Athenex – Too little, too late

Poorly designed clinical study for flagship drug outdated since 2005. Meanwhile, Directors siphon large amounts of cash from shareholders.

October 22, 2019 - Viceroy Research is short Athenex, Inc. (NASDAQ: ATNX). Our research has found significant causes for concern in the company’s operations, management and clinical trial design. Our research, paired with discussions with industry specialists, leads us to believe Oraxol is obsolete in modern world medicine. 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.

Viceroy value ATNX stock at US$2.83 – a 71% downside – 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 – 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 infamous frauds internationally, collectively resulting in billions of dollars of write-offs including Sino Forest and Suntech.
- ATNX directors have also acted as sellers and drop-shippers to rip off Athenex shareholders with margin-stealing 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 a separate 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 no 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 $ATNX in the first place.
- Athenex’s CFO J. Nick Riehle left unexpectedly for a “planned” retirement, just 10 months after joining the company but is now seeking work as a consultant.

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 current standard of care available in the USA.
- Oraxol’s clinical trial’s control dosing regimen of IV paclitaxel as monotherapy is an outdated treatment schedule dating from the 1990’s.

Viceroy Research Group

vicEROYResearch.org
- **Oraxol’s marketed quality of life improvements are redundant.** Patients will still require IV/treatment post-treatment, alongside 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 IV paclitaxel intake.

- **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.

- Through consultation with experts, we believe Athenex’s pursuit of the 505b(2) pathway for Oraxol will be 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 $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.

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.

**Contents**

1. Background........................................................................................................................................... 4
2. Clinical trials.......................................................................................................................................... 4
3. The Orascovery platform...................................................................................................................... 11
4. Management: Rogues Gallery ................................................................................................................ 13
5. Avalon Biomedical ............................................................................................................................... 17
6. Xiangxue Pharmaceuticals and Axis Therapeutics................................................................................ 23
7. J Nick Riehle & Simon Pedder – Chelsea Therapeutics ...................................................................... 27
8. Conclusion............................................................................................................................................... 28
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

This report has been prepared for educational purposes only and expresses our opinions. This report and any statements made in connection with it are the authors’ opinions, which have been based upon publicly available facts, field research, information, and analysis through our due diligence process, and are not statements of fact. All expressions of opinion are subject to change without notice, and we do not undertake to update or supplement any reports or any of the information, analysis and opinion contained in them. We believe that the publication of our opinions about public companies that we research is in the public interest. We are entitled to our opinions and to the right to express such opinions in a public forum. You can access any information or evidence cited in this report or that we relied on to write this report from information in the public domain.

To the best of our ability and belief, all information contained herein is accurate and reliable, and has been obtained from public sources we believe to be accurate and reliable, and who are not insiders or connected persons of the stock covered herein or who may otherwise owe any fiduciary duty or duty of confidentiality to the issuer. We have a good-faith belief in everything we write; however, all such information is presented “as is,” without warranty of any kind – whether express or implied.

In no event will we be liable for any direct or indirect trading losses caused by any information available on this report. Think critically about our opinions and do your own research and analysis before making any investment decisions. We are not registered as an investment advisor in any jurisdiction. By downloading, reading or otherwise using this report, you agree to do your own research and due diligence before making any investment decision with respect to securities discussed herein, and by doing so, you represent to us that you have sufficient investment sophistication to critically assess the information, analysis and opinions in this report. You should seek the advice of a security professional regarding your stock transactions.

This document or any information herein should not be interpreted as an offer, a solicitation of an offer, invitation, marketing of services or products, advertisement, inducement, or representation of any kind, nor as investment advice or a recommendation to buy or sell any investment products or to make any type of investment, or as an opinion on the merits or otherwise of any particular investment or investment strategy.

Any examples or interpretations of investments and investment strategies or trade ideas are intended for illustrative and educational purposes only and are not indicative of the historical or future performance or the chances of success of any particular investment and/or strategy. As of the publication date of this report, you should assume that the authors have a direct or indirect interest/position in all stocks (and/or options, swaps, and other derivative securities related to the stock) and bonds covered herein, and therefore stand to realize monetary gains in the event that the price of either declines.

The authors may continue transacting directly and/or indirectly in the securities of issuers covered on this report for an indefinite period and may be long, short, or neutral at any time hereafter regardless of their initial recommendation.
1. Background

Athenex is a biopharma company principally concerned with the development and marketing of the Orascovery platform in the field of anti-cancer treatment. The Orascovery program is HM30181A, an inhibitor of P-glycoprotein (PGP), a protein found in the gastrointestinal tract. The suppression of PGP allows the oral administration of drugs not previously possible.

The company’s flagship drug Oraxol is a formulation that combines the widely used paclitaxel chemical with HM30181A to create a novel oral chemotherapy formulation. The company generates some revenue through the sale of Active Pharmaceutical Ingredients (APIs) and has other drugs in the pipeline but Athenex’s value proposition is largely dependent on the success of Oraxol. Gross profits generated through the APIs business are not even sufficient to cover a third of the current company’s SG&A (not including R&D expenses).

2. Clinical trials

Our research into Athenex’s Oraxol clinical trials\(^1\) and review of existing literature leads us to believe that the company has significantly overstated its potential market. Viceroy discovered this isn’t the first time that directors of Athenex been alleged to overstate the success of a drug! Since the inception of the Orascovery platform the treatment landscape for cancer and particularly Metastatic Breast Cancer (MBC) has changed significantly.

Other circumstances around the clinical trials suggest the company may also face significant scrutiny of its results by the FDA. We do not think it is out of the question that the FDA places increased scrutiny, delays or rejects Oraxol’s approval as a result of these factors.

A summary of our concerns:

1. The Active Control Treatment of IV paclitaxel as monotherapy is no longer standard of care in the US.
2. One of Oraxol’s main draws: that it does not require premedication, has already been effectively solved by the industry incumbent Abraxane.
3. Oraxol’s side effects may cancel out its supposed benefits in any real-world application. Observed side effects may be worse in terms of patient quality of life than the incumbent treatment.
4. None of Athenex’s Oraxol clinical trials have been performed on a US population, generally recommended to obtain FDA approval. Viceroy believes this will seriously hamper its efforts to obtain FDA approval, and a result of the IV paclitaxel baseline treatment being redundant as US standard of care.
5. The FDA has not approved HM30181A, and may not allow Oraxol to continue with the 505b(2) regulatory pathway if it deems HM30181A a new drug.
6. Several of the CROs used by Athenex are related parties which may influence the FDA’s view on the validity of results from clinical trials conducted by them. ZenRx is part owned by CMO Rudolf Kwan and Athenex recently purchased assets and liabilities of CIDAL.

We will go through each of our concerns in turn in the following section.

Irregularities with the IV paclitaxel dosing regimen used in the phase 3 study.

Athenex has been conducting its Oraxol trials by comparing it to a course of IV paclitaxel as monotherapy. While IV paclitaxel is a valid monotherapy treatment for Stage IV MBC, this schedule is not widely used in the US and has not been since the 90’s. Most drug regimens prescribed today are either sequential (different treatments administered one after the other) or combination (several treatments with non-overlapping side effects at once) therapies\(^2\).

---

\(^{1}\) Athenex’s posters and papers can be found here [https://web.archive.org/web/20191015004538/https://www.athenexoncology.com/](https://web.archive.org/web/20191015004538/https://www.athenexoncology.com/)

Oncology professionals consulted by Viceroy told us Abraxane (nab-paclitaxel) is more likely to be used instead of IV paclitaxel as it does not need premedication to prevent solvent-related hypersensitivity reactions. By not using Abraxane as the active control treatment Athenex has been able to promote Oraxol's upside as a drug not requiring premedication.

**Abraxane, approved in 2005, already effectively solved this problem in the field.** Instead of using a solvent such as CrEL or polysorbate, Abraxane uses albumin and paclitaxel to more effectively deliver paclitaxel to the cells.

This approval was based on the findings of a randomized phase III pivotal trial involving women with MBC randomly assigned to receive nab-paclitaxel 260 mg/m² over a 30-minute infusion q3w (n = 229) or CrEL-paclitaxel 175 mg/m² over a 3-hour infusion q3w (n = 225) with corticosteroid or antihistamine premedication. Treatment with nab-paclitaxel led to a significantly higher ORR compared with CrEL-paclitaxel based on the intent-to-treat (ITT) population (33% vs. 19%, respectively; *P* = 0.001).

This is likely the reason the trials were run outside the US: patients without alternatives are more likely to go for the sub-optimal monotherapy treatment. While not out the question for a doctor to prescribe IV paclitaxel as monotherapy in the US, we were told such cases are relatively rare and depend on the patient and their needs.

This leads to another issue where Oraxol is likely to be prescribed as part of combination or sequential therapy leading to the same side effects in any case and at greater cost to the customer.

As already noted by some in the market, the ORR reported by the IV paclitaxel arm of the phase III study is at the lower range for paclitaxel administered in this dose. The 175mg/m² q3-weekly IV paclitaxel regimen generally reports a 20-40% ORR placing the Athenex phase 3 study control’s ORR of 24% at the lower end of the spectrum.

### Side effects

Stage IV Metastatic Breast Cancer (MBC) is incurable, so treatments are palliative and focused on Quality of Life (QoL), Progression Free Survival (PFS) and Overall Survival (OS) with order of importance largely determined by the patient. In its clinical trials Athenex noted several incidences of grade 4 neutropenia and grade 3 vomiting and one incidence of febrile neutropenia.

---

3. [https://web.archive.org/web/20191015004905/https:/theoncologist.alphamedpress.org/content/3/6/373.full](https://web.archive.org/web/20191015004905/https:/theoncologist.alphamedpress.org/content/3/6/373.full)
4. Defined as neutrophils <500 cells/mm³
5. Defined as neutrophils <500 cells/mm³ accompanied by fever
This is to be expected because the time over which a specific paclitaxel dose is administered is relevant to the incidence of several side effects:

- Shorter, higher $C_{\text{max}}$ regimens generally result in neuropathy: tingling and numbness of extremities which may or may not fade over time.
- Longer, lower $C_{\text{max}}$ regimens generally result in neutropenia: a low neutrophil count (a type of white blood cell).

Experts consulted by Viceroy informed us that, of the two, neutropenia was the less desirable as it left the patient’s body essentially unable to fend for itself.

Further, grade 3 vomiting, grade 4 neutropenia and febrile neutropenia require hospitalisation for the patient somewhat mooting Oraxol’s supposed quality of life improvements. For reference, grade 3 vomiting is defined as “≥6 episodes separated by 5 minutes in 24 hours; tube feeding, TPN or hospitalization indicated”.

Oraxol also recorded a higher incidence rate of gastrointestinal (GI) complications: this is characteristic of other PGP inhibitors and there are issues inherent with an oral medication causing vomiting as it may cause the patient to expel any unabsorbed medication.

If HM30181A is the suspected cause of the GI complication the FDA may require more trials to be conducted.

**Lack of US clinical trials**

So far none of Oraxol’s clinical trials have been held in the US nor had any US participants. While the FDA does technically accept data from clinical trials conducted entirely overseas such data is more likely to be subject to increased scrutiny by the FDA.

Recent developments in FDA guidance and sentiment have also resulted in a higher inspection rate for overseas trial locations.

The FDA also unofficially recommends that at least some percentage of patients in submitted clinical trials are in the US. This differs based on the intended indication for the drug. For example for cardiovascular and diabetes drugs the FDA expects roughly a quarter of patients to be enrolled in the US.

An article originally published by STAT noted that where data was available only 3 drugs approved in 2017 had fewer than a quarter of patients in the US.

---

Companies tend to comply with that expectation: Among the 2017 drug approvals where a detailed breakdown of the data was available, only a few companies enrolled fewer than a quarter of their patients in the U.S.: Genentech’s multiple sclerosis drug Ocrevus (22 percent U.S. patients), Johnson & Johnson’s psoriasis drug Tremfya (20 percent), and the Japanese drug maker Mitsubishi Tanabe Pharma’s ALS drug Radicava (6 percent).

**Figure 5** Most Experimental Drugs are Tested Offshore—Raising Concerns about Data

For example, Abraxane had a US/Canada population for its clinical trials with 8% of patients and 31% of sites in the US & Canada. Other oncology studies that did not provide as much transparency into patient numbers nonetheless reported a sizeable North America/Western Europe component with several US sites.

This international, randomized, open-label, phase III study was conducted at 70 sites (28 Russia/Ukraine sites, 350 patients; 22 United States/Canada sites, 37 patients; and 20 United Kingdom sites, 67 patients). The protocol and related materials were ap-

**Figure 6** Abraxane clinical trial data – Journal of Clinical Oncology

We do not believe this alone is grounds for the FDA to reject Oraxol’s data but do believe that the risk factors we outline in this report will influence the FDA’s treatment of that data.

**FDA clearance issues**

Athenex is pursuing the 505b(2) pathway for Oraxol: a hybrid between an NDA and an ANDA. Unlike an NDA, the 505b(2) pathway is not testing an entirely new drug, nor is it applying for a generic. In Oraxol’s case Athenex seeks to use the existing approval of paclitaxel for the indication with a novel delivery method.

When the trial’s objective is to establish efficacy of the new drug by showing superiority to the control, the control should have demonstrated efficacy, but its effect size is not critical. When the trial’s purpose is to compare the relative effectiveness of two drugs, the comparison should be fair, with optimal use (e.g., dose, timing of measurements) of the control drug.

Designing a fair comparison of an experimental drug to an active-treatment concurrent control involves consideration of all variables that might affect the safety or efficacy of the drugs being compared. The target patient population (i.e., demographic and baseline disease state), concomitant therapies, and endpoints should be examined for their effect on expected drug activity overall, and for their differential effect on the activity of the

**Figure 7** Good Review Practice: Clinical Review of Investigational New Drug Applications

However, the PGP inhibitor delivery method HM30181A has never received FDA approval. If this is the cause of the increased incidence of GI complications the FDA may restrict Athenex’s use of the 505b(2) pathway and question the use of IV paclitaxel as the active control treatment. While Athenex’s management has moved to reassure investors that this is unlikely we are not so sure.

As noted above the increased incidence rate of gastrointestinal complications has been observed in other PGP inhibitors.

---

14 https://www.fda.gov/media/87621/download
Related party CRO organizations

Zenith Technology & ZenRx

On May 6, 2013 Kinex Pharmaceuticals announced a licensing agreement with Zenith Technology Corporation through its affiliate ZenRx for Oraxol and Oratecan in New Zealand. In exchange, Zenith Technology would “commit a significant amount of resources to the Oraxol and Oratecan global development platforms”.

By a staggering coincidence ZenRx was only incorporated in July 2013, roughly a month and a half after Kinex’s agreement was signed.

![Figure 8 ZenRx company summary](image)

The important part of the above is ZenRx, which is partly held by Athenex’s now-Chief Medical Officer Rudolf Min-Fun Kwan, who joined the company in 2014 but had acted as an advisor since 2008. ZenRx is also in line for several milestone payments, the amounts of which are undisclosed by Athenex.

![Figure 9 Athenex 2018 10-K](image)

We view Zenith Technology and ZenRx as tied as:

1. Both ZenRx and Zenith Technologies list Cheung-Tak Hung as a shareholder
2. Both companies have the same address: 156 Frederick Street, North Dunedin, Dunedin, 9016, New Zealand
3. Athenex has not published any agreement with Zenith Technology, but does have one with ZenRx, who appears to collect all consideration from the agreement.

![Figure 10 ZenRx shareholder list](image)

16 [https://web.archive.org/web/20191018063309/https:/app.companiesoffice.govt.nz/companies/app/ui/pages/companies/4465400?backurl=H4sIAAAAAAAAAEXLsQ7CMAxF0b%2FJWhgYLcQCAx2Q6NTNSgxEauJgu0D%2BniKC2O47JuXXk726jgksPdfp9g42XK5yhatDrWQwq7z2z4b2qwH4bI8OWbPUUbCCVoPAD5DEFU9xscqT5ZAg1F0Vm2KKBuN8u4C4FN8YPYUTphApOZXOA8PM3K7vzLCAAA%3D]
17 [https://web.archive.org/web/20191015012243/https:/app.companiesoffice.govt.nz/companies/app/ui/pages/companies/4465400?backurl=H4sIAAAAAAAAAEXLsQ7CMAxF0b%2FJWhgYLcQCAx2Q6NTNSgxEauJgu0D%2BniKC2O47JuXXk726jgksPdfp9g42XK5yhatDrWQwq7z2z4b2qwH4bI8OWbPUUbCCVoPAD5DEFU9xscqT5ZAg1F0Vm2KKBuN8u4C4FN8YPYUTphApOZXOA8PM3K7vzLCAAA%3D]
The other shareholder of ZenRx apart from Kwan and Hung is Neill Hubert Stacey, founder and MD of Southern Cross Pharma, another company whose clinical trials have been conducted at the Zenith site according to New Zealand Ethics committee documentation.

The 99% shareholder of Zenith Technology is Cheung-Tak Hung (sometimes referred to as Tak Hung). Both Hung and Zenith Technology appear on several Athenex presentations and papers including those assessing the safety and efficacy of Oraxol and Oratecan.

![Figure 11: An open label, randomised cross-over bioavailability and extension study of Oral Paclitaxel and HM30181 (Oraxol) compared to weekly intravenous paclitaxel 80mg/m² in advanced solid tumours](image1)

![Figure 12: An open label, randomised cross-over bioavailability study of Oral Paclitaxel (Oraxol) compared to intravenous paclitaxel 80mg/m²](image2)

While the headline phase 3 study of Oraxol for MBC does not list any Zenith Technology/ZenRx sites the Australian and New Zealand Clinical Trials Registry shows an Oraxol trial currently being operated by Zenith Technology Corporation.

Zenith Technology was also responsible for the DemeRx clinical trials where the company’s Founder and Chief Scientific Officer resigned from the board over disagreements over conducting clinical trials in New Zealand instead of the United States.

Schwabe as COO in late 2012. In June 2013, due to disagreements with Dr. Friedhoff involving clinical trial designs and plans to conduct a pivotal study in New Zealand instead of the United States, Dr. Mash resigned from the Debtor’s Board of Directors. Thereafter, Dr. Friedhoff resigned.

![Figure 15: DemeRx Chapter 11 filings](image3)

---

We view the main issue at ZenRx to be the conflict of interest with Kwan and Hung which are made worse by potential previous issues at DemeRx at the same facility. The conflict increases the likelihood of interference in the trials.

CIDAL

On June 27, 2019, Athenex entered into an agreement to acquire certain assets and liabilities of CIDAL Limited\(^{21}\), a contract research organization which had provided services for Athenex including its Phase 3 study for Oraxol in metastatic breast cancer.

[Figure 16 Athenex Q2 2019 10-Q]

Notably, we perceive the notion of “milestone payments” to your own drug’s CRO as a major red flag.

11 days later Athenex released its Q2 2019 headline results including an extremely positive spin on its Oraxol phase 3 studies, all of which are being conducted by CIDAL in South America\(^{22}\).

CIDAL is technically a BVI entity and as such we are unable to obtain any relevant financial information on the terms of the Athenex deal. Whether the purchase was contingent certain conditions is unknown, but we do find the timing and the nature of the purchase suspicious.

We question why CIDAL were even acquired: CIDAL cites a significant number of clients that are internationally known\(^{23}\). By acquiring CIDAL, we question the future benefit or value of such an acquisition as the company’s conflicts are greatly increased.

Key Takeaways

We believe Athenex has overstated the target market for Oraxol and their conduct in clinical trials indicates the company is aware of this fact. The control regimen, choice of population and choice of location suggest the company was unable to find a significant population of patients willing to accept the control treatment or their own.

It is likely that Athenex and Hanmi Pharmaceutical before them were aware of these issues when going through the history of the Orascovery platform.

\(^{21}\) https://web.archive.org/web/20191015013101/http:/www.cidal.net/

\(^{22}\) https://web.archive.org/web/20191015013217/http:/clinicaltrials.gov/ct2/show/study/NCT02594371?show_locs=Y

\(^{23}\) http://www.cidal.net/clients.html
3. The Orascovery platform

Athenex’s Orascovery platform is far older than generally known: the cornerstone of the platform being PGP inhibitor encequidar. In addition to this the circumstances of Athenex’s acquisition suggest the product is worth far less than suggested by the company.

On September 20, 2000 Hanmi Pharmaceuticals and Dr. Yoo Sung-Eun’s Bio-organic Science Division of the Korean Research Institute of Chemical Technology announced success in oral paclitaxel (Oraxol) using an indole derivative (HM30181A) to block P-glycoprotein stomach lining24. This derivative is now referred to as encequidar.

As part of the announcement, Hanmi announced that they aimed to market the drug by 2002 and completely replace the injectables market.

![Figure 17 Korea develops world's first cancer pill – The Dong-a-ilbo](https://web.archive.org/web/20191015013404/http:/www.donga.com/en/article/all/20000920/193348/1/Korea-develops-world-s-first-cancer-pill)

A document dated December 2003 stated preclinical trials were scheduled to complete in 2003, with phase 1 to be completed by 2004 with licensing in place.

In September 2005 Hanmi said the platform was in late preclinical status25 with the drug in phase 1 in August 200626. A December 2007 document showed Oraxol to be in phase 1 trials with plans to move to phase 2 trials in H2 2008 by the Journal of Pharmaceutical Policy Research27.


On December 11, 2011, Hanmi submitted the details of “A Study of Oraxol in Gastric Cancer Patients” to clinicaltrials.gov located at the National Cancer Center and Seoul National University Hospital. The study is still listed as recruiting. 8 days later, Hanmi and Kinex Pharmaceutical announced a license agreement for the platform, over a decade after the fanfare over its invention.

- Why did Hanmi take so long to advance the development of Oraxol?
- Did Hanmi invest the KRW2b into the Oraxol platform?
- Why is so little literature on Oraxol available from the Hanmi era?

The license was the first of several license agreements with Athenex (then Kinex Pharmaceuticals) for the use of the Orascovery program in several geographies.

---

27 http://www.e-kippa.org/common_files/asp/down_load.asp?table=bbs_book&idx=15&fname=2008%203%B1%C71%C8%A3i%C5%8B1%C74%C8%A31.pdf&flag=1
<table>
<thead>
<tr>
<th>Date</th>
<th>License Terms</th>
<th>Licence Consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2011</td>
<td>Grants exclusive sublicense for development, commercialization of products</td>
<td>US$0.25 and tiered royalty payments in the teens based on net sales in those</td>
</tr>
<tr>
<td></td>
<td>containing KX-01 in North America, South America, the European Union,</td>
<td>geographies.</td>
</tr>
<tr>
<td></td>
<td>Australia, New Zealand, Russia, Eastern Europe, Taiwan and Hong Kong.</td>
<td></td>
</tr>
<tr>
<td>November 2012</td>
<td>Amends December 2011 agreement to include Macau and Singapore.</td>
<td>No consideration.</td>
</tr>
<tr>
<td>June 2013</td>
<td>Grants exclusive sublicense for development, commercialization of products</td>
<td>US$100k and tiered royalty payments in the teens based on net sales in China.</td>
</tr>
<tr>
<td></td>
<td>containing KX-01 in China.</td>
<td></td>
</tr>
<tr>
<td>October 2013</td>
<td>Amends December 2011 agreement to include Malaysia, Thailand, Vietnam, the</td>
<td>No consideration.</td>
</tr>
<tr>
<td></td>
<td>Phillipines and Indonesia.</td>
<td></td>
</tr>
<tr>
<td>March 2015</td>
<td>Amends December 2011 agreement to include India.</td>
<td>US$50k.</td>
</tr>
<tr>
<td>March 2017</td>
<td>Amends December 2011 agreement to include Japan.</td>
<td>US$7m convertible bond, exercised September 2017.</td>
</tr>
</tbody>
</table>

Hanmi received a total of only US$7.4m in upfront consideration for its Orascovery program through to March 2017. This is at odds with a complaint filed by Athenex against its Senior VP of Operations, Lyn Dyster for allegedly leaking details about its Orascovery program to Fulgent Therapeutics. The case was eventually settled: Athenex filed for US$2.9b in damages.

- Why did Hanmi sell a platform it intended to invest KRW2b in for a total of US$7.4m to Athenex?
- Why were the amendments to the December 2011 agreement to include Macau, Singapore, Malaysia, Thailand, Vietnam, the Phillipines and Indonesia done for no consideration?
4. Management: Rogues Gallery

Chairman & CEO - “Johnson” Yiu-Nam Lau

Roth Capital Partners

Johnson was a Managing Director at Roth Capital partners from 2005-2007. Readers should note that short sellers in particular analyze anything coming out of Roth Capital Partners with extreme skepticism given the group’s extraordinary record of listing garbage international companies especially when a relationship with China is concerned.

Former Independent Director – Song-Yi Zhang

Zhang joined the Athenex board in June 2015, and his resignation was announced in March 29, 2019. Despite this Zhang remains a controlling stakeholder in Athenex associates together with existing management, who benefit heavily from related party dealings.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Common Stock Equivalent Held</th>
<th>Market Value (USD in mn)</th>
<th>% of CEO</th>
<th>Change in Shares</th>
<th>% Change</th>
<th>Share Price (USD)</th>
<th>Sale Value $</th>
<th>Position Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jun-20-2019</td>
<td>4,225,789</td>
<td>46.2</td>
<td>5,487</td>
<td>(185,818)</td>
<td>(4.21)</td>
<td>18.63</td>
<td>(2,630,881)</td>
<td>Apr-15-2018</td>
</tr>
<tr>
<td>Jun-20-2019</td>
<td>4,225,789</td>
<td>83.7</td>
<td>5,483</td>
<td>(185,818)</td>
<td>(4.21)</td>
<td>19.8</td>
<td>(3,679,186)</td>
<td>Apr-15-2018</td>
</tr>
<tr>
<td>Mar-31-2016</td>
<td>4,411,807</td>
<td>54.0</td>
<td>8,568</td>
<td>(120,083)</td>
<td>(2.65)</td>
<td>12.26</td>
<td>(1,470,846)</td>
<td>Mar-15-2016</td>
</tr>
<tr>
<td>Dec-31-2018</td>
<td>4,551,960</td>
<td>57.5</td>
<td>6,774</td>
<td>(1,000,000)</td>
<td>(18.56)</td>
<td>12.69</td>
<td>(12,690,000)</td>
<td>Nov-30-2018</td>
</tr>
<tr>
<td>Sep-30-2018</td>
<td>5,531,960</td>
<td>88.0</td>
<td>9.29</td>
<td>(496,246)</td>
<td>(8.23)</td>
<td>15.54</td>
<td>(7,711,694)</td>
<td>Aug-29-2018</td>
</tr>
<tr>
<td>Jun-20-2019</td>
<td>4,531,960</td>
<td>112.8</td>
<td>9.94</td>
<td>(496,246)</td>
<td>33.02</td>
<td>16.66</td>
<td>(7,719,346)</td>
<td>Aug-29-2018</td>
</tr>
<tr>
<td>Mar-31-2018</td>
<td>4,531,960</td>
<td>77.1</td>
<td>7.137</td>
<td>(2,744,035)</td>
<td>(37.72)</td>
<td>17.01</td>
<td>(46,670,035)</td>
<td>Mar-27-2018</td>
</tr>
<tr>
<td>Dec-31-2017</td>
<td>7,375,806</td>
<td>118.7</td>
<td>12,546</td>
<td>0</td>
<td>0</td>
<td>15.9</td>
<td>0</td>
<td>Sep-30-2017</td>
</tr>
<tr>
<td>Sep-30-2017</td>
<td>7,276,695</td>
<td>122.4</td>
<td>12.75</td>
<td>0</td>
<td>0</td>
<td>15.71</td>
<td>0</td>
<td>Sep-30-2017</td>
</tr>
<tr>
<td>Mar-31-2017</td>
<td>6,716,784</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Mar-31-2017</td>
</tr>
</tbody>
</table>

Figure 19 Song-Yi Zhang insider transactions

The above extract from S&P Capital IQ suggests large disposals by Zhang and his holding companies, however we note that these transactions are extremely hard to follow due to Zhang’s withdrawal from the Athenex board and his maintained interest in the Avalon group (which owns substantial parcels of Athenex stock) alongside current management. Disclosures regarding the ownership split of Avalon Group show the Zhang’s stake has changed over time further obscuring how much of Athenex he actually owns.

Mandra

Readers may recall the Mandra name from Sino Forest, a massive Chinese timberland fraud that collapsed in 2011.

Mandra Forestry Finance was launched by Zhang to acquire 270,000 ha of Chinese timberland with US$195m in funding. At the outset Sino Forest was a 15% shareholder, Morgan Stanley 10% and Zhang the remaining 75%. Zhang had left Morgan Stanley prior to the US$195m debt raise but was still engaged as an “advisory director” at the time of the bond sale.

By March 2006 with the first payments due on its loan in a year, Mandra had only acquired 17,231 ha. Mandra missed its May 2009 payment after several downgrades to its debt. The company had also failed to obtain permission to increase its timber production. The company was on its last legs prior to this offering: only one of three Mandra subsidiaries has done any business prior to 2009, with one having ceased operations in 2006 stating: “plan to purchase forest land could not be carried out” in Chinese filings and the other having conducted no business in its life.

28 https://www.bloomberg.com/profile/person/3456446
29 S&P Capital IQ
On July 6 2009, Mandra terminated two management agreements with Sino Forest, a move that the latter said it would dispute. The now-infamous Sino Forest purchased substantially all the assets of Mandra Forestry Holdings Limited in February 2010 for US$9m in stock and assuming US$187m in debt. At the time, Mandra had acquired 150,000ha of forest land citing its ability to produce “sustainable cash flow”. On the same day Sino Forest announced its intention to raise US$800m of new capital arguably using the announcement to prop up its weak cash flows at the time.

Suntech Power Holdings

Zhang was also involved in Suntech Power Holdings as director and chairman of the audit committee, a fact omitted in his Athenex biography. Suntech was forced into liquidation following its default on a US$541m bond payment in March 2013. The story of how the default came about is frankly fantastical.

Suntech aimed to expand into Italy in 2008 through a partnership with the Global Solar Fund SCA, which was established by Javier Ignacio Romero Ledesma. To bankroll this expansion, Suntech tapped the China Development Bank for an EUR554m loan with EUR560m in German government bonds pledged as security. The German government bonds were pledged by Romero’s personal investment vehicle, GSF Capital (separate from the Global Solar Fund SCA).

Romero went through two individuals to purchase pre-developed land in Italy, which was later alleged to be a fraudulent scheme to siphon government funds. The Italian courts allege Romero made off with EUR6.5m in government funds. 27 of Suntech’s solar plants were seized by authorities.

On July 30, 2012, with a bond payment coming due, Suntech announced that the German bonds it had been pledged from GSF Capital did not exist, nor had they ever existed. Court documents show that Suntech’s CEO had knowledge of this from February 2012, that Suntech had knowledge of Romero misrepresenting himself as a company executive and that through shifting of Italian operation ownership Suntech had booked huge gains through effectively selling to itself.

We find believe this fact pattern, involvement with mismanagement and bailing out with suspiciously good timing, has continued at Athenex where Zhang appears to continue to “fail upward”.

---

34 https://www.newswire.ca/news-releases/sino-forest-completes-acquisition-of-mandra-forestry-539273481.html
President (China Division) – William Zuo

Polymed and the Chongqing Factory

Zuo served as president of Polymed Therapeutics and Chairman of Chongqing Taihao Pharmaceutical, both of which were acquired by Athenex in June 2015.

We question Athenex’s judgement in this transaction: Chongqing Taihao received a form 483 from the FDA in March 2015 as a result of an inspection. Form 483s are issued where violations of the Food Drug and Cosmetic Act and related Acts may have occurred. This was not mentioned in Athenex’s prospectuses or other filings: the various underwriting agreements in their prospectus states the company had not received any such notes.

While this may not technically be a lie considering Athenex didn’t own the Chongqing facility at the time of receiving the Form 483 we have to ask why they would acquire such a liability in the first place.

Inovachem

Zuo was also the CEO of Inovachem, a short lived US company whose only activity was the purchase of goods and licenses from Polymed. Inovachem generated no revenue and shared the same address and officers as Polymed pretty much making the entire venture an exercise in siphoning away the cash of Inovachem investors.

---

Inovachem raised a total of XX before the loss-making entity was sold and used to reverse list NuGen holdings on January 29, 2010. It was a short and downhill ride for those investors who saw the company generate a cumulative loss of US$1.26m generating for no revenue whatsoever. Most of those expenses were accounted for by compensation, professional fees and travel expenses.

<table>
<thead>
<tr>
<th>Revenues</th>
<th>For Year Ended September 30, 2009</th>
<th>For Period from February 14, 2008 (inception) to September 30, 2008</th>
<th>Cumulative For Period from February 14, 2008 (inception) to September 30, 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating expenses</td>
<td>$433,572</td>
<td>$502,210</td>
<td>$935,782</td>
</tr>
<tr>
<td>Compensation</td>
<td>16,987</td>
<td>101,652</td>
<td>118,609</td>
</tr>
<tr>
<td>Professional fees</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impairment expense</td>
<td>45,944</td>
<td></td>
<td>45,944</td>
</tr>
<tr>
<td>Travel expenses</td>
<td>89,684</td>
<td>50,805</td>
<td>130,489</td>
</tr>
<tr>
<td>Other general and administrative expenses</td>
<td>23,279</td>
<td>20,421</td>
<td>43,700</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>560,522</td>
<td>701,022</td>
<td>1,264,554</td>
</tr>
</tbody>
</table>

The licenses and goods that Inovachem purchased from Polymed had several patent applications for the creation of sucralose, a non-caloric sweetener which due to “the poor economy” was never produced.

Inovachem does not appear on any of Zuo’s Athenex bios, nor did we really expect it to considering his joining of Athenex is much like a graduation to the major leagues of ripping off investors. From that perspective, Zuo is uniquely qualified for his role at Athenex.

**William Zuo**

Dr. Zuo joined our company in 2015 as President of our China operations in conjunction with our acquisition of Polymed Therapeutics. Dr. Zuo had served as President of Polymed Therapeutics since 1995 and Chairman of Chongqing Taihao Pharmaceutical since 2012. Dr. Zuo’s career has focused on the development, manufacture, and sale and marketing of various complex API on a global basis, especially injectable oncology active pharmaceutical ingredients. Dr. Zuo was the chief executive officer of the Fibrocell Science Group Companies in Asia from 2010 to 2013. Dr. Zuo oversaw the introduction of the U.S. FDA approved cell therapeutics product, LaViv, to the Asia market. He has overseen the construction of multiple current Good Manufacturing Practices

https://ir.athenex.com/static-files/9334a09e-3ab9-4538-b9e2-8c93e5bb5795
Rudolf Kwan

Viceroy Research loves coincidence and there is no greater coincidence than Dr Kwan’s involvement with a Parker Petit-related entity. Kwan served as president of privately held DemeRx on whose founding board sat Parker Petit and which was founded by several of Petit’s associates. Kwan appears to have gone by the name Rudy Kwan at this time most available information is from chapter 11 filings. In 2013, Lawrence Friedhoff MD was recruited as CEO and President of DemeRx. In June that year VP of R&D and Chief Scientific Officer Dr. Deborah C. Mash resigned from the board over a clinical trial held in New Zealand instead of the United States. Another staggering coincidence is that ZenRx was only founded in July 2013.

Schwabe as COO in late 2012. In June 2013, due to disagreements with Dr. Friedhoff involving clinical trial designs and plans to conduct a pivotal study in New Zealand instead of the United States, Dr. Mash resigned from the Debtor’s Board of Directors. Thereafter, Dr. Friedhoff resigned.

5. Avalon Biomedical

Three senior Athenex executives are involved with Avalon Global Holdings: a company engaged in margin stripping and cash siphoning deals with Athenex. Our research indicates Avalon Global Holdings enters into commercialization agreements with the Hong Kong Polytechnic University or other institutions, creates a subsidiary for each innovation and then licenses them out again.

From their most recent disclosures, Avalon Global is 80% held by Lau, Fok, Zhang and their spouses through various investment vehicles. Zhang holds his through a Mandra Forestry affiliated entity. At the time of Athenex’s prospectus, 90% of Avalon Global was held by the three with the remaining 10% unaccounted for.

Dr. Lau owns all of the outstanding interests in Creative Decade Global Limited, which owns 30% of the outstanding interests in Avalon Global, and Dr. Lau serves on the board of directors of Avalon Global and has shared voting and dispositive power with respect to the shares held by Avalon Biomedical.

Mr. Zhang, together with his spouse, indirectly owns all of the outstanding interests in Mandra Medical Limited, which owns 30% of the outstanding interests in Avalon Global, and Mr. Zhang serves on the board of directors of Avalon Global and has shared voting and dispositive power with respect to the shares held by Avalon Biomedical.

Athenex’s CEO and Chairman Johnson Yiu-Nam Lau is the only Director at Avalon Biomedical (Management) Limited, per its Annual Returns Filings for 2016.

### Figure 27 Athenex Form S-1

Avalon Biomedical (Management) Limited Ownership Annual Returns Filings 2016

2014 three Directors were present at Avalon Biomedical (Management) Limited:

- Yiu Nam Lau (Athenex CEO and Chairman)
- Creative Decade Global Limited of which Lau owns all of the outstanding shares42.
- Sino Glory Developments Limited of which Manson Fok and his spouse, owns all of the outstanding shares43.

### Figure 28 List of Avalon Biomedical (Management) Limited Directors in 2014

Until February 2015, Creative Decade Global Limited and Sino Glory Developments Limited were the equal owners of Avalon Biomedical (Management) Limited. In February 2015, they transferred the shares over to the BVI company Avalon Biomedical Holdings Limited.

42 https://www.sec.gov/Archives/edgar/data/1181165/000120919119053290/xslF345X03/doc4.xml
43 https://www.sec.gov/Archives/edgar/data/1300699/000090514817000606/xslF345X03/form4.xml
In effect Johnson, Zhang and Fok are on both sides of these transactions: licensing deals from third parties to Avalon and then selling some of them on to Athenex and taking a cut in the process.

So far two of the Avalon entities have done business Athenex: Avalon Polytom, Avalon Biomedical and Avalon HepaPOC.

Avalon Polytom

Athenex licensed Pegtomarginase from Avalon Polytom as part of an agreement between them as of June 29, 2019 for US$3m in cash and US$2m in stock.

An announcement by the Hong Kong Polytechnic University dated December 10, 2018 states that Avalon Polytom presented a cheque to the Department of Applied Biology and Chemical Technology in exchange for the Arginase License. An attached photo shows the amount to be HKD1.17m (US$0.150m)

Athenex shouldered the regulatory workload as well as potentially being on the hook for ~US$50m of payments to Avalon Polytom. Considering Athenex’s precarious financial position we see this as management taking investors for a ride pocketing a 3,300% profit by flipping a license to Athenex.
Avalon HepaPOC

We made an upfront payment of cash of $0.5 million to HepaPOC upon effectiveness of the HepaPOC License Agreement, and we were required to make payments to HepaPOC worth up to $4.8 million in our common stock or in cash upon the occurrence of certain regulatory and sales milestones. In addition, we have agreed to pay royalty payments of 5% based on aggregate net sales of any products utilizing the intellectual property that is the subject of the HepaPOC License.

Figure 33 Agreement between Athenex and Avalon HepaPOC dated June 29, 2018

Athenex’s collaboration with Avalon HepaPOC appears to be a simple drop-shipping operation. While Avalon HepaPOC has the same contact address and person as Avalon Polytom, the return address for any defective products is No. 7, Li-Shin 5th Rd., Hsinchu Science Park, Hsinchu, Taiwan.

Figure XX Agreement between Athenex and Avalon HepaPOC dated June 29, 2018

That address is Apex Biotechnology Taiwan, whose business is the production and sale of blood testing systems.

Figure 34 ApexBio Taiwan contact details

Avalon’s agreement with Athenex prices goods purchased from Avalon HepaPOC at 110% of cost invoiced from 3rd party manufacturers.

(a) **Price.** Athenex shall purchase the Goods from Avalon at 110% of Avalon’s documented and verified cost that Avalon is invoiced by the third-party manufacturing such products for Avalon (“Prices”).

Figure 35 Agreement between Athenex and Avalon HepaPOC dated June 29, 2018

The goods in question are a galactose meter and measuring strip, pictured in the agreement.

Figure 36 Picture of Avalon HepaPOC Galactose Meter

We question which part of this agreement was worth the payments made by Athenex to Avalon or why Athenex doesn’t simply buy these meters directly from Apexbio themselves, considering Avalon appears to be simply forwarding on product to Athenex with a **10% markup and pocketing the increased margin.**

Comprehensive Drug Enterprise Ltd.

---

47 https://www.sec.gov/Archives/edgar/data/1300699/000119312518211357/d653771dex105.htm
According to Athenex’s prospectus the company acquired Comprehensive Drug Enterprises Ltd. (CDE) in June 2015 for US$14.9m in shares. What was not said was that this transaction generated Athenex directors a 263% return on an investment made just prior.

On June 1, 2015, just six weeks before Athenex’s announcement of the US$14.9 million acquisition of 100% of Athenex’s management and/or affiliated entities were allotted 8,304,986 shares of CDE at a price of HKD1.74 (US$0.23) per share.

The beneficiaries of this scheme are Manson Fok (director), Johnson Yiu Nam Lau (CEO), Rudolf Min-Fun Kwan (CMO), Flint Besecker (CFO) and James H Zukin

As a result, the total number of CDE shares increased to 18,089,547 on June 1, 2015.

As disclosed in SEC filings on July 17, 2015 Athenex bought all 18,089,547 outstanding shares of CDE for US$14.9m or US$0.82 per share. Athenex’s management pocketed an astonishing 262.83% return by flipping CDE shares they acquired on June 1, 2015 for US$0.23 per share to Athenex on July 17, 2015 for US$0.82 a share.
We can pretty clearly gauge the actual value of the shares: CDE bought back its shares from existing shareholders at HKD1.28 (US$0.16) per share in July 2014. We doubt the company increased in value 513% 12 months later.

The allocation of shares on June 1, 2015 Athenex increased Avalon Biomedical (Management) Limited stake to 7,320,092 shares in CED (40.46% stake). Doing the math shows Avalon Biomedical (Management) held 29% of the CDE float prior to the allocation.
Athenex did disclose the related nature of the parties, but not how the deal had been financially engineered to benefit insiders at investors’ expense. Amazingly a “special committee of disinterested directors” found nothing wrong with the CDE acquisition agreement.

CDE also rents office space to Avalon Biomedical at Units 608-613, No. 6 Science Park West Avenue, Hong Kong Science Park, Sha Tin, Hong Kong. We question what exactly the point of this transaction was beyond enriching directors in addition to share option promissory note enrichment.

We at Viceroy are almost impressed with the many and various ways Athenex’s insiders have managed to fleece investors.

6. Xiangxue Pharmaceuticals and Axis Therapeutics

On July 1, 2018 Athenex entered into a joint venture with Xiangxue Life Sciences (XLifeSc)\(^\text{49}\), a wholly owned subsidiary of Guangzhou Xiangxue Pharmaceutical Co., Ltd for the research, development and commercialization of anti-cancer T-cell receptor therapy. This joint venture would be called Axis Therapeutics Limited and owned 55% by Athenex and 45% by XLifeSc.

In exchange for this Athenex would issue US$5m of stock to XLifeSc and US$30m in cash to the joint venture. Axis would pay up to US$110m to XLifeSc. XLifeSc would also retain the mainland China rights with royalties on net income payable for Axis.

In summary:

- Athenex paid US$30m for 55% of Axis therapeutics
- Athenex issued US$5m to XLS for the privilege of partnering with them.
- Axis would pay up to US$110m to XLS subject to regulatory and clinical milestones.

All XLS had to do was contribute a license for IPR&D of certain immunotherapy technology. This platform is cancer treatment through T-cell receptor therapy. Given consideration paid by Athenex, we decided to get a closer look at what they are getting out of the deal.

What value Athenex is getting from XLS’s T-cell therapy platform?

Our research suggests XLifeSc’s flagship technology may already be owned by GSK and further along the development pipeline: GSK’s solution is currently undergoing phase 2 trials in the US\(^\text{50}\).

XLifeSc’s central platform is TAEST technology: TCR Affinity Enhanced Specific T-cells for NY-ESO-1 and specifically the TAEST 16001 product. On March 21, 2019 Athenex announced that XLifeSc had received IND approval from China National Medical Products Administration (formerly China FDA)\(^\text{51}\) for the TAEST 16001 injection.

---

\(^{49}\) Sometimes translated Xiangxue Precision Medical Technology

\(^{50}\) https://web.archive.org/web/20191018070647/http://clinicaltrials.gov/ct2/show/NCT02992743

This product appears to be identical to the NY-ESO SPEAR T-cell therapy program currently being developed by GSK after acquiring the platform from Adaptimmune. Both products use enhanced affinity receptor T-cells to recognize a peptide shared by cancer antigens. How this happened is less than coincidence.

The star of XLifeSc is Dr. Yi Li, formerly of the Guangzhou Institute of Biomedicine and Health which he joined in December 2011 as part of the Thousand Talents Program.

The program, designed to facilitate an influx of know-how and expertise to China, has been criticized by several US governmental bodies for facilitating theft of intellectual property53.

Prior to returning to China Dr. Li worked at Adaptimmune’s sister company Immunocore and was credited in several papers regarding T-cell therapy as well as several patents held by Immunocore and Adaptimmune54, 55.

54 https://patents.justia.com/assignee/adaptimmune-limited
55 https://patents.justia.com/assignee/immunocore-limited
In a submission for a clinical trial conducted by Xiangxue Life Sciences, Dr. Li claims to have developed the anti-NY-ESO-1-specific TCR in 2005, which while not strictly incorrect fails to mention he did this at another company:

In 2015, TCR-T cell treatment achieved a breakthrough and gratifying effect. A trial with high-affinity anti-NY-ESO-1 and LAGE-1-specific TCR-T cell therapy for multiple myeloma were published in Nature Medicine at the University of Pennsylvania, University of Maryland and Adaptimmune, which showed that 16 of 20 patients (80%) obtained clinically effect with 19.1 months for an average of disease free survival. Moreover, there were no serious side effects.

On July 24, 2018 GSK and Adaptimmune announced transition completion for the NY-ESO SPEAR programme to GSK. A search of clinicaltrials.gov shows GSK’s trials are currently in phase 2 in the US.

A point of clarity: we are not claiming that Dr. Li stole the technology currently being licensed by Athenex. We are simply remarking on the circumstances that led to Li leaving a UK company which later invented what appears to be an identical product to the one he developed in China in following years.

---

57 https://web.archive.org/web/20191018073359/https://clinicaltrials.gov/ProvidedDocs/16/NCT03462316/Prot_000.pdf
We have serious reservations about the value of XLifeSc’s product offering and the decisions made by Athenex management in entering into a JV for a platform which has a better-funded competitor ahead in the regulatory schedule.
7. J Nick Riehle & Simon Pedder – Chelsea Therapeutics

J. Nick Riehle joined Athenex in January 2017 and was appointed as CFO in February of that year, only to depart from the company in December 2017. Prior to this Riehle was CFO at Chelsea Therapeutics: he was in good company at Athenex. A year earlier Athenex announced the addition of former Chelsea CEO and President Simon Pedder\(^{58}\) as Chief Business and Strategy Officer, Proprietary Products.

We believe that the story that unfolded at Chelsea is the same as the one unfolding at Athenex: management misrepresenting a drug’s chances of FDA approval to fleece investors.

Chelsea attempted and failed to receive FDA approval for its drug Northera to treat primary autonomic failure and its executives were later the subject of a shareholder class action for, among other things, failing to provide an accurate representation of the success of clinical trials and FDA meetings.

This led to a shareholder class action which gives us an insight to what was happening at the company.

---

**3. J. Nick Riehle**

21. Defendant J. Nick Riehle (“Riehle”) served as Chelsea’s Vice President, Administration and Chief Financial Officer (“CFO”) at all relevant times. Because of his positions with the Company, Riehle had access to the adverse, undisclosed information concerning the safety and efficacy of droxidopa for patients with NOH, the results of the Phase III trials, the post-marketing events in Japan, the NDA submitted to the FDA, the communications with the FDA, the prospects for FDA approval and all material facts concerning the development of droxidopa for patients with NOH. Riehle directly participated in and responded to questions about droxidopa. Defendant Riehle stated that “[t]he excitement around the conclusion of both Phase III and NOH studies is growing by the day. Based on the open label data that we’ve seen to-date, we are highly confident in a favorable outcome in both studies.” Similarly, addressing a question about the “effect” of droxidopa on the patients,

---

**Figures 47, 48 & 49 Extracts from Case 3:12-cv-00213-MO&-DCK**

Northera’s clinical trials were unable to achieve their primary endpoints in all but one trial, which only lasted a week and used a highly disputed assessment tool. All other trials (which had longer treatment periods) either failed to meet their primary endpoints or were abandoned after interim analyses showed they would not meet their endpoints.

The FDA were in communication with Chelsea about these issues including their assessment tools, the need for further confirmatory studies and evidence of long-term improvements. The drug also resulted in increased incidences of death, adverse effects, strokes, myocardial infarctions and worsening of conditions.

Throughout the class period Pedder, Riehle and other Chelsea executives represented to investors that all was progressing well with the Northera trials and that FDA approval was all but guaranteed. This culminated in the FDA finally denying approval of Northera on March 28, 2012.

Any reputable company would avoid individuals so closely involved with this farce, but not Athenex!

---

Another piece of the puzzle: there are several circumstances around Riehle’s tenure and departure which we view as strange. The reasons cited by the company were Riehle’s “planned” retirement from full-time employment to spend more time with his family; no prior notice was given to investors that Athenex’s CFO intended to retire.

Additionally, 10 months as an exceptionally short tenure for a CFO of a freshly listed company. Riehle doesn’t appear to have retired at all: his LinkedIn profile shows he now acts as an independent consultant and his resume website is still active and bears a 2019 date.

8. Conclusion

Athenex has a net-cash balance sheet as of its most recent financial statements, however also burnt over $110m cash in the last 12 months. The company’s licensing and consulting segments both appear to be operationally loss making and have plateaued over the last 6 months (LTM June 30, 2019 revenues down against CY 2018). These revenue streams may be worth a nominal amount to the right buyer.

Optimistically, we value Athenex at $2.83 per share, which is the sum of its tangible book value and a 1x valuation on its revenue streams, both for the year ending June 30, 2019. This suggests a 71% downside.

Athenex is a perfect storm of investor deception, insider enrichment and clinical trial risks.

We have no faith in the trial methodology being used by Athenex and do not believe that Oraxol’s true market potential has been represented to investors. Beyond that the history of the Orascovery program and involvement with CROs shows a complete disregard for best practices and an intention to manipulate data.

Athenex itself has become a self-enrichment tool for its directors and insiders: investors interests are not being protected at all. Management and the board of directors are either complicit, complacent or completely inadequate to the task. At this point the company appears to exist solely to transfer cash to China, a jurisdiction notoriously hard to repatriate it from.

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.

<table>
<thead>
<tr>
<th>Athenex, Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exchange</td>
</tr>
<tr>
<td>Ticker</td>
</tr>
<tr>
<td>Shares Outstanding m</td>
</tr>
<tr>
<td>Share Price* US$</td>
</tr>
<tr>
<td>Market Cap US$m</td>
</tr>
<tr>
<td>Net Cash US$m</td>
</tr>
<tr>
<td>NCI US$m</td>
</tr>
<tr>
<td>EV US$m</td>
</tr>
<tr>
<td>NTA US$m</td>
</tr>
<tr>
<td>Licensing Revenue US$m</td>
</tr>
<tr>
<td>Revenue Multiple</td>
</tr>
<tr>
<td>Viceroy Valuation US$m</td>
</tr>
<tr>
<td>Viceroy Price Target US$</td>
</tr>
<tr>
<td>Downside %</td>
</tr>
<tr>
<td>* As at close of market - Oct 21, 2019</td>
</tr>
<tr>
<td>NB: LTM/balance from Jun 30, 2019</td>
</tr>
</tbody>
</table>