



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Poorly designed clinical study for flagship drug outdated since 2005.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 Our research, paired with discussions with industry specialists, leads us to believe **Oraxol is obsolete in modern world medicine**.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.*

Athenex, Inc.		
Exchange Ticker		NASDAQ ATNX
Shares Outstanding	m	77.3
Share Price*	US\$	9.60
Market Cap	US\$m	742.0
Net Cash	US\$m	78.7
NCI	US\$m	11.7
EV	US\$m	651.6
NTA	US\$m	131.6
Licensing Revenue	US\$m	87.2
Revenue Multiple	X	1.0
Viceroy Valuation	US\$m	218.8
Viceroy Price Target	US\$	2.83
Downside	%	-71%
* As at close of market - Oct 21, 2019		
NB: LTM/balance from Jun 30, 2019		

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**.



- **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.

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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

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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 trials¹ 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) therapies².

¹ Athenex's posters and papers can be found here <https://web.archive.org/web/20191015004538/https://www.athenexoncology.com/>

² https://web.archive.org/web/20191015004644/http://theoncologist.alphamedpress.org/content/7/suppl_6/13.full



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 albumin³ and paclitaxel to more effectively deliver paclitaxel to the cells.

unless clinically contraindicated).²¹ 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.²² 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).

Figure 1 Taxanes for the Treatment of Metastatic Breast Cancer⁴

This is likely the reason the trials were run in 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

<i>Fountzilas</i> [8]	Phase II	175 mg/m ² i.v., 3-h infusion Cycles repeated q 3 wk	33	42	Anthracycline resistant.
<i>Gianni</i> [18]	Phase II	175 or 225 mg/m ² i.v., 3-h infusion Cycles repeated q 3 wk	50	38	Up to two prior regimens, one adjuvant and one metastatic.
<i>Vici</i> [19]	Phase II	135 or 175 mg/m ² i.v., 3-h infusion Cycles repeated q 3 wk	41	22	Two to five prior therapies for advanced disease.

Figure 2 Paclitaxel in Breast Cancer⁵

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 neutropenia⁶ and grade 3 vomiting and one incidence of febrile neutropenia⁷.

³ <https://web.archive.org/web/20171109124458/http://www.breastcancer.org/research-news/taxol-better-than-ixempra-or-abraxane>

⁴ <https://web.archive.org/web/20191015004820/https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3486789/>

⁵ <https://web.archive.org/web/20191015004905/https://theoncologist.alphamedpress.org/content/3/6/373.full>

⁶ Defined as neutrophils <500 cells/mm³

⁷ 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_{max} regimens generally result in neuropathy: tingling and numbness of extremities which may or may not fade over time.
- Longer, lower C_{max} regimens generally result in neutropenia: a low neutrophil count (a type of white blood cell).

with 3-h infusion. More grade 3 and 4 neutropenia was reported in patients receiving the 24-h infusion, while peripheral neuropathy was more common in the 3-h schedule.

Figure 3 Paclitaxel in Breast Cancer

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"⁸

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.

incidence of alopecia, arthralgia and myalgia in the Oral Paclitaxel group. The incidence of neutropenia was similar in both groups, but there were more incidents of grade 4 neutropenia and infection in the Oral Paclitaxel group. There were also more gastro-intestinal side effects in the Oral Paclitaxel group.

Figure 4 Athenex Press Release dated August 7, 2019⁹

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 locations¹⁰.

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 US¹¹. 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.

⁸ https://web.archive.org/web/20191015005133/http://www.bccancer.bc.ca/nursing-site/Documents/11_Nausea_and_Vomiting.pdf

⁹ <https://web.archive.org/web/20191015005211/https://www.globenewswire.com/news-release/2019/08/07/1898167/0/en/Athenex-Announces-Oral-Paclitaxel-and-Encequidar-had-a-Significantly-Higher-Response-Rate-Over-IV-Paclitaxel-in-a-Phase-III-Pivotal-Study-in-Metastatic-Breast-Cancer.html>

¹⁰ <https://web.archive.org/web/20191015011552/https://www.statnews.com/pharmalot/2019/09/10/fda-inspections-china-india/>

¹¹ <https://web.archive.org/web/20191015011755/https://www.scientificamerican.com/article/most-experimental-drugs-are-tested-offshore-raising-concerns-about-data/>



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 (0 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 & Canada¹². 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 ANDA¹³. 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 Applications¹⁴

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 inhibitors¹⁵.

¹² https://web.archive.org/web/20191015011853/http://clinicaltrials.gov/ct2/show/study/NCT00844649?show_locs=Y

¹³ <https://web.archive.org/web/20191015011942/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/determining-whether-submit-anda-or-505b2-application>

¹⁴ <https://www.fda.gov/media/87621/download>

¹⁵ <https://web.archive.org/web/20191015012027/http://www.scielo.br/pdf/bjps/v48n3/a02v48n3.pdf>



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.

ZENRX LIMITED (4465400) Registered			
To maintain this company log on here			
View as Single Page Certificate of Incorporation Company Extract			
Company Summary	Addresses	Directors (3)	Shareholdings (3)
Company number:	4465400		
NZBN:	9429030200326		
Incorporation Date:	22 Jul 2013		

Figure 8 ZenRx company summary¹⁶

The important part of the above is ZenRx, which is partly held by Athenex’s now-Chief Medical Officer Rudolf Min-Fun Kwan¹⁷, 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.

Dr. Kwan has served as our Chief Medical Officer since 2014 and has advised our company since 2008. Until February 2017, Dr. Kwan was engaged on a consultant basis. Dr. Kwan has over twenty years of experience in the pharmaceutical industry in global clinical development and operations.

Figure 9 Athenex 2018 10-K

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.

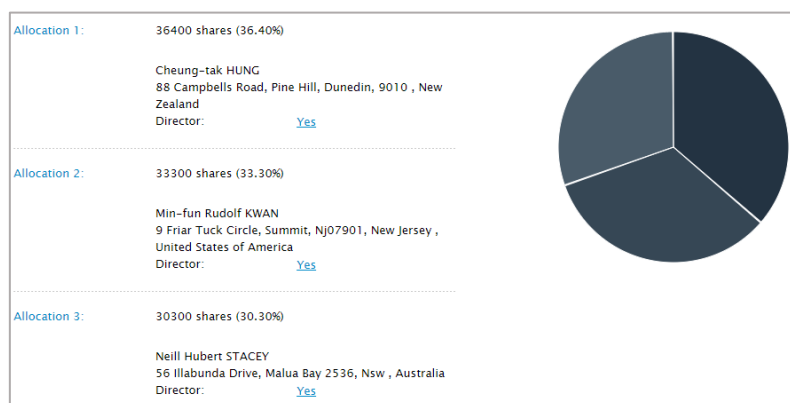


Figure 10 ZenRx shareholder list ¹⁸

¹⁶

<https://web.archive.org/web/20191018063309/https://app.companiesoffice.govt.nz/companies/app/ui/pages/companies/4465400?backurl=H4siAAAAAAAAEXLsQ7CMAXF0b%2FJWhgYLCQCAX2Q6NTNSgxEauJgu0D%2BniKC2O470usKXkk7z6lgjkspofjb9g4jZXk5yhatDrWQwq7v2z4b2qwH4bl8OWbPUvbCCVoPDA5DEFL9vxscqT5ZAjg1FIOVm2KKBuuN08uC4fN8YPYUTphpApOZXOJA8PM3KTrYZLcAAAA%3D>

¹⁷ <https://web.archive.org/web/20191015012418/https://www.prnewswire.com/news-releases/kinex-pharmaceuticals-and-zenith-technology-corporation-announce-the-execution-of-a-collaborative-licensing-agreement-206251411.html>

¹⁸

<https://web.archive.org/web/20191015012243/https://app.companiesoffice.govt.nz/companies/app/ui/pages/companies/4465400?backurl>



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.

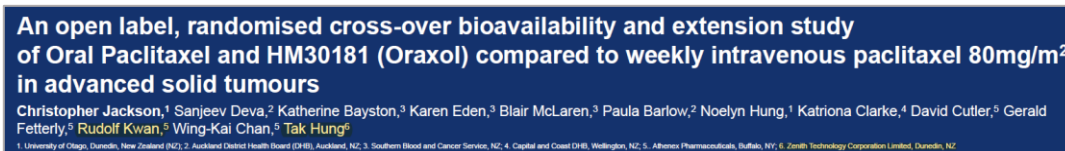


Figure 11 An open label, randomised cross-over bioavailability and extension study of Oral Paclitaxel and HM30181 (Oraxol) compared to weekly intravenous paclitaxel 80mg/m² in advanced solid tumours



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

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.

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Figures 13 & 14 ANZCTR ACTRN12615000881538¹⁹ & ACTRN12613000539730²⁰

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

=H4siAAAAAAAEXLsQ7CMAxFOb%2FJWhgYLcQCAX2Q6NTNSgxEauJgu0D%2BniKC2O470usKXkk7z6lgjkspofib9g4jZXk5yhatDrWQwq7v2z4b2qwH4bl8OWbPUVbCCVoPDA5DEFL9vxsqT5Zajg1FIOVm2KKBuN08uC4fN8YPYUtpApOZJOA8PM3KTryZLCAAAA%3D

¹⁹ <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=368755>

²⁰ <https://web.archive.org/web/20191015013014/https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=363832>



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 Limited²¹**, a contract research organization which had provided services for Athenex including its Phase 3 study for Oraxol in metastatic breast cancer.

CIDAL

On June 27, 2019, the Company entered into a definitive asset purchase agreement with CIDAL Limited (“CIDAL”), which was formed under the laws of the British Virgin Islands, a contract research organization with headquarters in Guatemala and operations in various countries in Latin America, whereby the Company will acquire certain assets and assume certain liabilities in exchange for approximately 45,000 shares of the Company’s common stock, subject to certain adjustments at closing, assumed liabilities, and milestone payments of up to an aggregate of 67,796 shares of our common stock upon the achievement of certain developmental and regulatory milestones through the third quarter of 2021. The

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 America²².

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 known²³. 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.

Hanmi Pharmaceutical succeeded in transforming the mixture of Paclitaxel and Indane derivatives into a water-soluble form. "In a laboratory animal testing with rats, the oral form of the agent was found to be highly effective," Yoo said. "Especially, there were not side effects or cancer cell tolerance discovered."

Hanmi Pharmaceutical will invest an additional 2 billion won and will have the oral form of the Paclitoxel, marketed as Oraxol, out by 2002.

Figure 17 Korea develops world's first cancer pill – The Dong-a-ilbo

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.

3. R&D Figures

Field	Candidates	Indication	Description / Indication	Status
	Oraxol™(Paclitaxel + HM-30181A)	Cancer	Oral Paclitaxel Copackaged drug of Paclitaxel and a novel PGP inhibitor (HM30181A)	Phase I

Figure 18 2007 Korea Pharmaceutical Industry Directory

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.

²⁴ <https://web.archive.org/web/20191015013404/http://www.donga.com/en/article/all/20000920/193348/1/Korea-develops-world-s-first-cancer-pill>

²⁵ <https://web.archive.org/web/20191015020831/https://pharmexcil.com/v1/docs/KoreanCompanies/hanmi.pdf>

²⁶ https://web.archive.org/web/20191015021213/http://www.pharmacist.or.kr/sites/default/files/wp-content/uploads/2007/05/Industry_Profile_2006.pdf

²⁷ [http://www.e-kippa.org/common_files/asp/down_load.asp?table=bbs_book&idx=15&fname=2008%203%B1%C71%C8%A3\(%C5%EB%B1%C74%C8%A3\).pdf&flag=1](http://www.e-kippa.org/common_files/asp/down_load.asp?table=bbs_book&idx=15&fname=2008%203%B1%C71%C8%A3(%C5%EB%B1%C74%C8%A3).pdf&flag=1)



Date	License Terms	Licence Consideration
December 2011	Grants exclusive sublicense for development, commercialization of products containing KX-01 in North America, South America, the European Union, Australia, New Zealand, Russia, Eastern Europe, Taiwan and Hong Kong.	US\$0.25 and tiered royalty payments in the teens based on net sales in those geographies.
November 2012	Amends December 2011 agreement to include Macau and Singapore	No consideration.
June 2013	Grants exclusive sublicense for development, commercialization of products containing KX-01 in China.	US\$100k and tiered royalty payments in the teens based on net sales in China.
October 2013	Amends December 2011 agreement to include Malaysia, Thailand, Vietnam, the Phillipines and Indonesia.	No consideration.
March 2015	Amends December 2011 agreement to include India.	US\$50k.
March 2017	Amends December 2011 agreement to include Japan.	US\$7m convertible bond, exercised September 2017.

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 2005-2007²⁸. 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.

Effective Date	Common Stock Equivalent Held	Market Value (USD in mm)	% Of CSO	Change in Shares	% Change	Share Price (USD)	Sale Value \$	Position Date
Latest	4,225,789	46.2	5.467	(185,818)	(4.21)	10.93	(2,030,991)	Apr-15-2019
Jun-30-2019	4,225,789	83.7	5.483	(185,818)	(4.21)	19.8	(3,679,196)	Apr-15-2019
Mar-31-2019	4,411,607	54.0	6.582	(120,053)	(2.65)	12.25	(1,470,649)	Mar-13-2019
Dec-31-2018	4,531,660	57.5	6.774	(1,000,000)	(18.08)	12.69	(12,690,000)	Nov-30-2018
Sep-30-2018	5,531,660	86.0	8.28	(496,248)	(8.23)	15.54	(7,711,694)	Aug-29-2018
Jun-30-2018	6,027,908	112.5	9.49	1,496,248	33.02	18.66	27,919,988	Jun-29-2018
Mar-31-2018	4,531,660	77.1	7.137	(2,744,035)	(37.72)	17.01	(46,676,035)	Mar-27-2018
Dec-31-2017	7,275,895	115.7	12.545	0	0	15.9	0	Sep-30-2017
Sep-30-2017	7,275,895	127.4	12.75	1	0.0	17.51	18	Sep-30-2017
Jun-30-2017	7,275,894	116.4	12.773	555,910	8.27	16.0	8,894,560	Jun-28-2017
Mar-31-2017	6,719,784	-	-	-	New	-	-	Mar-31-2017

Figure 19 Song-Yi Zhang insider transactions²⁹

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 funding³⁰. 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 debt³¹. The company had also failed to obtain permission to increase its timber production³². 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

³⁰ <https://web.archive.org/web/20191015013800/https://www.scmp.com/article/499454/plantation-firm-raises-us195m-debt-issue>

³¹ <https://web.archive.org/web/20191018063904/https://www.theglobeandmail.com/globe-investor/the-roots-of-the-sino-forest-mystery/article594111/>

³² <https://web.archive.org/web/20191015013932/https://www.wsj.com/articles/SB124380835787070229>

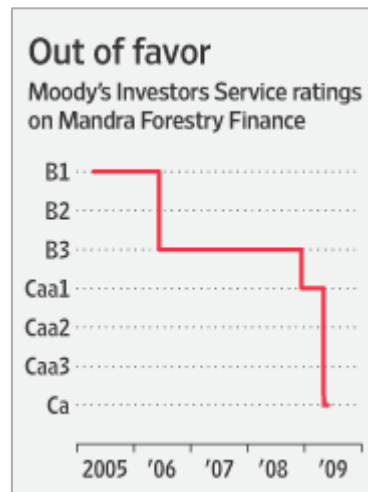


Figure 20 "After China Boom, Debt Risks Appear" – Wall Street Journal June 1, 2009

On July 6 2009, Mandra terminated two management agreements with Sino Forest, a move that the latter said it would dispute³³. 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 debt³⁴. 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 fantastical³⁵.

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".

³³ <https://web.archive.org/web/20191018064111/https://www.reuters.com/article/sinoforest-idUSBNG15697420090706>

³⁴ <https://www.newswire.ca/news-releases/sino-forest-completes-acquisition-of-mandra-forestry-539273481.html>

³⁵ <https://web.archive.org/web/20191018064310/https://www.reuters.com/article/suntech-bonds-fraud-idUSL4E8J309X20120806>



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.

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

Figure 21 William Zuo biography - Athenex³⁶

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 inspection³⁷. Form 483s are issued where violations of the Food Drug and Cosmetic Act and related Acts³⁸ 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.

Material Adverse Effect. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company and its subsidiaries (i) are, and at all times have been in material compliance with all statutes, rules and regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, storage, import, export or disposal of any product manufactured or distributed by the Company ("Applicable Laws"); and (ii) have not received any U.S. Food and Drug Administration ("FDA") Form 483, written notice of adverse finding, warning letter, untitled letter or other correspondence or written notice from any court or arbitrator or governmental or regulatory authority alleging or asserting non-compliance with (x) any Applicable Laws or (y) any licenses, exemptions, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws except in each case as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

Figure 22 Athenex Form S-1A dated June 2, 2017

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.

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. **same address/officers** as Polymed Therapeutics. Athenex acquired Polymed in June 2015, so why was this not disclosed?

Inovachem

Zuo was also the CEO of Inovachem, a shortlived 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.

³⁶ <https://web.archive.org/web/20191018065458/https://www.athenex.com/dt-team/william-zuo-phd/>

³⁷ <https://web.archive.org/web/20191020231912/https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2016/2/us-fda-inspections-in-china-an-analysis-of-form-483s-from-2015>

³⁸ <https://web.archive.org/web/20191015014155/https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions>



FORM 10-K
(Mark One)

☒ ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended September 30, 2008

or

☐ TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____
Commission file number 000-52865

INOVACHEM, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

c/o Polymed Therapeutics, Inc.
3040 Post Oak Boulevard, Suite 1110
Houston, TX
(Address of principal executive offices)

36-1946130
(I.R.S. Employment Identification No.)

77056
(Zip Code)

(713) 777-7088
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of Act:

Figure Inovachem Form 10-K 2008

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.

	For Year Ended September 30, 2009	For Period from (inception) to September 30, 2008	Cumulative For Period from February 14, 2008 (inception) to September 30, 2009
Revenues	\$ -	\$ -	\$ -
Operating expenses			
Compensation	433,572	502,210	935,782
Professional fees	16,987	101,652	118,639
Impairment expense	-	45,944	45,944
Travel expenses	89,684	30,805	120,489
Other general and administrative expenses	23,279	20,421	43,700
Total operating expenses	563,522	701,032	1,264,554

Figure 23 Inovachem 2009 10-K

The licenses and goods that Inovachem purchased from Polymed? 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

Figure 24 Athenex Notice of Annual Meeting and Proxy Statement³⁹

³⁹ <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 filings⁴⁰.

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

Figure 25 DemeRx Chapter 11 filings

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.













 AVALON GENOMICS Avalon Genomics (HK) Limited Big data genomics analysis and consultation services; digital healthcare Visit	 AVALON NANOFIBER Avalon Nanofiber Limited Development of consumer healthcare products using nano-fiber technology Visit	 AVALON PHOTONICS Avalon Photonics (HK) Limited LED-based phototherapy for neonatal jaundice and dermatological diseases Visit
 Avalon SpineCare Avalon SpineCare (HK) Limited Visit	 EMV Enhance EMV Enhance (HK) Limited Visit	 AVALON HepaPOC Avalon HepaPOC Limited Point of Care diagnostic solution for hepatological diseases Visit
 Avalon POLYTOM Avalon Polytom (HK) Limited Biologics drug development using proprietary arginine-based technology Visit	 EMERGING VIRAL Emerging Viral Diagnostics (HK) Limited Point of Care rapid diagnostic solution for viral and bacterial diseases Visit	 NANSHA BIOLOGICS Nansha Biologics (Hong Kong) Limited Biologics drug development for chemotherapy induced thrombocytopenia Visit
 OrthoPoly OrthoPoly (HK) Limited Visit	 OrthoSmart OrthoSmart Limited Development of range of orthopedic medical devices Visit	 Avalon PolyMills Avalon PolyMills (HK) Limited Visit

Figure 26 Avalon Biomedical – Companies⁴¹

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.

⁴⁰ <https://www.docketbird.com/court-documents/DemeRx-Inc/Chapter-11-Small-Business-Plan-of-Reorganization-and-Combined-Disclosure-Statement-Filed-by-Debtor-DemeRx-Inc/flsb-1:2018-bk-14149-00073>

⁴¹ <https://web.archive.org/web/20191018070017/http://www.avalonbiomedical.com/>



subsidiary of Avalon Global Holdings Limited ("Avalon Global"). 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.

Dr. Fok, together with his spouse, owns all of the outstanding interests in Sino Glory Developments Limited, which owns 30% of the outstanding interests in Avalon Global, and Dr. Fok serves on the board of directors of Avalon Global and shares voting and dispositive power with respect to the shares held by Avalon Biomedical.

is the sole owner and director of iBase Ltd. and has sole voting and dispositive power over the shares held by iBase Ltd. 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.

Figure 27 Athenex Form S-1

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 28 shows the 'NAR1' form for Avalon Biomedical (Management) Limited. The company name is 'Avalon Biomedical (Management) Limited' and the company number is '1689544'. The director is 'Johnson Yiu-Nam Lau' with the company number '1689544'. The form also includes fields for the director's capacity, name in Chinese, name in English, and residential address.

Figure 28 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 29 shows the 'NAR1' form for Avalon Biomedical (Management) Limited, listing three directors. The first director is 'Yiu Nam Lau' with the company number '1689544'. The second director is 'Creative Decade Global Limited' with the company number '1689544'. The third director is 'Sino Glory Developments Limited' with the company number '1689544'. The form also includes fields for the director's capacity, name in Chinese, name in English, and residential address.

Figure 29 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>



Passed on 17/02/2015

By a WRITTEN RESOLUTION signed by all the Members of the company, the following Resolution was duly passed:-

TRANSFER(S) OF SHARE(S)

It was resolved that the following transfer(s) of share(s) be approved:-

<u>Transferor</u>	<u>Transferee</u>	<u>No. of Share(s) to be transferred</u>
CREATIVE DECADE GLOBAL LIMITED	Avalon BioMedical Holdings Limited	5,000
中嘉發展有限公司 SINO GLORY DEVELOPMENTS LIMITED	Avalon BioMedical Holdings Limited	5,000

Figure 30 Avalon Biomedical (Management) Limited resolution dated February 17, 2015

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.

We made an upfront payment of cash of \$3.0 million and common stock of \$2.0 million to Polytom upon effectiveness of the Arginase License, and we were required to make payments to Polytom worth up to \$45.0 million of our common stock or of cash upon the occurrence of certain regulatory and sales milestones. We have also agreed to pay royalty payments ranging from 10% to 12% based on net sales of any products utilizing the intellectual property that is the subject of the Arginase License. Such royalties will be reduced by 40% when competing generic products have 25% of the market share in the applicable country and will be eliminated entirely when competing generic products have 50% of the market share in the applicable country.

Figure 31 Athenex 2018 10-K⁴⁴

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 License⁴⁵. An attached photo shows the amount to be HKD1.17m (US\$0.150m)



Figure 32 Avalon Polytom presents cheque to Hong Kong Polytechnic University⁴⁶

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.

⁴⁴ <https://www.sec.gov/Archives/edgar/data/1300699/000119312518211357/d653771dex104.htm>

⁴⁵ <https://web.archive.org/web/20191015014345/https://www.polyu.edu.hk/itdo/text/tc/highlights.php?hlight=4943>

⁴⁶ <https://web.archive.org/web/20191015014438/https://www.polyu.edu.hk/itdo/tc/gallery.php?gallery=4458&page=3>



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, 2018⁴⁷

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.

risk of loss, all Nonconforming Goods to Avalon's designated facility located at No. 7, Li-Hsin 5th Rd. Hsinchu Science Park, Hsinchu City 30078, Taiwan or to such other location as Avalon may instruct Athenex in writing. If Avalon exercises its option to replace Nonconforming Goods, Avalon shall ship to the Delivery Location, at Avalon's expense and risk of loss, the replacement Goods.

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.

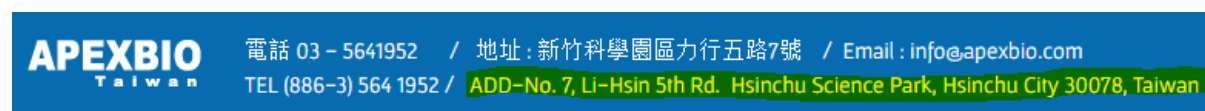


Figure 34 ApexBio Taiwan contact details⁴⁸

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>

⁴⁸ <https://web.archive.org/web/20191015014617/https://www.apexbio.com/Web/Products/>



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.

NSC1 Form

公司名稱 Company Name: 全球藥物科技有限公司 COMPREHENSIVE DRUG ENTERPRISES LIMITED

2 配發股份的日期 Date of Allotment: 01 06 2015

3 是次股份配發的總款額 Totals of this Allotment: 14,450,675.64

4 配發股份的詳情 Details of Shares Allotted

股份類別 (如普通股/優先股等) Class of Shares (e.g. Ordinary/Preference etc.)	貨幣單位 Currency	所配發的股份數目 Number of Shares Allotted	已繳或視作已繳每一股份應付的款額 Amount Paid or Regarded as Paid on Each Share	未繳或視作未繳每一股份應付的款額 Amount Unpaid or Regarded as Unpaid on Each Share
ORDINARY	HKD	8,304,986	1.74	0.00

8m shares at 1.74 HKD each (0.2262 USD each)

5 獲配股份者的詳情 Details of Allottee(s)

姓名/名稱 Name	地址 Address	獲配股份數目 No. of Shares Allotted
AWALON BIOMEDICAL (MANAGEMENT) LIMITED	10/F, Fung House, 19-20 Connaught Road Central, Hong Kong	4,526,540
Flint D BESECKER	26 Edwoud Court, Orchard Park, NY 14127 USA	707,989
James H ZUKIN	Houlihan Lockey, 10250 Constellation Blvd, Los Angeles, CA 90067 USA	1,014,961
劉子興 LAU Yu Hing Stephen	25 Ching Sau Lane, Chung Hom Kok, Hong Kong	739,918
李耀廷 LEE Benjamin Tak Kwong	Fat 6A, University Residence 14, The Chinese University of Hong Kong, Shatin, N.T., Hong Kong	172,414
梁若愚 LEUNG Yauk Chuen	3/F, Culturecome Center, 47 Hung To Road, Kwun Tong, Kowloon, Hong Kong	695,856
Mark YONG	68 The Baron, Chiant, Discovery Bay, Hong Kong	335,239
Rudolf KWAN	2/F Hing Ying Mansion, 42 Bonham Road, Mid-Level West, Hong Kong	112,069

6 股本說明 (以股份配發的日期為準) Statement of Capital (As at the Date of the Allotment of Shares)

A. 股本 Share Capital

股份類別 (如普通股/優先股等) Class of Shares (e.g. Ordinary/Preference etc.)	貨幣單位 Currency	已發行股份 Issued Shares			
		總數 Total Number	總款額 Total Amount (a)	已繳或視作已繳的總款額 Total Amount Paid up or Regarded as Paid up (b)	未繳或視作未繳的總款額 Total Amount Unpaid or Regarded as Unpaid (c) - (b)
ORDINARY	HKD	18,089,547	34,869,718.20	34,869,718.20	0.00

Figure 37 Share issue documents

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 pocked 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.**



Date to which this Return is Made Up
21 09 2016
日 DD 月 MM 年 YYYY

公司編號 Company Number
996965

非上市公司的成員詳情 (第 13 項)
Particulars of Member(s) of a Non-listed Company (Section 13)
(非股本的上市公司必須填報此頁。如空間不足，或超過一類股份，可另加附表。)
(Non-listed company having a share capital must complete this page. If the space provided is insufficient, or if there is more than one class of shares, please use additional Schedule 13.)
截至本申報表的結算日期的成員詳情 Particulars of Member(s) as at the Date to which this Return is Made Up

股份類別 Class of Shares: ORDINARY

此類別股份的已發行總數 Total Number of Issued Shares in this Class: 18,089,547

姓名 / 名稱 Name	地址 Address	現時持有量 Current Holding	轉讓 * Transferred *		備註 Remarks
			數目 Number	日期 Date	
Athenex API Limited (Formerly KINEX POLYMED LIMITED)	18th Floor, Edinburgh Tower, the Landmark, 15 Queen's Road, Central, Hong Kong	18,089,547			Name changed

Figure 38 Athenex acquires all outstanding shares of Comprehensive Drug Enterprises

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.

LEE TAK KWONG BENJAMIN
(DIRECTOR)

SPECIAL RESOLUTION
OF
COMPREHENSIVE DRUG ENTERPRISES LIMITED
Passed on the 10 day of July 2014

It was noted that a draft repurchase agreement (the "Repurchase Agreement") had been circulated to all members of the Company for consideration.

By a written resolution signed by all the Members of the Company pursuant to the Article 24 of the Articles of Association of the Company, the following Special Resolution was duly passed:

1. "That Repurchase of Shares by the Company of all the shares held by Kan Shiu Cheong Frederick, Lun Wilson Wai Shing, Chow Moses Sing Suni and Fortune Express Global Limited at the purchase price calculated as follows be approved:-

Name of Vendor	Acquisition Price of Existing Shares x 1.28 = Purchase Price
Frederick Kan	HK\$681,250 x 1.28 = HK\$872,000.00
Wilson Lun	HK\$681,250 x 1.28 = HK\$872,000.00
Moses Chow	HK\$452,378 x 1.28 = HK\$579,043.84
Fortune Express	HK\$136,875 x 1.28 = HK\$175,200.00

Figure 39 Avalon Biomedical (Management) Limited resolution dated July 10, 2014

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.

股份類別 Class of Shares		ORDINARY			
此類別股份的已發行總數 Total Number of Issued Shares in this Class		18,089,547			
姓名 / 名稱 Name	地址 Address	現時持有量 Current Holding	轉讓 * Transferred *		備註 Remarks
			數目 Number	日期 Date	
冠龍生物醫藥科技(管理)有限公司 AVALON BIOMEDICAL (MANAGEMENT) LIMITED	10/F, Fung House, 19-20 Connaught Road Central, Hong Kong	7,320,092			Allotted 4,526,540 shares on 01-Jun-2015
崔文通 FOK Manson	Pedder Clinic, 4th Floor, 9 Queen's Road Central, Central Hong Kong	0	1,584,000	19 Dec, 2014	To: AVALON BIOMEDICAL (MANAGEMENT) LIMITED
Flint D BESECKER	26 Edswood Court, Orchard Park, NY 14127, USA	1,415,978			Allotted 707,989 shares on 01-Jun-2015
James H. ZUKIN	Houlihan Lockey, 10250 Constellation Blvd, 5th Floor, Los Angeles, CA 90067 USA	2,029,922			Allotted 1,014,961 shares on 01-Jun-2015

Figure 40 CDE share ownership



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.

including Dr. Lau, Mr. Fok, Mr. Zhang and Dr. Kwan, had a financial interest in CDE. In addition, Dr. Lau and Mr. Fok served as directors of CDE. Consequently, our board of directors established a special committee of disinterested directors with authority to review, evaluate, negotiate, and approve or reject the terms and conditions of the transaction and to retain its own financial and legal advisors to assist in connection therewith. Following negotiation of the transaction between the committee and its advisors and representatives of CDE, the special committee determined that the proposed terms of the transaction were fair to us from a financial point of view and approved our entry into the definitive agreements and consummation of the transactions contemplated thereby.

Figure 41 Athenex Form S-1

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)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 US⁵⁰.

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)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>

⁵¹ <https://web.archive.org/web/20191018071156/https://ir.athenex.com/news-releases/news-release-details/athenex-announces-xiangxue-life-sciences-receives-ind-allowance>



March 21, 2019

Athenex Announces Xiangxue Life Sciences Receives IND Allowance from China's National Medical Products Administration for Cancer Immunotherapy Drug Candidate

This company-sponsored IND allows Xiangxue Life Sciences (XLifeSc) to proceed to the next stage of clinical studies in China

Encouraging positive clinical safety and efficacy signals were observed in preliminary investigator-initiated pilot studies in China

Athenex is XLifeSc's partner (ex-China) for cancer immunotherapy development and global development of this technology is being conducted through Axis Therapeutics Limited, a joint venture between Athenex and XLifeSc

Figure 42 Athenex Announces Xiangxue Life Sciences Receives IND Allowance

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.



work experience

2012.10 - present

Researcher (part-time) National Key Laboratory of Respiratory Diseases, Guangzhou Medical College / Chinese Academy of Sciences Guangzhou Institute of Biomedicine and Health; President of Health Institute / **Xianxue Pharmaceutical Joint Lab, Guangzhou**

2011.12 - present

Researcher (**Specially Appointed Expert of the National Thousand Talents Program, Leading Talent in Guangdong Province**), Guangzhou Institute of Biomedicine and Health, Chinese Academy of Sciences, Guangzhou

2011.01 — 2011.11

Director, Protein Technology, Immunocore Ltd., Oxford, UK

Figure 43 Dr Yi Li profile (translated)⁵²

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 Adaptimmune^{54,55}.

⁵² <https://web.archive.org/web/20191018071440/http://peopleucas.edu.cn/~45566>

⁵³ <https://web.archive.org/web/20191018071547/https://sanfrancisco.cbslocal.com/2019/10/06/fbi-warns-us-colleges-china-theft/>

⁵⁴ <https://patents.justia.com/assignee/adaptimmune-limited>

⁵⁵ <https://patents.justia.com/assignee/immunocore-limited>



Katy Adams, Rebecca Ashfield, Emma Baston, Edward Beaumont, Alan Bennett, Frayne Bianchi, Giovanna Bossi, Jo Brewer, Brian Cameron, Rebecca Dennis, Martin Ebner, Jessie Gavarret, Andrew Gerry, Jane Harper, Namir Hassan, Andy Johnson, **Yi Li**, Nat Liddy, Nikolai Lissin, Tara Mahon, Yvonne McGrath, Peter Molloy, Sam Paston, Nick Pumphrey, Malkit Sami, Deborah Sutton, Penio Todorov, Annelise Vuidepot, Dan Williams, Fang Yuan

Figures 44 Immunocore team photo dated 2009

High affinity NY-ESO T cell receptor

Patent number: 8143376

Abstract: The present invention provides T cell receptors (TCRs) having the property of binding to SLLMWITQC-HLA-A*0201, the SLLMWITQC (SEQ ID NO:126) peptide being derived from the NY-ESO-1 protein which is expressed by a range of tumour cells. The TCRs have a KD for the said peptide-HLA complex of less than or equal to 1 μ M and/or have an off-rate (koff) of 1×10^{-3} S⁻¹ or slower.

Type: Grant

Filed: May 18, 2005

Date of Patent: March 27, 2012

Assignee: Immunocore Limited

Inventors: Jonathan Michael Boulter, Lucy Boulter, legal representative, Bent Karsten Jakobsen, **Yi Li**, Peter Eamon Molloy, Steven Mark Dunn

Figure 45 Immunocore patent list⁵⁶

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 2005⁵⁷, 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 I / II clinical 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 (**the same high-affinity anti-NY-ESO-1-specific TCR was developed by Dr. Li Yi in 2005 using phage display technology**). Moreover, there were no serious side effects.

Figure 46 XLifeSc Phase 1 application

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.

⁵⁶ <https://web.archive.org/web/20191018071738/https://sitc.sitcancer.org/meetings/am09/presentations/fri/Jakobsen.pdf>

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.

广东普雷精准医疗技术有限公司

电话: 020-22211419 查看详情 修改电话 邮箱: ***@xphcn.com 查看详情
地址: 广州市黄埔区科学城金坑路2号 (南岗第1栋) 附近公司
简介: 本公司致力于研发具有自主知识产权的一类新药用于肿瘤治疗, 具有自主知识产权及临床验证, 同时开发针对肿瘤的个性化治疗药物...

企业认证

展示认证标识
提升企业评分
编辑联系方式
获取认证证书

立即认证

天眼查小程序
无需下载 查询更便捷

同地区同行业公司

广州普雷精准医疗技术有限公司
法定代表人: 王强
注册资本: 1000万人民币
成立日期: 2015-11-12
统一社会信用代码: 91440101MA59AP314X
纳税人识别号: 91440101MA59AP314X
公司类型: 其他有限责任公司
核准日期: 2017-11-03
营业期限: 2015-11-12至无固定期限
人员规模: -
曾用名: -

实缴资本: 17550万人民币
经营状态: 在业
工商注册号: 440101000386580
组织机构代码: MA59AP314
行业: 研究和试验发展
登记机关: 广州市黄埔区市场监督管理局
纳税人资质: -
参保人数: -
英文名称: -



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 Pedder⁵⁸ 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.

<p>3. J. Nick Riehle</p> <p>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</p> <p>a. During the Class Period, Riehle participated in the issuance of false and misleading statements and failed to disclose the known adverse, undisclosed information concerning the safety, efficacy and trial design of droxidopa for patients with NOH in Chelsea's clinical trials. As detailed below, Riehle publicly communicated with investors and the market 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,</p>
--

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!

⁵⁸ <https://www.prnewswire.com/news-releases/athenex-announces-the-addition-of-simon-pedder-phd-and-raymond-yeung-msc-mba-to-its-global-leadership-team-300217379.html>



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 family⁵⁹; 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 date⁶⁰.

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.

Athenex, Inc.		
Exchange		NASDAQ
Ticker		ATNX
Shares Outstanding	m	77.3
Share Price*	US\$	9.60
Market Cap	US\$m	742.0
Net Cash	US\$m	78.7
NCI	US\$m	11.7
EV	US\$m	651.6
NTA	US\$m	131.6
Licensing Revenue	US\$m	87.2
Revenue Multiple	X	1.0
Viceroy Valuation	US\$m	218.8
Viceroy Price Target	US\$	2.83
Downside	%	-71%
* As at close of market - Oct 21, 2019		
NB: LTM/balance from Jun 30, 2019		

⁵⁹ <https://web.archive.org/web/20191018070429/https://www.globenewswire.com/news-release/2017/12/01/1216169/0/en/Athenex-Announces-Planned-Retirement-of-Chief-Financial-Officer-Nick-Riehle.html>

⁶⁰ <https://web.archive.org/web/20191018070549/https://ir.riehle.com/>