# Athenex – Big trouble in little Chongqing

Not only is the factory in the wrong place, it's not built yet

**November 20, 2019** – On the ground investigation of Athenex's Chongqing factory show that the **Athenex's new API plant is not located in the Chongqing International Bio-City, and is still heavily under construction**. This deception extends to Chinese press releases.

The site visits were conducted on the week ending November 15, 2019, several months after the announcement of its "completion" by Athenex.

- The factory is not located in the Chongqing International Bio-City development, but some 25 miles away near Maliuzui toll station.
- The building has no sealed road access nor car parking facilities; we were unable to ascertain whether basic utilities had been connected but this seems unlikely.
- Everyone within the facility is still wearing hardhats, and the site is still full of heavy machinery, including cranes.
   Equipment has yet to be installed company statements about validation testing in Q4 2019 are false.





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

Figure 1 Viceroy Investigator photo of Athenex "completed" API facility

The announcement by Athenex on September 23, 2019 claiming the facility to be complete and in the midst of a validation batch paints a pretty picture, which is completely false.

# Athenex Completes Construction of New API Facility in Chongqing

BUFFALO, N.Y., Sept. 23, 2019 (GLOBE NEWSWIRE) – Athenex, Inc. (Nasdaq: ATNX), a global biopharmaceutical company dedicated to the discovery, development and commercialization of novel therapies for the treatment of cancer and related conditions, today announced that it has completed construction of its new API (active pharmaceutical ingredients) facility in Chongqing, China. The 440,000-square-foot facility will produce validation batches in the fourth quarter of 2019 and is expected to commence operations in the first half of 2020. The construction of the facility is part of Athenex's strategy for vertical integration in order to capture value across the supply chain. Once operational, the facility is expected to expand the company's API production capabilities to further support its global clinical development needs and ensure the supply of API for commercial launches.

Figure 2 – Athenex Press Release – September 23, 2019

To be clear: **there is no completed API Facility**. This fraud mirrors the various sham businesses Athenex's directors have orchestrated in the past.

On November 19, 2019 Athenex announced the title of their presentation at the San Antonio Breast Cancer Symposium. This is a blatant strategy to pump the price of their stock by changing the title of the presentation which has had **no change in content to the one announced on September 23, 2019** (ironically, the same date Athenex's Chongqing plant was allegedly "completed"), which was **submitted in June 2019**.

#### September 23, 2019: Date: Friday, December 13, 2019 Time: 5pm CT KX-ORAX-001: an open-labeled, multicenter, phase 3 registrational study to Title: determine the safety, tolerability and tumor response of oraxol (HM30181A and oral paclitaxel) and its comparability to iv paclitaxel in patients with metastatic breast cancer (MBC) Session: General Session 6 Location:Hall 3 November 19, 2019: Oral Presentation Details Oral Paclitaxel with Encequidar: The first orally administered paclitaxel shown to be superior to IV paclitaxel Abstract Title: on confirmed response and survival with less neuropathy: a Phase III clinical study in metastatic breast cancer. Session: General Session 6 Date and Time: Friday, December 13, 2019 at 3:15pm CT Hall 3 / Henry B. Gonzalez Convention Center, San Antonio, Texas Location For more information, please visit https://www.sabcs.org/Program/Daily-Schedule/Day-4 Abstracts that have been selected for the press program will only have titles posted to the SABCS website until the embargo lifts on December 13, when the complete abstract will post online

Figure 13 1,2

#### In summary:

- 1. Abstracts were due by July 8, 2019.
- 2. Athenex's abstract title was announced on September 23, 2019
- 3. Athenex changed their abstract title on November 19, 2019
- 4. Athenex is not presenting in the Ongoing Clinical Trials category, and therefore cannot have had new information since July 8, 2019.

Athenex's SABCS presentation is the same as the one announced on September 23. RBC analyst Kennen MacKay's reiteration of an outperform on a "SABCS win" sounds ridiculous considering that this is the same data that prompted such an unremarkable title 2 months earlier caused the collapse of the stock.

Of course, when Athenex originally announced the presentation, the issues we highlighted in our reports had not yet been brought to light.

We continue to believe investors are being duped by Athenex management through virtually identical charades orchestrated at their previous failed ventures, such as Sino Forest.

We have annexed an extended summary of all of Viceroy's findings, and all of our pictures of Athenex's actual, unfinished, API plant.

You can find our previous reports on Athenex on www.viceroyresearch.org

<sup>&</sup>lt;sup>1</sup> https://www.globenewswire.com/news-release/2019/09/23/1919022/0/en/Athenex-to-Present-at-the-2019-San-Antonio-Breast-Cancer-Symposium.html

<sup>&</sup>lt;sup>2</sup> https://www.globenewswire.com/news-release/2019/11/19/1949506/0/en/Athenex-Announces-Key-Company-Activities-at-San-Antonio-Breast-Cancer-Symposium.html



#### 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.

#### **About Viceroy**

Viceroy Research are an investigative financial research group. As global markets become increasingly opaque and complex – and traditional gatekeepers and safeguards often compromised – investors and shareholders are at greater risk than ever of being misled or uninformed by public companies and their promoters and sponsors. Our mission is to sift fact from fiction and encourage greater management accountability through transparency in reporting and disclosure by public companies and overall improve the quality of global capital markets.

### Important Disclaimer - Please read before continuing

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# 1. Bio-City Introduction

Investigators visited the Athenex site at Chongqing International Bio-City, only to find Athenex was not located at the site and that the actual building was far from completion.

Athenex claim to have completed this facility on September 23, 2019 and had prior expedited press releases showing progress and finalization at the facility. The company is also mentioned in several Chinese press releases and news articles as having its API manufacturing operations in the Chongqing International Bio-City,

Chongqing International Bio-City is a large industrial complex located within a Chinese Government development, apparently housing several bio-medical companies and factories.



Figure 3 Extract from cqcb.com – Article dated October 25, 2019<sup>3</sup>

Chinese state-sponsored media have mentioned Athenex is located within the site as does the website for the development<sup>4</sup>.

There are several discrepancies regarding when the site was actually completed:

- The website for Chongqing International Bio-City claims that Athenex's "main API project" was completed on May 14, 2019, a full 4 months before management made the same claim.
- New site cq.ifeng.com claimed the project was completed on September 19, 2019.
- An Athenex press release claims the site was completed on September 23, 2019.

All of these were at odds with on the ground research conducted, which shows the API facility is not only not within Chongqing International Bio City, but is also not completed.

<sup>&</sup>lt;sup>3</sup> https://www.cqcb.com/hot/2019-10-25/1936267 pc.html

<sup>4</sup> http://www.cqbiocity.com/ml/pc/news/detail.html?id=117&columnsId=10

# 2. Discrepancies in company announcements, lack of detail

The announcement of the site's completion on Athenex's website had no photos or links to other news. The cq.ifeng.com article only has a shot of several people walking through white hallways and an Athenex sign.



Figure 4 Extract from cq.ifeng.com<sup>5</sup> - Dated October 20,2019

Shenzhen China's government website also show pictures of the entry to the facility dated 25 October 2019. Readers will note that there is not even a ramp into the front door, let alone roads into the facility.



Figure 5 Extract from sz.gov.cn<sup>6</sup> - Dated October 20,2019

Readers also note the Athenex sign inside the facility.

<sup>&</sup>lt;sup>5</sup> https://cq.ifeng.com/a/20190919/7739486 0.shtml

<sup>&</sup>lt;sup>6</sup> http://www.sz.gov.cn/cn/zjsz/fwts 1 3/tzdt 1/201909/t20190925 18233170.htm

The photos of lab facilities are stock or promotional photos used in almost every announcement about the Chongqing Bio City, and photos of Athenex's actual site show there is not even a road to facility to get this equipment inside.



Figure 6 Extracts from cqcb.com<sup>7</sup> - dated November 20, 2019

For such a large development, almost no information is available about the Chongqing site. No address for the site could be found in any filings by Athenex, nor on any Chinese press releases about the company. Considering the development zone is 23 square miles in size this is strange.

In addition, there are very few photos of the site either under construction or complete. Note that the photo below of the "opening ceremony" clearly displays the date, September 19, 2019 with a clearly scaffolded building in the background.



Figure 7 Extract from cqcb.com article - dated October 25, 2019

We had previously written this off as a miscommunication but following our on the ground checks we now see this as a clear indication that the site is still not complete.



# 4. Putting things into context

Investigators visited the Chongqing International Bio-City on the week ending November 15, 2019, and were informed that Athenex's pharmaceutical base was not there. Here is one of our photos of the Bio-City site for reference:





Figure 8 Investigator photographs of Chongqing Bio-City (a.k.a. "not Athenex's API plant") vs cqcb.com article

Investigators were advised that the actual Athenex API site was near Maliuzui toll station, roughly 25 miles away from Bio-City.

Investigators visited this site and confirmed that the main investor was "Chongqing Maliu Development Zone Investment Co.", the state-owned enterprise referred to in Athenex filings.

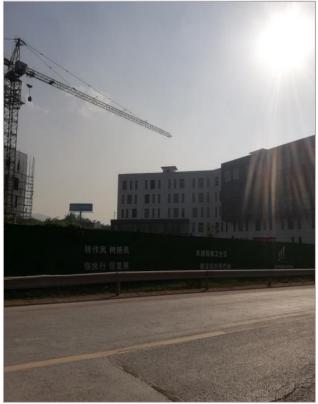
Here's what the site looks like:



Figure 9 – Athenex API facility park

There are no roads, no active tenants, and everyone inside this facility is still wearing hardhats. We find it difficult to comprehend how Athenex is currently conducting validation drug runs in this facility.

In case you are not convinced: enquiries made with employees of nearby pharmaceutical entities confirmed that this was the new factory for "Chongqing Taihao Pharmaceutical Company", Athenex's subsidiary. Also, our investigator found the same Athenex ramp-less entrance which was published in the Shenzhen China government website:





Figures 10 & 11 Viceroy Investigator Photographs vs Athenex



No-one could reasonably claim that the facility in the photos below is complete given it appears to be a shell. We do not anticipate that Athenex will be manufacturing APIs, or even validation batches at the Chongqing factory anytime soon.



Figure 12 Viceroy Investigator Photograph

# 5. Investors beware

Shareholders: you have been taken for a ride, once again. There is no completed API factory. It is not in Chongqing International Bio City. Validation batch will not be completed this year.

Athenex management have played investors in the same way they have played investors from all of their collective previous frauds. Pull back the veil of pretty site pictures of a veneer lobby and staged factory openings and take a step back to see the full picture.

This is the same management team spoon feeding the investment community pharmaceutical data, which we have already expressed our concerns about.

We have annexed our investigators full photoset of the Athenex construction site.



# 6. Addressing Announcement on Nov 19, 2019

We see management's recent announcement of Athenex's presentation at the San Antonio Breast Cancer Symposium is a blatant stock promotion move.

On November 19, 2019 Athenex announced the title of their presentation at the San Antonio Breast Cancer Symposium. This is a blatant strategy to pump the price of their stock by changing the title of the presentation which has had no change in content to the one announced on September 23, 2019 (ironically, the same date Athenex's Chongqing plant was allegedly.

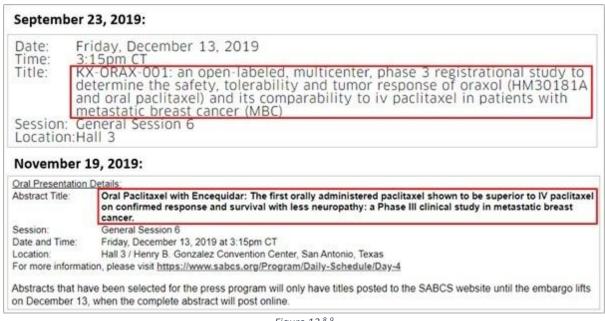


Figure 13 8,9

The original title for the presentation was the title of an abstract dated May 26, 2019 on the Journal of Clinical Oncology website.

A ascopubs.org > doi > abs > JCO.2019.37.15\_suppl.TPS1116 KX-ORAX-001: An open label, randomized, multicenter, phase ...

by GA Umanzor Funez - 2019

May 26, 2019 - KX-ORAX-001: An open label, randomized, multicenter, phase III registrational study to determine the safety, tolerability, and tumor response of oraxol (HM30181A + oral paclitaxel) and its comparability to IV paclitaxel in patients with metastatic breast cancer (MBC).

Figure 1410

https://www.globenewswire.com/news-release/2019/09/23/1919022/0/en/Athenex-to-Present-at-the-2019-San-Antonio-Breast-Cancer-Symposium.html

https://www.globenewswire.com/news-release/2019/11/19/1949506/0/en/Athenex-Announces-Key-Company-Activities-at-San-Antonio-Breast-Cancer-Symposium.html

<sup>&</sup>lt;sup>10</sup> https://ascopubs.org/doi/abs/10.1200/JCO.2019.37.15 suppl.TPS1116



When viewing the submission rules for the symposium it is clear that the only thing Athenex has changed is the title of the presentation: abstracts for the symposium were due on July 8, 2019.

#### Submission

- . Please click here to submit an abstract for the 2019 San Antonio Breast Cancer Symposium. You are required to submit your abstract online.
- When finished with your online submission, be sure to submit payment. Click the "Submit" button. Abstracts received without a properly
  completed Disclosure Declaration will not be considered. The size limit for the abstract (including title, body, and tables) is 3400 characters this
  does not include spaces. Please see the submissions website for specific details regarding tables.
- Any author who cannot present on a particular day of the week must provide that information upon submission. No rescheduling will be possible after July 8, 2019.
- Abstracts are due by July 8 at 11:59 pm Central Time US.
- For questions about abstract submission, contact CTI Meeting Technology by phone 217-398-1792 or by email sabcs@support.ctimeetingtech.com

Figure 15<sup>11</sup>

We can also rule out the possibility that Athenex is publishing under the ongoing clinical trials category and that new data has come to light as these are not subject to embargo policies, and Athenex's is on the list of embargoed abstracts<sup>12</sup>.

Again, inclusion of preliminary or final trial results will disqualify an abstract in this category and is not allowed on the poster, though information on accrual to date or confirmation of feasibility is acceptable.

Poster presentations in the Ongoing Clinical Trials category are not subject to SABCS prepublication and embargo policies.

Figure 16 SABCS Abstract Preparation

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<sup>11</sup> http://www.sabcs.org/2019-SABCS-sup-sup-/Call-for-Abstracts/Abstract-Preparation

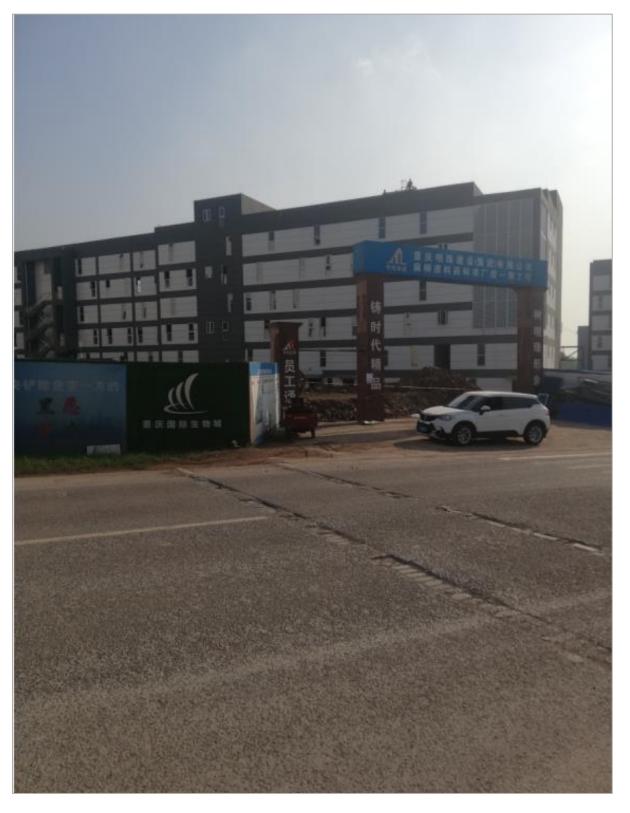
<sup>12</sup> https://www.sabcs.org/Portals/SABCS2016/2019%20SABCS/Embargoed%20Abstracts.pdf?ver=2019-11-19-122156-357



# 7. Annexure A: Photos of Site Visit

















































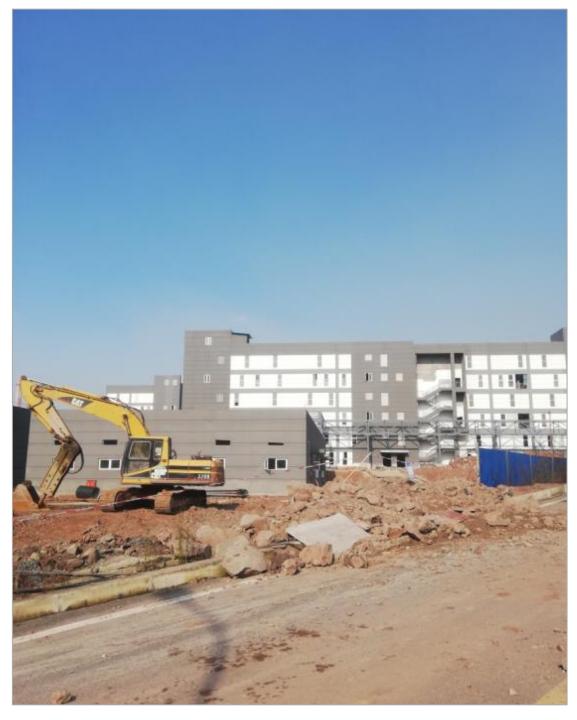


































# 8. Annexure B – An extended summary

# Management – A Company of Rogues

- Several members of Athenex's management team have a history of what appears to be either gross incompetence in fiduciary duties or clever mismanagement in <u>infamous frauds</u> internationally, collectively resulting in billions of dollars of write-offs including Sino Forest, Suntech, GCL Silicon/Poly, and China Lumena.
- Athenex directors have acted as on sellers and drop-shippers to rip off Athenex shareholders with marginstealing exercises through their investment entity: Avalon Global. Cash has consistently exited the business via similar related-party deals.
- Breaches in corporate governance principles: Athenex directors screwed investors by purchasing CDE for themselves and flipping it to Athenex for a 262% profit in 6 weeks. The company failed to report the circumstances of the transaction in any meaningful way.
- In another instance, Directors pocketed a 3,300% profit by flipping an "anti-cancer mechanism" license to Athenex for US\$5m, for which they paid just US\$150,000 just 6 months earlier.
- Directors award themselves millions of dollars worth of stock at <u>no</u> cost through the issuance of promissory notes that are cancelled on a time-vested basis.
- Athenex directors have an uncanny ability to avoid any disclosure or reference to their involvement in historical fraud or related party deals. It's Viceroy's view that if investors were aware, they would not have bought Athenex in the first place.
- Our investigations have found ties between Athenex subsidiary Polymed and its management team to the largest taxol smuggling ring in history, Yunnan Hande, which resulted in 50 arrests and 32 imprisonments.
   Taxol is a key ingredient in anti-cancer drug paclitaxel and its harvesting is heavily controlled.

### Oraxol – Flagship or Shipwreck?

Athenex has been reliant on the marketed prospect of Oraxol in order to obtain access to capital, having received going concern qualifications from Deloitte since 2016 and current yearly cash-burn rates of ~\$100m. The company has raised ~US\$360m in equity and US\$80m in debt since 2017. Even if R&D costs are removed from the equation, Athenex's licensing and consulting segments are operationally loss-making.

- After consultation with industry specialists and oncologists, Viceroy believes Athenex's flagship paclitaxel drug, Oraxol, cannot compete with the <u>current standard of care</u> available in the USA.
- Oraxol's clinical trials control dosing regimen of IV paclitaxel as monotherapy is an <u>outdated treatment</u> schedule dating from the 1990's.
- Oraxol's marketed quality of life improvements are redundant. Patients will still require IV treatment/post-treatment, alongside gastrointestinal complications from oral treatment.
- Oraxol's side effects appear more severe than those of the current US standard of care, Abraxane, and may require hospitalization due to their life-threatening nature. Reported adverse effects grade 4 neutropenia, grade 3 vomiting and unspecified GI complications were more severe than the IV paclitaxel group.
- None of Oraxol's clinical trials have included a US patient component. While the FDA does allow data overseas trials, these results are treated with much higher scrutiny. Viceroy believe ATNX studies are being conducted in South America due to a lower local standard of care: US patients could not be enticed to trial a drug against an outdated active control regimen.
- Athenex's Orascovery program key to its marketed value proposition was purchased for just US\$7.5m upfront in 2011 after its previous owner experienced decade-long development delays with little headway into development. The Orascovery platform is busted.



- hampered by the fact that its paclitaxel delivery mechanism, HM30181A, has never been approved by the FDA. The FDA may require Athenex to pursue a further NDA for HM30181A.
- Viceroy have identified what we believe to be Intellectual Property Theft from UK company Immunocore. XLifeSc's flagship technology (in which ATNX put US\$35m upfront) may already be owned by GSK and further along the development pipeline: GSK's solution is currently undergoing phase 2 trials in the US.
- With a BONUS round of issues in Buffalo where Athenex issues are mired with State issues of fraud and corruption. Although Athenex won't find that being an issue, as investors can see with Viceroy's Zhang's "Rinse-&-Repeat" Bankruptcy Playbook."

# Independent Review of Oraxol Data

Viceroy commissioned a report from a highly reputable, independent biotech consulting firm into the prospective NDA approval for Oraxol. This report is available on our website

- Consistent with previous expert opinions we have received in relation to Oraxol, this report concludes that
   "Oraxol will likely not secure approval following Athenex NDA submission in 1Q 2020."
- Experts refute management claims in Q3 earnings call that "FDA previously provided positive feedback to Athenex that it would accept the results of this one pivotal trial for license application in the U.S. if the primary endpoint is met", noting that there must also be an acceptable benefit/risk profile.
- Our Experts note that the treatment regiment for the IV Paclitaxel control group is a high-dose, three week
  regiment. This regimen has tested as inferior to the low-dose, weekly treatment. This would have created
  a much higher threshold for Oraxol's primary endpoint.
  - It's noteworthy that oral paclitaxel competitors, such as Daewa Pharmaceutical Co., have not shied away from this low-dose, weekly regimen as a higher threshold control.
- Differing outcomes in safety profile of Oraxol, when compared to IV paclitaxel, "is likely due to the delivery mechanism and formulation which includes the novel, unapproved PGP inhibitor HM30181A". Our consultants believe this may prompt further studies into the Oraxol delivery method, consistent with our prior reporting about adverse effects.
- The report also highlights issues in relation to the rarity of the FDA approving drugs with no USA clinical patient data. This presents a greater question mark for Athenex, who have already announced plans to commercialize this in the USA.
- Experts have noted Athenex's absence in providing any detail relating to Oraxol's adverse effects, in particular those effects which are inconsistent with IV paclitaxel, such as GI complications.
- Viceroy elected to file all our findings to the SEC, FDA and New York Governor due to the highly irregular corporate governance and business practices committed by the company. We note the company have failed to address or deny one issue, despite repeated requests to identify one single falsity.

### Factory Shutdown

- An investigation into Chinese regulatory notes from the Ministry of Emergency Management and Polymed's history of objectionable site inspections by Chinese regulators and the FDA lead us to believe that Polymed's manufacturing facility suspension not voluntary. In any event, Athenex's Chongqing 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.

Collectively, our research, informed by discussions with industry specialists, leads us to believe that Athenex's **Oraxol is obsolete in modern world medicine**. Athenex claims to "take pride" in the integrity of its management team. This same management team has overseen the evaporation of billions of dollars from shareholder capital in past ventures.

We reiterate our belief that Athenex exists to abuse capital markets and enrich its management through <u>related</u> <u>party transactions and licensing deals rather than bring revolutionary drugs into the market</u>.



Viceroy value ATNX stock at <u>US\$2.83 – a 71% downside</u> —the sum of its tangible book value and 1x valuation on its licensing & consulting revenue streams, for the year ending June 30, 2019. With ATNX's questionable license acquisitions and management's precedent for overstated top line figures in previous ventures: this is optimistic.

# Management Rap Sheet – in short

### Johnson Yiu Nam Lau – CEO and Chairman

- Undisclosed anti-cancer side business Taivex developing compounds in parallel with Athenex, created during time at Athenex
- Owns a share in the Avalon entities:
  - o Bought shares in CDE just before Athenex acquired it for a 262% profit in 6 weeks
  - o Avalon Polytom flipped the arginase license to Athenex for a 3,300% return
  - Avalon HepaPOC sells galactose meters to Athenex for 10% more than it pays from a manufacturer, a margin stealing drop shipping operation
- Undisclosed ownership of Sinophyto Solutions with Rudolf Kwan a Traditional Chinese Medicine company that has only received one shipment with its purpose listed as "investment"

#### Rudolf Min-Fun Kwan – Chief Medical Officer

- Owns a share in ZenRx, a CRO conducting Athenex's Oraxol clinical trials in New Zealand. ZenRx also has several rights to Oraxol in certain geographies
- Took part in flipping CDE to Athenex
- Undisclosed ownership of Sinophyto Solutions with Johnson Lau

#### Jeffrey Yordon – Chief Operating Officer

- Former Chief Operating Officer of American Pharmaceutical Partners where he misled investors about the prospects and abilities of their Abraxane drug.
- Formerly of Lyphomed where data related to 35 ANDA studies was tampered with or misrepresented.

# Song-Yi Zhang – Former director and large shareholder

- Owns a share in the Avalon entities
  - o See Johnson Lau
- Head of audit committee at Suntech when it was pledged fake german bonds, the non-existence of which later cause bankruptcy
- Sold Mandra Forestry to Sino-Forest on the verge of collapse after multiple loan defaults
- Sold Sino Polymer to China Lumena; Sino Polymer's revenues overstated by ~90%
- Displaced investors in GCL Silicon then siphoned cash out of GCL-Poly with the company's CEO.
- Several alumni and employees of investment vehicle, Mandra Capital, embedded at key positions at Athenex.

## Manson Fok – Director

- Owns a share in the Avalon entities
  - See Johnson Lau



## William Zuo – President, China Operations

- Likely liaison of taxol smuggling operation out of China into the US, Director of Yunnan Hande's US
  operations during the relevant time
- Sold Yunnan Hande US successor company Polymed to Athenex
- CEO of Inovachem, whose only activity was to purchase goods and services from Polymed with investor's money.
- CEO of Chinese Operations for Fibrocell for 3 years in which Fibrocell had no Asian operations after a Chiense joint venture failed to obtain state approval.

## Simon Pedder – Vice President of Corporate Strategy and Business Development

- Former CEO of Chelsea Therapeutics whose Northera's NDA was rejected by the FDA based on lack of credibility of its clinical studies.
- Effectively data mined a short trial to meet drug endpoints where all other trials had failed.
- Routinely misled investors about Northera's prospects of success and the FDA's view of the clinical trials.

### Nick Riehle – Former CFO

- Former CFO of Chelsea Therapeutics, see Simon Pedder.
- Left Athenex unexpectedly citing retirement, now seeking work as a consultant.

## Xiaojing Wu Li – Senior Vice President, Polymed Therapeutics

- Sister to Wu XiaoJing, Chairman of Yunnan Hande. Significant investor in Yunnan Hande, the largest world's largest illegal taxol smuggling operation. Remember Athenex are involved and need taxol!!
- Director, Vice President and Corporate Secretary of Inovachem