



Athenex – Rehash



Athenex recycle press releases to pump investors. Viceroy release details of further conflicts with Athenex CROs.

October 28, 2019 – This report will continue to touch on major Athenex conflict of interest issues.

- In another slap to the face for investors, Athenex, instead of addressing any of the major issues Viceroy have put forward, have chosen to instead **re-publish a press release from March 4, 2019, marketing the results of topical medication with their project partner, Almirall.**
- In case the connections to fraud were not already apparent, **Almirall has recently settled both a \$3.5m Department of Justice and \$3.1m California Department of Insurance claims relating to kickbacks and bribery** of physicians for the promotion of their product. Athenex aim to use Almirall for their vast sales network.
- Viceroy today release data showing PharmaEssentia, Athenex CRO, is also a related party. To recap, **all three major Athenex CROs have an interest in the approval and ongoing success of the products they are conducting the trials for,** as we have previously reported on CIDAL and ZenRx.
- Athenex CEO Johnson Yiu Nam Lau is a busy man, **moonlighting at yet another anti-cancer company, Taiwanese company Taivex Therapeutics.** Investors should be asking what Athenex's Chief Executive Officer is doing at another anti-cancer biotechnology company, especially if he finds the time to be credited in numerous academic papers sponsored by that company, and what possible conflicts of interest may have arisen.

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.*

Viceroy remain short Athenex.

A link to Viceroy's previous reports are as follows:

Report 1:

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

Report 2:

<https://viceroyresearch.org/2019/10/23/athenex-where-theres-smoke/>

Report 3:

<https://viceroyresearch.org/2019/10/24/athenex-no-integrity/>

Report 4:

<https://viceroyresearch.org/2019/10/25/athenex-bonus-round/>



1. Athenex moves into recycling

On October 28, 2019 Athenex released a press release titled: “Athenex Announces Progress Update from Partner Almirall on Tirbanibulin Ointment”¹

Athenex Announces Progress Update from Partner Almirall on Tirbanibulin Ointment

BUFFALO, N.Y., Oct. 28, 2019 (GLOBE NEWSWIRE) – Athenex, Inc. (Nasdaq: ATNX), a global biopharmaceutical company dedicated to the discovery, development and commercialization of novel therapies for the treatment of cancer and related conditions, today announced a progress update from partner Almirall on tirbanibulin ointment (also known as ALM14789, formerly known as KX-01 or KX2-391) for the treatment of actinic keratosis (AK).

Figure XX Athenex Announces Progress Update from Partner Almirall on Tirbanibulin Ointment

This is a complete rehash of a release dated March 4, 2019 relating to a March 2, 2019 presentation². There is no new information about the clinical trial, nor have new results come to light. The only new content on this press release is the quote by Athenex Chief Medical Officer Rudolf Kwan who is either 7 months late to the party, or putting on a brave face.

We must question the motives of rehashing a positive press release in the context of Viceroy’s publication of its research into Athenex. As with Ebix, we believe this type of misleading announcements constitutes stock promotion and serves to stray away from addressing any major issues we have highlighted.

In their defense, it may be difficult to refute allegations of related party transactions given the fact management have continuously disclosed that the company frequently engages in transactions that are not at arms’-length.

We may have conflicts of interest with our affiliates and related parties, and in the past we have engaged in transactions and entered into agreements with affiliates that were not negotiated at arms’ length.

Figure XX Extract – ATNX 10Q – Q2 2019

It will be curious to see Athenex’s auditors first ever internal control attestation report at the end of 2019, as the company falls from exemption under emerging growth company.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, we are not required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm until we issue financial statements for the year ending December 31, 2019 because we are an emerging growth company. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. We have limited experience complying with Section 404, and such compliance may require that we incur substantial accounting expenses and expend significant management efforts. Our testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. In the event we identify significant deficiencies or material weaknesses in our internal controls that we cannot remediate in a timely manner, the market price of our shares could decline if investors and others lose confidence in the reliability of our financial statements, we could be subject to investigation by the SEC or other applicable regulatory authorities and our business could be harmed.

Figure XX Extract – ATNX 10Q – Q2 2019

In case the connections to fraud were not already apparent, **Almirall has recently settled a \$3.5m Department of Justice and \$3.1m California Department of Insurance claims relating to kickbacks and bribery of physicians for the promotion of their product. Athenex aim to use Almirall for their vast sales network**³.

¹ <https://web.archive.org/web/20191028084356/https://ir.athenex.com/news-releases/news-release-details/athenex-announces-progress-update-partner-almirall-tirbanibulin>

² <https://www.biospace.com/article/releases/almirall-and-athenex-announce-positive-topline-results-from-two-phase-iii-studies-of-kx2-391-ointment-1-percent-featured-in-late-breaker-program-at-the-2019-american-academy-of-dermatology-annual-meeting/>

³ <https://www.fiercepharma.com/pharma/doj-secures-yet-another-pharma-kickbacks-settlement-time-from-almirall>



2. Taivex

Athenex CEO Johnson Yiu Nam Lau is a busy man: especially given he is moonlighting at yet another anti-cancer company, Taiwanese company Taivex Therapeutics (泰緯生命科技股份有限公司). Taivex's management page states its original investor be Taivex, LLC, a company launched by Lau in 2010.

History

Taivex Therapeutics Corporation (TTC), founded in 2010, is focus on the development of "Novel", "Niche" and "Targeting" anti-cancer drugs. We are original invested by Taivex, LLC in California which is launched by Dr. Johnson Y.N. Lau. The core proprietary technology platform of Taivex is to identify compounds that inhibit the Hec1-Nek2 interaction which is authorized by Univ. Texas, San Antonio. After combination with the two key techniques: "Methods and Compounds for inhibiting HEC1 for the Treatment of Proliferative Diseases" and "Methods and Compounds for inhibiting Rad51 for the Treatment of Proliferative Diseases", TTC will work on the development of new anti-cancer drugs in Taiwan. The company is also led by the experienced management team and looks forward the success in new drug development.

Figure XX Taivex.com History⁴

Taivex acquired all its anticancer patents during Lau's tenure at Athenex, raising questions as to why he didn't simply bring them into the Athenex umbrella⁵. Of course, he could have been planning to resell them to the company for a profit, if history is any guide.

Taivex is still active, in April 17, 2019 Taiwan's National Health Research Institutes entered into a licensing agreement for DBPR216, an anti-cancer developmental drug candidate⁶. We are unable to ascertain if this undisclosed activity is in breach of Lau's employment agreement without more information on DBPR216 and Taivex's other formulations.

6. Non-Competition.

(a) Field of Interest. Executive recognizes and acknowledges the competitive and proprietary nature of the Corporation's business operations. Executive acknowledges and agrees that a business will be deemed competitive with the Corporation if it provides products or services related to the current or proposed products or services, or information now or hereafter provided or offered by the Corporation or under development by the Corporation that are in the Corporation's "Field of Interest." For purpose of clarity, the Corporation's Field of Interest is the discovery, development, commercialization and marketing of therapeutics (i) based on kinase inhibitors discovered through Mimetica and OPAL, (ii) pre-tubulin polymerization inhibitors, small molecules against OraA1, or (iv) P-glycoprotein inhibitors based on HM30181A for enhanced oral absorption.

We are unable to ascertain if this undisclosed activity is in breach of Lau's employment agreement without more information on DBPR216 and Taivex's other formulations.

Investors should be asking what Athenex's Chief Executive Officer is doing at another anti-cancer biotechnology company, especially if he finds the time to be credited in numerous academic papers sponsored by that company.

3. PharmaEssentia

Our previous research has shown how Athenex's Contract Research Organisations (CROs) ZenRx and CIDAL are conflicted with incentives to produce favorable clinical trial results. Another CRO is similarly conflicted, Taiwanese operator PharmaEssentia⁷ (TWSE:6446). PharmaEssentia is conducting clinical trials for several of Athenex's products including Oraxol for breast cancer, Oraxol + Ramucirumab for Gastric Cancer and KX-01 for psoriasis.

There are several ties between PharmaEssentia and Athenex

- Athenex owns a 68,000 share equity stake in PharmaEssentia worth ~US\$250,000 likely received as part of certain regulatory and milestone payments
- Athenex receives consulting and cost-sharing funds from PharmaEssentia (include relevant amount)
- PharmaEssentia holds the exclusive license for development and commercialization of Oraxol and Oratecan in Taiwan, Vietnam and Singapore.

⁴ <https://web.archive.org/web/20191028094544/http://www.taivex.com/en/board.html>

⁵ <https://web.archive.org/web/20191028094355/http://taivex.com/en/news.html>

⁶ <http://enews.nhri.org.tw/en/?p=765>

⁷ <http://www.pharmaessentia.com/>



- PharmaEssentia holds the exclusive license for KX-01 and KX-02 for treating psoriasis and other non-malignant skin conditions in China, Taiwan, Macau, Hong Kong, Singapore and Malaysia.

To recap, **all three major Athenex CROs have an interest in the approval and ongoing success of the products they are conducting the trials for.** We are currently investigating Athenex’s clinical trial relationships and will keep the market informed of our research as and when it becomes relevant.

However even the CRO’s appear to be getting screwed by the many stumbling blocks in Oraxol’s development.

We previously discussed how Hanmi Pharmeceutical, after a decade of almost no progress on the Orascovary platform, handballed it to Athenex for US\$7.5m upfront. It appears like Athenex is now doing the same to its Contract Research Organisation, PharmaEssentia.

Concentration	PharmaEssentia Technology	Target	Market	Pipeline Status			
				Phase I	Phase II	Phase III	Approved
Hematology	P1101	PV	EU	2019年2月獲歐盟核准			
		PV	US, JP, CN, KR, TW	[Progress bar]			
		ET	Global	[Progress bar]			
		CML*	EU	[Progress bar]			
		PMF*	US	[Progress bar]			
Infectious Disease	P1101	HCV-G2	TW, KR, CN	[Progress bar]			
		*HBV e+	TW, KR, CN, VN, TH	[Progress bar]			
		*HBV e+ add on	Global	[Progress bar]			
		*Precision Medicine(anti-HBc)	Global	[Progress bar]			
Oncology	Oraxol	Breast	TW, SG, VN	[Progress bar]			
	Oraxol+Ramucirumab	Gastric	TW	[Progress bar]			
	PD-1/P1101 **ITT Trial	**HCC	Global	[Progress bar]			
Dermatology	KX01	Psoriasis	TW	[Progress bar]			

Figure XX PharmaEssentia presentation⁸

PharmaEssentia originally had grand plans for Oraxol: PharmaEssentia CEO Ko-Chung Lin believed that Oraxol, Oratecan and KX-01 would be available for sale “within two or three years”.

Dr. Ko-Chung Lin, Chief Executive Officer of Yaohua Pharmaceutical, said: "Based on existing treatment options, we believe that Kinex's compounds can bring unique benefits to the global healthcare system, which of course includes Taiwan and Singapore. Importantly, We believe that these late products will be available for sale within two or three years. Obviously, patients and doctors need extra choices when treating challenging diseases like cancer. Yaohua Medicine is very happy as Kinex, Hanmi (Hanmi)) and part of the ZenRx team to help create these new choices."

Figure XX

⁸ http://www.pharmaessentia.com/uploads/images/6446_20190514_法說會簡報.pdf



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.

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Annexure A

We believe it is fitting that we reiterate our previous summaries, and stand behind our work in its entirety, given management have decided not to address our data in specifics:

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



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.