence of taxol processing. This subsidiary, which used to harvest yew illegally, now owns a tent that dries tea leaves.

**So where exactly does Hande, and therefore Polymed, get its raw material?**

### Yunnan Hande: corruption, smuggling, illegal sales

Taxol is the primary ingredient in the manufacture of paclitaxel and is distilled from the bark of the pacific yew. Removing the bark from the Yew tree causes it to die: 360,000 mature trees per year would be required for production of taxol as calculated by NCI’s Gordon Crag<sup>2</sup>. As such the excessive harvesting and smuggling of yew bark is illegal in many countries, China included.

Yunnan Hande was one of China’s first and largest taxol suppliers and a joint venture 80% owned by Chinese American Wu Xiaojing until it was charged with:

- Illegally obtaining 55,519.12kg of yew bark extract and 10,765.475g of semi-finished product (chloroform)
- Fraudulently obtaining export licenses
- Fraudulently mis-labelling goods.
- Evading customs checks and inspections
- Illegally sold ~100kg of paclitaxel although the eventual buyers were not identified in the media.

Among the 32 arrests, Chairman Wu Jun was sentenced to 18 years imprisonment and a 2m yuan fine, President Li Song was sentenced to 9 years imprisonment and vice president Qi Wei was sentenced to 7 years prison. The period for these offences was between September 10, 1999 and November 2001, which will be important when showing the complicity of Zuo with this scheme.

We believe William Zuo, Athenex’s President of China Operations was implicitly involved with this entity and that Zuo facilitated and may continue to facilitate this scheme.

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<sup>1</sup> <http://collection.sina.com.cn/jjhm/yjzx/2018-07-11/doc-ihfefkqg0086571.shtml>

<sup>2</sup> <https://www.foxnews.com/health/pacific-yew-a-potent-cancer-fighting-agent>





## Polymed's connection to Hande Yunnan

The 2015 acquisition of Polymed Therapeutics secured Athenex supply of Taxol which it uses in its API operations. The importance of Taxol is highlighted in sell side reports and the raw materials disclosure in Athenex's own 10K. Polymed represented about US\$20m of the company's ~US\$90m current revenues in 2018.

Our research group evaluated the purity and potency of some of the largest global suppliers of paclitaxel API. In 2015, we acquired one of these suppliers, Polymed Therapeutics Inc. and Chongqing Taihao Pharmaceutical Co. Ltd., or Taihao. Taihao is a cGMP manufacturer of high potency oncology API based in Chongqing, China and Polymed Therapeutics Inc. is the U.S. marketing entity for Taihao's API in North America and Europe. Historical production and sales of API by this subsidiary were to third parties. **We anticipate a greater share of Taihao's manufacturing capacity will be used for our internal needs in the future**, and, therefore, sales

31

to third parties may decrease. Historically, Polymed Therapeutics Inc. sold certain of these API products internationally to mostly large multi-national pharmaceutical companies. For the years ended December 31, 2018, 3% of our total revenue came from Intas Pharmaceuticals and 6% came from Ebewe Pharmaceuticals.

Figure 1 Athenex 10K - 2018

**Polymed itself does not appear to own any taxol production facilities but instead procure them from a third party: Yunnan Hande.**

## William Zuo: A "Hande" guy to know

On July 31, 1995 William Zuo registered Hande Develop Co. USA Inc in Texas which owned and operated [www.handetech.com](http://www.handetech.com) (now defunct).

HANDE TECH DEVELOP CO U S A INC	
Texas Taxpayer Number	17604765481
Mailing Address	11155 MAIN ST HOUSTON, TX 77025-5600
Right to Transact Business in Texas	FRANCHISE TAX ENDED
State of Formation	TX
Effective SOS Registration Date	07/31/1995
Texas SOS File Number	0136391600
Registered Agent Name	WILLIAM W ZUO
Registered Office Street Address	11155 MAIN STREET HOUSTON, TX 77025

Figure 2 Texas Taxable Entity Search – Taxpayer number 17604765481

Hande's third party distributor in the US was Hande Tech Development Corp USA and shared the same address as Polymed until Polymed acquired the company in 2004, all the while Zuo was listed as the agent for each company.



The first archived copy of the [www.handetech.com](http://www.handetech.com) site dates to 1997, and touts Yunnan Hande as the key paclitaxel producer in China. There is also a profile for Hande Tech Development Co. USA, Inc, the owner and operator of the website.

#### Hande Tech Development Co. USA, Inc.



Hande Tech USA, located in Houston, Texas, **was founded in August 1995**, as the marketing subsidiary for Hande's products in North America, South America and Europe. This subsidiary also provides advanced technical support to Hande, by investigating viable projects to be developed in headquarters for the Chinese market.

Furthermore, Hande Tech USA has set up its own laboratory in USA, engaged in New Drug Discovery and its Preclinical Research and Development. This laboratory concentrates on drugs developed from natural products.



Yunnan Hande Technological Development Co. Ltd. (Hande) was founded in 1993. Hande's headquarters and major [facilities](#) are located in the city of [Kunming](#), the capital of [Yunnan Province](#) and one of the major cities in the Southwest region of China. This city is known as the scenic "Spring City" in China. The surrounding area possesses abundant botanical resources.

The company's immediate goal is the manufacturing and marketing of high quality anti-cancer pharmaceutical products. Starting as a bio-technology research company in 1990, it gradually acquired sufficient venture capital, and consolidated with leading organizations in the field of advanced botanical chemical research, to excel in both extensive basic research and product development. Product development include product refining, product manufacture and raw material plantation. **The company has engaged in the manufacturing of paclitaxel**, a naturally occurring anti-cancer compound found in certain species of yew (Taxus) trees. Hande has been recognized as a leading company for its technical achievement, high quality products and market domination in China.

Since then, the company has expanded from producing pharmaceutical products, and diversified into many other areas:

A key figure in [natural bulk product manufacture](#)

An active member of the [food processing industry](#).

An integral player in [agriculture](#)

Currently, Hande has the following joint ventures and subsidiaries:

- Yunnan National Institute for Technology and Economy
- [Lijiang Hande Yulong Forest Products Development Co. Ltd.](#)
- [Hande Tech USA, Inc.](#)
- Hande Tech Beijing, Ltd.
- Hande Kunming Trading Co. Ltd.
- Xishuang-Banna City of Credit Union Yunnan United Foods Co. Ltd.
- Hande Agriculture Development Co. Ltd.

*Figures 3 & 4 handetech.com archive dated December 21, 1997<sup>3</sup>*

However the May 18, 2004 archive<sup>4</sup> of [www.handetech.com](http://www.handetech.com) redirects to [www.polymed.com](http://www.polymed.com). The last link without a redirect is dated April 5, 2004<sup>5</sup>. Comparing with the timeline of the events at Hande Yunnan we can see that this covers the period of Hande Yunnan's illicit activities.

There is more evidence of complicity between Polymed: Hande Yunnan's imprisoned Chairman's sister, Wu XiaoJing, who was a major enough investor in Yunnan Hande to bear a mention in the media.

This company located in Kunming Jinding Technology Park, **80% of the shares are in the United States, the US investors for the United States Deyun company - Wu Jun's sister**, American Chinese Wu Xiaojing and other companies established in Texas, the main business It is the operation of yew products. Before becoming a Chinese American, Wu Xiaojing worked in the

*Figure 5 The truth of the destruction of 100 kilograms of paclitaxel and dead yew<sup>6</sup>*

<sup>3</sup> <https://web.archive.org/web/19971221192708/http://handetech.com:80/>

<sup>4</sup> <https://web.archive.org/web/20040518165140/http://handetech.com:80/>

<sup>5</sup> <https://web.archive.org/web/20040405194510/http://handetech.com:80/>

<sup>6</sup> <http://www.people.com.cn/GB/huanbao/57/20021206/882815.html>



Ms. Wu Li has actually represents herself under several names but helpfully used her full name in her Facebook profile.

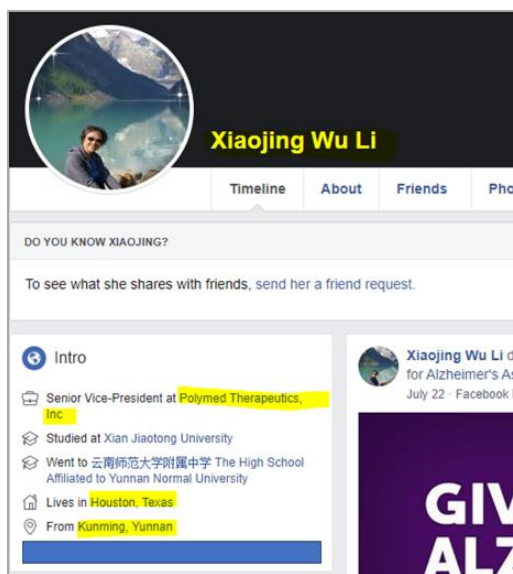


Figure 6 Xiaojing Wu Li Facebook Profile<sup>7</sup>

**Xiaojing Li** was appointed as a director and as our Vice President and Corporate Secretary as of February 11, 2008. Ms. Li is currently a Vice President of Polymed Therapeutics, Inc., a pharmaceutical manufacturing and distribution company she co-founded in 1995. From 1995 to 2001, Ms. Li also served as President of Hand Tech USA a pharmaceutical manufacturing and distributing company. Ms. Li is a graduate of Xian Jiaotong University, Xian, China.

Figure 7 Inovachem 10-K 2009

We also have to applaud Ms. Wu Li for concealing her involvement with Hande Tech by misspelling it in her bio for Inovachem, a company that existed solely to purchase goods and services from Polymed founded by William Zuo. More information on Inovachem can be found in our previous report.

## Phantom pain

We understand Hande Yunnan Biotechnology Co. Ltd (云南汉德生物技术有限公司) has remained Polymed's supplier and business partner. Patent application CN102336726A filed September 30, 2011 by Polymed subsidiary Chongqing Taihao Pharmaceutical shows the company purchased taxol from Yunnan Hande.

[0070] The present invention may be available from the market reagent. Wherein the compound of formula II was purchased from **Nan Hande Biotechnology Co. cloud**; tetrahydrofuran solution of sodium bis-trimethylsilyl amines and is available from Guangzhou Chemical Co., Ltd.; the compound of formula IV available from **Nan Hande Biotechnology Co. cloud**.

[0070] 本发明所用试剂均可由市场购得。其中式II所示化合物购自**云南汉德生物技术有限公司**；双三甲基硅胺钠的四氢呋喃溶液购自广州和为化工有限公司；式IV所示化合物购自**云南汉德生物技术有限公司**。

Figures 8 & 9 Paragraph 70 from Patent CN102336726A and translation

<sup>7</sup> <https://www.facebook.com/xiaojing.w.li>





Of Hande's 5 subsidiaries, 4 have been deregistered with one former taxol collection company still operating as a tea company, and has changed its name accordingly. The company's profile on TianYanCha.com shows part of its mandate was the growing of yew trees<sup>8</sup>.

对外投资 5 (查看更多2条 对外投资披露)								Serial number	Name of the invested company	Legal representative	Date of establishment	Amount of investment	Investment ratio	Business status	Related products	Associate institution
序号	被投资企业名称	法定代表人	注册资本	投资比例	投资金额	成立日期	状态	1								
1	 景洪市怡康茶业有限公司 股权结构>	陈勇 他关联3家企业>	1600万元人民币	96.88%	1550万元人民币	1998-08-26	存续	1	 Kunming Alcoholic Spirit Biotechnology Co., Ltd. 股权结构>	Guo Zhanwei He has a company>	2013-01-29	RMB 50 million	100%	Logout	-	-
2	 昆明中科生物技术股份有限公司 股权结构>	吕林 他关联1家企业>	70万元人民币	49.00%	34.3万元人民币	2001-05-09	吊销	2	 Jinghong Yikang Tea Co., Ltd. 股权结构>	Chen Yong He has 3 companies>	1998-08-26	155 million yuan	96.88%	Subsisting	-	-
3	 昆明中科生物技术股份有限公司 股权结构>	陈梦站 他关联1家企业>	220万元人民币	45.45%	100万元人民币	2008-04-17	吊销	3	 Kunming Zhongke Biotechnology Co., Ltd. 股权结构>	Lu Lin He has a company>	2001-05-09	34.3 million	49%	Revoked, not cancelled	-	-
4	 迪庆香格里拉紫金生物技术有限公司 股权结构>	汪洋 他关联16家企业>	500万元人民币	44.00%	220万元人民币	2005-03-25	吊销	4	 Diqing Shangri-La Zijin Biotechnology Co., Ltd. 股权结构>	Wang Yang He has 15 companies>	2005-03-25	220,000	44%	Revoked, not cancelled	-	-
5	 昆明中科生物技术股份有限公司 股权结构>	郭占伟 他关联1家企业>	50万元人民币	100%	50万元人民币	2013-01-29	注销									

Figure 10

Viceroy's investigators found more complications on the ground in China. The following observations were made in Q1-Q2 2019. Investigators visited Hande's remaining operation Jinghang Yikan Tea Co., Ltd (景洪市怡康茶业有限公司)

Yikan Tea turned out, predictably, to be drying tea.



Figures 11 & 12 Photos at Yikang tea industries

The investigator questioned locals who confirmed that there were no yew trees at the facility although villagers remember yew production many years ago.

Investigators also visited Polymed's Chongqing API factory. Note that this visit was prior to the voluntary temporary suspension of operations announced in Athenex's 2019 Q2 10-Q (more on this later).

<sup>8</sup> [https://translate.googleusercontent.com/translate\\_c?depth=1&hl=en&prev=search&rurl=translate.google.com&sl=zh-CN&sp=nmt4&u=https://www.tianyancha.com/company/310211756&xid=25657,15700019,15700186,15700190,15700256,15700259,15700262,15700265,15700271&usg=ALkJrhjJnxcSrjTGS\\_y1MwZ55auJ3MuiKA](https://translate.googleusercontent.com/translate_c?depth=1&hl=en&prev=search&rurl=translate.google.com&sl=zh-CN&sp=nmt4&u=https://www.tianyancha.com/company/310211756&xid=25657,15700019,15700186,15700190,15700256,15700259,15700262,15700265,15700271&usg=ALkJrhjJnxcSrjTGS_y1MwZ55auJ3MuiKA)



According to observations, only finished/semi-finished products entered the facility.

***These facts once again raise the question: where does Hande – and therefore Polymed – get their taxol from?***

It is of further concern that Hande Yunnan have been slapped by the FDA for multiple objectionable offences in routine inspections of their facility, and lack of corrective action, as determined by the FDA.

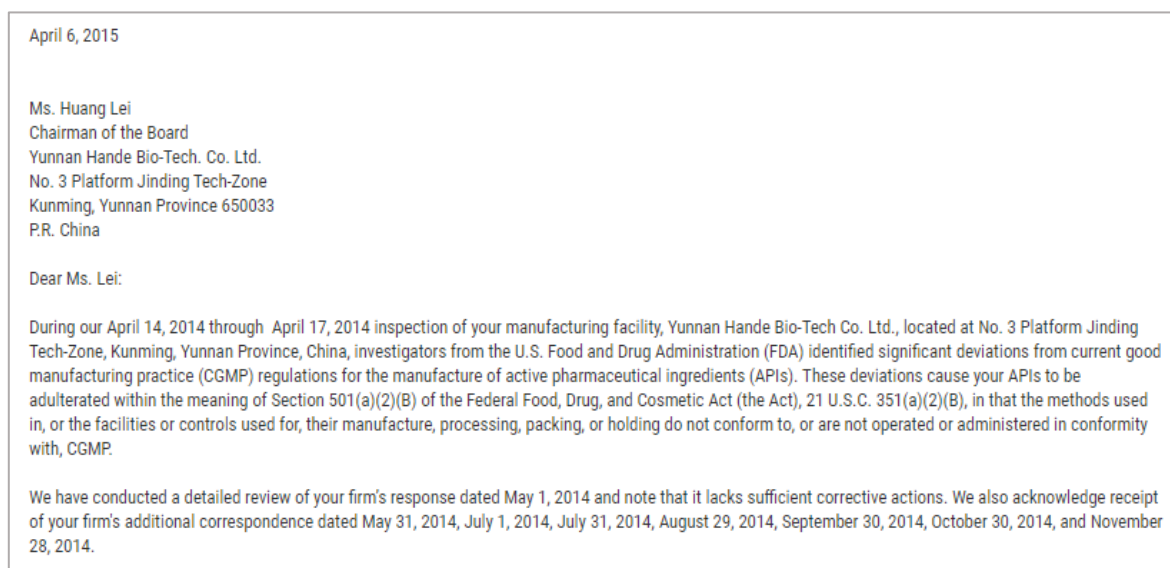


Figure 13 Extract - Chongqing Pharmaceutical Co's occupational disease hazard assessment report<sup>9</sup>

District	Firm Name	City	State	Zip Code	Country / Area	Inspection End Date	Center	Project Area	Classification
ORA	Shandex Personal Care Manufacturing Inc.	Perth			CA	11/28/14	CDER	Drug Quality Assurance	VAI
ORA	Yunnan Hande Bio-Tech. Co. Ltd.	Kunming			CN	02/26/16	CDER	Drug Quality Assurance	OAI
ORA	Yunnan Hande Bio-Tech. Co. Ltd.	Kunming			CN	04/17/14	CDER	Drug Quality Assurance	OAI
ORA	Shandex Personal Care Manufacturing Inc.	Perth			CA	09/29/17	CDER	Drug Quality Assurance	NAI
ORA	Yunnan Hande Bio-Tech. Co. Ltd.	Kunming			CN	06/23/11	CDER	Drug Quality Assurance	VAI
ORA	Yunnan Hande Bio-Tech. Co. Ltd.	Kunming			CN	12/12/12	CDER	Drug Quality Assurance	NAI
ORA	Yunnan Hande Bio-Tech. Co. Ltd.	Kunming			CN	05/21/10	CDER	Drug Quality Assurance	OAI

Figures 14 & 15 – FDA Assessments of Chongqing facility<sup>10</sup> & Classification Guide<sup>11</sup>

<sup>9</sup> [webcache.googleusercontent.com/search?q=cache:http://www.cqsfy.com/uploads/soft/180312/1-1P312161642.doc](http://webcache.googleusercontent.com/search?q=cache:http://www.cqsfy.com/uploads/soft/180312/1-1P312161642.doc)

<sup>10</sup> <https://www.accessdata.fda.gov/scripts/inspsearch/index.cfm>

<sup>11</sup> <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspections-database-frequently-asked-questions#classification>





## 2. Factory shutdown

In May 2019, Athenex advised that its Polymed facility in Chongqing was voluntarily suspended:

Our revenue may be impacted by the current suspension of our operations at our API plant in Chongqing, China. We chose to suspend production based on concerns raised by the Department of Emergency Management of Chongqing related to the location of our plant. The voluntary temporary suspension began in May 2019 and we hope to reach a resolution of the suspension with the DEMC, but we can provide no assurances of when, if at all, production of API will resume at the plant. While we currently have secured additional API suppliers for our ongoing clinical studies, in the event

Figure 16 Athenex 2019 Q2 10-Q

This statement released by Athenex is totally contradictory to its voluntary suspension: why would a resolution need to be had with the Department of Emergency Management of Chongqing if the suspension was voluntary?

A search of the Chinese Government's Ministry of Emergency Management conversely showed that required local province investigators were advised to heavily scrutinize these types of plants upon back-to-back catastrophic disasters at two unrelated biochemical API factories, resulting in almost 100 deaths and hundreds of injuries.

**Athenex announces the voluntarily suspension of production activities, following several incidents at chemical factories across China,**



The company suspended production activities at its active pharmaceutical ingredient (API) plant in Chongqing, China, last month.

The action was taken following industry-wide inspections and evaluations by the Department of Emergency Management of Chongqing, after two separate explosions at chemical factories in March and April that resulted in fatalities.

The incident in April, related to [Qilu Tianhe Huishi Pharmaceuticals](#), left 10 workers dead at the API producer's facility. While the prior explosion at a pesticide plant in eastern China killed 78 people and injured 617.

As a result, industry-wide inspections focused on production safety took place and Athenex voluntarily ceased production, though it will be able to supply API through existing inventories until, at least, the third quarter of this year, the company stated.

Regarding its decision, Athenex said that *"this self-imposed action demonstrates the company's good faith in working with the Department of Emergency Management of Chongqing and that the company takes work safety very seriously."*

Athenex noted that its clinical trials will not suffer from suspended API production, it currently has two pivotal Phase III clinical candidates and six additional candidate in Phase I and II studies.

The company will soon possess another API plant in the city, with a new plant expected to be completed in the first half of 2020.

Despite the suspension of activity, Athenex stated that it projects product sales to increase by 25% to 30% during 2019.

Athenex further stated, *"The company believes the API plant has been in compliance from a safety and regulatory perspective. The company will continue to work closely with the department and aims to conclude the inspection as soon as practicable."*

Figure 17 – Extract from *in-pharmatechnologist* article<sup>12</sup>

We understand guidelines for investigations were established around April 2019, per the following link which can be translated directly from the Ministry of Emergency Management:

<sup>12</sup> <https://www.in-pharmatechnologist.com/Article/2019/06/10/Athenex-suspends-API-production-in-China>



<http://120.52.31.79:7040/ezweb/ctrl/news/D1BE086F5A667038644C0C910329AF2D>

Specifically, more recent communications from the Ministry of Emergency Management advised that the crackdown should not only be focused on the safety aspects, but also illegality of operations, following further accidents and biological plants:

<http://120.52.31.79:7040/ezweb/ctrl/news/6EBBB0F1EE61094101EC8322EF96CD25>

Most telling, however, is Polymed's atrocious track record of safety inspections in the past. For instance, a 2017 review of Chongqing Pharmaceutical Co's occupational disease hazard assessment report by the Chongqing Occupational Disease Prevention and Treatment Institute concludes that the risk of occupational disease hazards at the site are classified as "serious":

	Specifications	
This report confirms that the risk of occupational disease hazards of Chongqing Taihao Pharmaceutical Co., Ltd. is classified as <b>serious</b> .		
V. Review of the technical review expert group		

Figure 18 Extract - Chongqing Pharmaceutical Co's occupational disease hazard assessment report<sup>13</sup>

Reviews by the FDA also reported objectionable conditions/practices were found during inspections, similar to Hande, who we maintain is a supplier of Polymed:

District	Firm Name	City	State	Zip Code	Country / Area	Inspection End Date	Center	Project Area	Classification
ORA	Chongqing Taihao Pharmaceutical Co., Ltd.	Chongqing, P.R.			CN	05/23/12	CDER	Drug Quality Assurance	VAI
ORA	Chongqing Taihao Pharmaceutical Co., Ltd.	Chongqing, P.R.			CN	05/10/18	CDER	Drug Quality Assurance	NAI
ORA	Chongqing Taihao Pharmaceutical Co., Ltd.	Chongqing, P.R.			CN	03/13/15	CDER	Drug Quality Assurance	VAI

After an inspection, FDA determines if the areas evaluated are in compliance with applicable laws and regulations. FDA and the Inspection Classification Database classifies the inspection by each project area with one of three classifications. The three classifications displayed are:

- No Action Indicated (NAI) which means no objectionable conditions or practices were found during the inspection (or the objectionable conditions found do not justify further regulatory action),
- Voluntary Action Indicated (VAI) which means objectionable conditions or practices were found but the agency is not prepared to take or recommend any administrative or regulatory action, or
- Official Action Indicated (OAI) which means regulatory and/or administrative actions will be recommended.

Figures 19 & 20 – FDA Assessments of Chongqing facility<sup>14</sup> & Classification Guide<sup>15</sup>

*Given its track record, we are cynical that Polymed's voluntary suspension was voluntary at all, and believe the company will face heavily scrutiny both for its current and past failures in corporate governance and health and safety.*

### 3. Show me what you got?

<sup>13</sup> [webcache.googleusercontent.com/search?q=cache:http://www.cqsfy.com/uploads/soft/180312/1-1P312161642.doc](http://webcache.googleusercontent.com/search?q=cache:http://www.cqsfy.com/uploads/soft/180312/1-1P312161642.doc)

<sup>14</sup> <https://www.accessdata.fda.gov/scripts/inspsearch/index.cfm>

<sup>15</sup> <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspections-database-frequently-asked-questions#classification>





All else excluded, we have put together a comparison on what Athenex would like you to believe they run, versus the actual state of operations within Polymed.

Here is Polymed's website:

<http://polymedt.com>

As you will see, the company boasts headquarters in Houston, manufacturing plant in China, and offices in Japan.

## China

The company's manufacturing location is listed in Changshou National Chemical Industry Zone, with "communal facilities". The depiction of the factory, however, is completely fabricated:



Figure 21 – Extract from Polymed website<sup>16</sup>

This is hard to spot unless you blow up the image, in which Athenex have blatantly photoshopped their name to a building, photoshopped a garden and bushes out front, and photoshopped an American flag on a pole outside. Further, it is laughable that this "communal facility" is entirely "branded" as Polymed Therapeutics.

<sup>16</sup> [http://polymedt.com/index.php?option=com\\_content&view=article&id=49&Itemid=61](http://polymedt.com/index.php?option=com_content&view=article&id=49&Itemid=61)





Inspecting a bird's eye view of the surrounding area of the site, nothing appears to resemble the photoshopped facility:



Figure 22 – Google Maps view of Polymed Japan Site<sup>17</sup>

## Houston

The Houston Headquarters of Polymed, depicted below, are not actually the headquarters of Polymed:

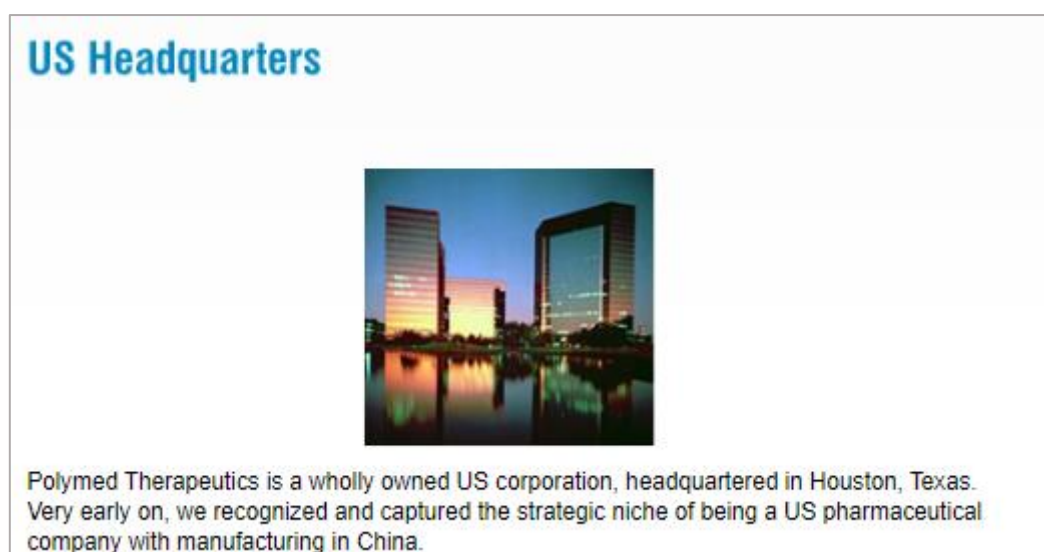


Figure 23 – Extract from Polymed website<sup>18</sup>

<sup>17</sup> [http://polymedt.com/index.php?option=com\\_content&view=article&id=63&Itemid=58](http://polymedt.com/index.php?option=com_content&view=article&id=63&Itemid=58)

<sup>18</sup> [http://polymedt.com/index.php?option=com\\_content&view=article&id=48&Itemid=60](http://polymedt.com/index.php?option=com_content&view=article&id=48&Itemid=60)



A simple reverse image search of this location identifies it as 3050 Post Oak Boulevard<sup>19</sup>, a much, much nicer office than Polymed's actual headquarters, 4 miles away, at 6200 Savoy Drive, Houston.



Figure 24 – Google Maps Streetview of Polymed Japan Site<sup>20</sup>

## Japan

In a laughable over exaggeration, Polymed shows depicts the Nagayo Bridge<sup>21</sup> over the Tokyo skyline as its frame for their Japanese “IT Chemical Specialist” site, which allegedly custom manufactures pharmaceutical and specialty chemicals.

<sup>19</sup> <https://42floors.com/us/tx/houston/3050-post-oak-blvd>

<sup>20</sup> [http://polymedt.com/index.php?option=com\\_content&view=article&id=63&Itemid=58](http://polymedt.com/index.php?option=com_content&view=article&id=63&Itemid=58)

<sup>21</sup> <https://www.pixtastock.com/photo/37786658>





## Japan Polymed - Your IT Chemical Specialist

Japan Polymed specializes in Custom Manufacturing, and serves the Japanese and other Asia markets of Pharmaceutical and Specialty Chemicals. Our team of scientists is expert in the whole range, from R&D, pilot scale, to industrial scale manufacture. Being flexible and fast, our plants achieve extremely complex and simple synthesis, large and small demands.



### Our main reactions cover:

Acylation, Amidation,  
Amination (Reductive),  
Asymmetric Synthesis,  
Azide Reactions, Butyl Lithium Chemistry,  
Carbohydrate Chemistry,  
Claisen Rearrangement,  
Cross Coupling Reactions (include: Heck Reaction, Suzuki Reaction),  
Cryogenic Reactions,  
Epoxidation,  
Esterification,  
Etherification,  
Friedel-Crafts Reaction, Grignard Reaction,  
Halogenation,  
Heterocyclic Synthesis,

Figure 25 – Extract from Polymed website<sup>22</sup>

*We sincerely doubt that Polymed can pull this off from its tiny, residential location, which isn't even in Tokyo!*

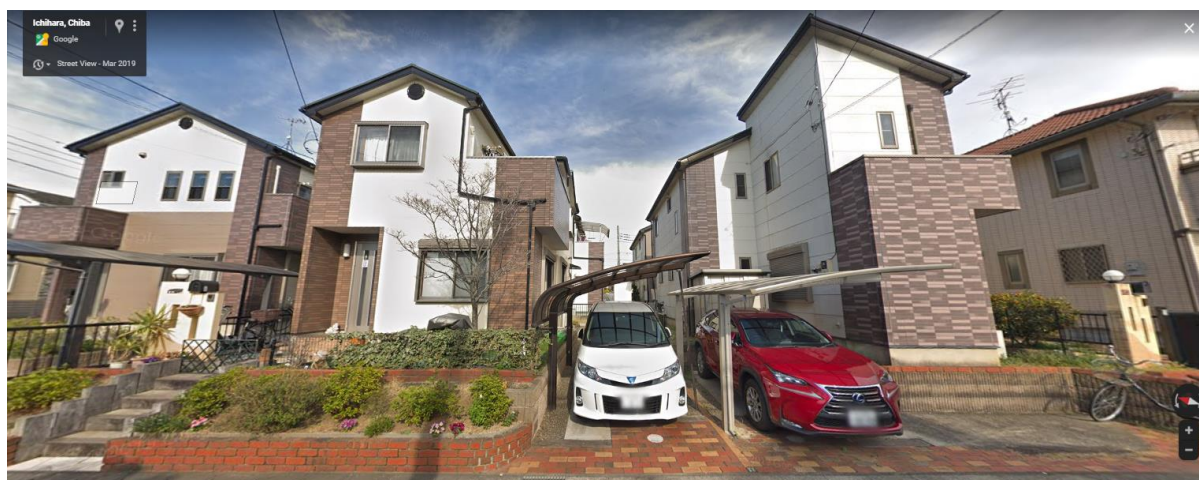


Figure 26 – Google Maps Streetview of Polymed Japan Site<sup>23</sup>

<sup>22</sup> [http://polymedt.com/index.php?option=com\\_content&view=article&id=50&Itemid=62](http://polymedt.com/index.php?option=com_content&view=article&id=50&Itemid=62)

<sup>23</sup> [http://polymedt.com/index.php?option=com\\_content&view=article&id=63&Itemid=58](http://polymedt.com/index.php?option=com_content&view=article&id=63&Itemid=58)







## 4. Fibrocell & Zuo – The man who wasn't there

It's a lot easier to say you did something than to actually do it. William Zuo's Athenex bio says he was the CEO of the Chinese operation for Fibrocell (NASDAQ:FCSC) from 2010 to 2013 and introduced the LaViv cell therapy product to the market. This is a mixture of untruths and outright lies.

**William Zuo, PhD**

William Zuo has served as President of Polymed Therapeutics since 1995 and Chairman of Chongqing Taihao Pharmaceutical since 2012. William specializes in the development, manufacturing, global sale and marketing of various complex Active Pharmaceutical Ingredients ("API"), especially the injectable Oncology APIs. William was the CEO of the Fibrocell Science (NYSE: FCSC) companies in Asia from 2010 to 2013. He introduced the first US FDA approved cell therapeutics product, LaViv, to the Asia market. William has been responsible for the building of numerous cGMP facilities in China and has extensive experience in dealing with the Food and Drug Administration in both China and the United States.

Figure 27 William Zuo, PhD<sup>24</sup>

There is no mention of Zuo in any of Fibrocell's SEC filings for the period except for his sale of shares in the company's prospectus<sup>25</sup> in which he is not mentioned as an employee. The Asia section is a little stranger.

On November 3, 2010 Fibrocell announced the establishment of a joint venture with Hefei Meifu Bio-Tech Limited Co. for development and marketing of its products in Asia. This was the first mention of Asia in the company's announcements. Coincidentally, Hefei Meifu Bio-Tech manufactures and distributes APIs including paclitaxel and docetaxel.

**Fibrocell Science, Inc. Establishes Joint Venture to Market Its Technology Platform in Asia**

***Agreement to Provide Fibrocell with Access to Large and Growing Aesthetic Market in Asia***

November 03, 2010 06:00 AM Eastern Daylight Time

EXTON, Pa.--(BUSINESS WIRE)--Fibrocell Science, Inc. (OTCBB: FCSC), a biotechnology company focused on the development of autologous cell therapies for aesthetic, medical and scientific applications, announced today that it has signed an agreement to establish a joint venture (JV) with Hefei Meifu Bio-Tech Limited Co. (Meifu) for developing and marketing autologous fibroblast therapies in Asia, excluding Japan. The JV will be called Fibrocell Science Asia Co. Ltd.

**About Hefei Meifu Bio-Tech Limited Co.**

Headquartered in Hefei, a significant biological and medical industry zone in central China, Hefei Meifu Bio-Tech Limited Co. develops, manufactures and distributes pharmaceutical anticancer intermediates and APIs, generic drugs, such as Paclitaxel, Docetaxel, dietary supplements including Vitamin E, and medical devices for beauty treatments.

Figure 28 Fibrocell Science, Inc. Establishes Joint Venture to Market Its Technology Platform in Asia <sup>26</sup>

No website, Chinese name or other identifying information was ever given for Hefei Meifu Bio-Tech. The company had no other information available on the internet both at the time and now. Hefei Meifu Bio-Tech appears to disappear except for Fibrocell's 2014 10-K and 2014 Q1 10-Q where it stated:

<sup>24</sup> <https://www.athenex.com/dt-team/william-zuo-phd/>

<sup>25</sup> <http://ir.fibrocellscience.com/static-files/ce148bbc-c987-404e-8373-772cf94c4904>

<sup>26</sup> <https://www.businesswire.com/news/home/20101103005730/en/Fibrocell-Science-Establishes-Joint-Venture-Market-Technology>



*"In April 2010, we entered into a letter of intent with Chinese company Heifei Meifu Bio-Tech Limited Co. to form a joint venture... to date we and Heifei Meifu have not received Chinese governmental approval to form the proposed joint venture..."<sup>27</sup>*

*We face risks in connection with doing business in China.*

In April 2010, we entered into a letter of intent with Chinese company Heifei Meifu Bio-Tech Limited Co. to form a joint venture to commercialize autologous fibroblast therapies in Asia (excluding Japan) and to produce and develop such therapies in China. This letter of intent was intended to serve as the template for a joint venture agreement between us and Heifei Meifu, which would expand the scope of our operations to China and Asia more broadly. However, to date we and Heifei Meifu have not received Chinese governmental approval to form the proposed joint venture and we are considering alternative business structures in Asia (excluding Japan). If we are able to consummate alternative business structures in Asia (excluding Japan), we expect to generally no longer have an independent right to make or sell autologous fibroblast therapies in Asia (excluding Japan). If, however, we are unable to finalize alternative business structures in Asia (excluding Japan), our business could be harmed.

*Figure 29 Fibrocell 2014 10-K*

It appears as though Zuo oversaw absolutely nothing at Fibrocell, and we are unsure whether he was ever there at all. Crediting him with introducing LaViv to the Asian market appears to be an outright lie considering the company had no Asian operations during that time.

As a side -note Fibrocell shares are now virtually worthless, having been at the center of a stock manipulation scheme during the time Zuo was "employed"<sup>28</sup>.

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***What was Zuo doing from 2010 to 2013?***

***Are investors aware of the falsehoods in William Zuo's biography?***

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<sup>27</sup> The misspelling of Hefei Meifu has been copied verbatim from the Fibrocell filings

<sup>28</sup> <https://www.finra.org/media-center/news-releases/2015/finra-hearing-panel-expels-john-carris-investments-and-bars-ceo-george>