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Quoin Pharmaceuticals (QNRX-NASDAQ)

QNRX: Several Recent Milestones - Cash Runway Extended into '27, Orphan Drug Designation Received, Positive Interim Data

QNRX has attained several milestones recently, including extending its cash runway into 2027, attaining Orphan Drug Designation for QRX003 in Netherton Syndrome in the US & EU as it generates positive data from the ongoing studies it is conducting, streamlining the product pipeline and hiring a new CFO to support expected upcoming commercialization activities.

Current Price (11/18/25) \$19.24
Valuation \$27

OUTLOOK

The FDA recently granted QRX003 Orphan Drug Designation for the treatment of NS. The European Medicines Agency had granted Orphan Drug Designation to QRX003 earlier. The company believes these designations reinforce the potential of QRX003 as a therapeutic candidate and could shorten the time to potentially attain regulatory approval & accelerate the timeline to market and commercial prospects. Moreover, with the company advancing its investigator led pediatric NS study and advancing other assets, including Rapamycin, QNRX is expanding its potential opportunities, we believe.

SUMMARY DATA

52-Week High \$48.30
52-Week Low \$5.01
One-Year Return (%) -12
Beta 1.96
Average Daily Volume (sh) 617,770

ADSs Outstanding (mil)* 0.6
Market Capitalization (\$mil) 15
Short Interest Ratio (days) N/A
Institutional Ownership (%) 7
Insider Ownership (%) 31

Annual Cash Dividend \$0.00
Dividend Yield (%) 0.00

5-Yr. Historical Growth Rates
Sales (%) N/A
Earnings Per Share (%) N/A
Dividend (%) N/A

P/E using TTM EPS N/A
P/E using 2025 Estimate N/A
P/E using 2026 Estimate N/A

Risk Level High,
Type of Stock N/A
Industry Med-Drugs

ZACKS ESTIMATES

Revenue (in millions of \$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	0 A	0 A	0 A	0 A	0 A
2023	0 A	0 A	0 A	0 A	0 A
2024	0 A	0 A	0 A	0 A	0 A
2025	0 A	0 A	0 A	0 E	0 E

Loss / Earnings per ADS*

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022					-\$70A
2023	-\$4.09 A	-\$2.13 A	-\$1.95 A	-\$2.08 A	-\$9.64A
2024	-\$38.73 A	-\$13.68A	-\$16.29A	-\$15.29A	-\$72.22A
2025	-\$6.50 A	-\$6.28 A	-\$6.71 A	-\$6.42 E	-\$25.92E

Quarters might not sum due to rounding & share counts

Disclosures on page 11

*23 Not PF

QRX003 DESIGNATIONS POTENTIALLY ACCELERATE TIMELINE TO MARKET

Quoin Pharmaceuticals (QNRX-NASDAQ), a clinical stage, specialty pharmaceutical company focused on developing treatments for rare and orphan diseases, has extended its cash runway into 2027 from 2026 earlier, generated positive data from ongoing studies, streamlined its product pipeline to focus on assets it believes have greatest near- to medium-term potential and hired a new CFO to support its asset commercialization activities.

Recent measures to support development and commercialization

- Extended cash runway into 2027
- Generated positive data from ongoing studies
- Streamlined product pipeline
- New CFO to support commercialization activities
- Launched Netherton Syndrome awareness campaign
- Attained Orphan Drug Designation for QRX003 in Netherton Syndrome
- Achieved target loading concentrations for 2 topical rapamycin delivery technologies
- Reported positive interim data, recruited 3 new patients in investigator led pediatric NS study

The company's lead asset, QRX003, is being evaluated for the treatment of Netherton Syndrome (NS), pediatric NS and Peeling Skin Syndrome (PSS). QRX003 is a topical lotion with a broad-spectrum serine protease inhibitor that has demonstrated the ability to significantly downregulate the hyperactivity of the kallikreins in the skin that are responsible for the excessive skin shedding that is associated with NS and other dermatological diseases. QNRX has active Netherton Syndrome (NS) studies that are being conducted concurrently under an FDA open Investigational New Drug (IND) application to assess QRX003 for treatment of NS.

Netherton Syndrome is a debilitating skin disorder caused by mutations in the Serine Protease Inhibitor Kazal-type 5 (SPINK5) gene, SPINK5 is crucial in regulating serine proteases that hydrolyze extracellular proteins that bind corneocytes. In other words, SPINK5 is critical to the skin's regular and necessary shedding and replenishing and moisture retention. People suffering from NS do not have as many layers of outer skin as they need, which means that their skin does not perform its primary function as a protective barrier. In turn, this increases the risk of infections, warts, irritation and even skin cancer in some patients. Moreover, their skin tends to be prone to scaling and is accompanied by hair anomalies, along with increased susceptibility to atopic eczema and itching. Patients with NS can also experience trans-epidermal water loss (TEWL).

Quoin expects NDA submission in 2026

Last month the FDA granted Orphan Drug Designation (ODD) to QRX003, for the treatment of NS. Previously, the European Medicines Agency (EMA) granted QRX003 Orphan Drug Designation in May 2025. The FDA designation provides certain tax credits for qualified clinical testing, waiver or partial payment of FDA application fees and seven years of market exclusivity, if approved, among other benefits. The FDA had previously granted QRX003 Rare Pediatric Disease (RPD) Designation for the treatment of NS.

The company believes these designations reinforce the potential of QRX003 as a therapeutic candidate as it advances clinical studies towards a potential New Drug Application (NDA) for QRX003 as the first approved treatment for NS. The potential for an expedited regulatory pathway is supported by the significant increase in approvals of products to treat rare and orphan diseases in recent years.

Demonstrating evidence of benefits of QRX003; currently no NS treatments are approved

Quoin is currently conducting two pivotal clinical studies for QRX003 in Netherton Syndrome in the U.S., Europe and the Middle East. Recruitment into both was set for 4Q25 and full enrollment is expected in early to mid 1Q26.

Clinical data thus far from Quoin's ongoing studies has demonstrated clear evidence of rapid, prolonged and almost complete skin healing following twice-daily application of QRX003 to the treatment areas along with the almost complete elimination of key symptoms such as chronic, debilitating pruritus and has facilitated zero nightly sleep disturbances.

There are no approved NS treatments currently and Quoin is optimistic about QRX003's prospects to be the first approved treatment for NS. Current standard of care seeks to manage the associated symptoms and complications of NS but The NIH notes that "[t]here is no specific treatment" for Netherton syndrome. The overall patient population is fairly sizable. Quoin estimates that there are about 6,000-7,000 patients in the U.S. and EU suffering with Netherton syndrome. Data is not readily available and these estimates are within the range of other published estimates. The National Organization for Rare Disorders (NORD) indicates that the actual number of people suffering from Netherton syndrome might exceed the number of reported cases because it is often undiagnosed.

Quoin is studying QRX003 as a monotherapy and as an adjuvant therapy for treatment of NS. The company is building a robust database and, depending on the data from the studies, potentially increasing pathways to regulatory approval, in our view. Quoin expects its clinical activities will produce a solid database that will be key to its regulatory approval submission supporting the safety and efficacy of QRX003.

The company believes the results indicate that ongoing, chronic treatment with QRX003 is needed to treat NS and control patients' symptoms. If QRX003 is proven to be safe and effective and achieves regulatory approval, the company believes long term daily application of QRX003 could lead to the development of a more normally functioning skin barrier and a significant improvement in the quality of life of NS and potentially other patients down the road following other clinical activities.

Moving forward with Rapamycin & advancing pediatric Netherton Syndrome study

In addition to studying QRX003 for NS, Quoin is evaluating other assets and recently announced that the target loading concentrations for its two topical rapamycin delivery technologies have been achieved: 1) a rapamycin loading concentration of 4% w/w for Quoin's proprietary topical formulation and 2) a higher rapamycin concentration of 5% w/w has been formulated in a proprietary dermal patch system. Initial clinical indications for which there currently are no FDA approved treatments or cures that Quoin has identified as targets include Microcystic Lymphatic Malformations and Venous Malformations among others.

Quoin also has recruited three additional patients - two in Austria and one in Ireland - in its investigator led pediatric NS study who will all receive twice-daily whole-body application of QRX003, initially for a period of twelve weeks before continuing in a long-term extension protocol until/if regulatory approval is granted. Quoin believes data from these additional subjects will add to its growing clinical database supporting QRX003 as a potential treatment for NS. The company expects clinical data from these subjects will continue to demonstrate positive clinical outcomes of QRX003 in NS without adverse events, representing a continuation of positive data generated thus far.

Following 9-months of continued whole body application of QRX003, positive clinical data from the first pediatric patient in the study demonstrates that the subject's skin remains completely healed, which QNRX notes shows the durability of ongoing daily treatment with QRX003. Prior to initiation of treatment with QRX003, the subject's skin had a baseline Investigator's Global Assessment (IGA) of 4 (the most severe score possible on a scale of 0-4).

At 9 months, the IGA had improved materially to 0 and the subject's skin is completely clear. In addition, the subject's pruritus score changed from 5 at baseline to 0 at 9 months (on a scale from 0-10, with 10 being the worst itch). For the first time in the person's life, the subject continues to experience zero nightly sleep disturbances with no need for sedatives, as well as no need for previously needed medications such as antibiotics, antivirals, antihistamines and glucocorticoids. No adverse events have been reported to date.

Patent submissions to protect IP

The company also continues to file multiple patent applications to protect its assets and IP. The company has filed numerous patent applications to protect its IP. Recently, QNRX filed patents for novel topical rapamycin formulations. On March 4, 2025, Quoin announced the filing of U.S. and international patent applications for novel topical rapamycin formulations targeting microcystic lymphatic malformations, venous malformations and angiofibromas. The products are being developed using Quoin's in-licensed proprietary Invisicare® delivery technology. The company believes this represents an important measure in expanding its pipeline addressing rare dermatological diseases.

Quoin has extended cash runway into 2027 with recent financing

Quoin had roughly \$5.4 million in cash and equivalents and marketable securities at the end of 3Q25, which the company expects is sufficient to fund operations into 1Q26. Subsequently, Quoin raised capital through a PIPE financing with initial upfront funding of \$16.5 million and up to an additional \$88.0 million if warrants are exercised (for aggregate up to \$104.5 million in gross proceeds). The private placement was priced at a premium to the prior day's closing stock price.

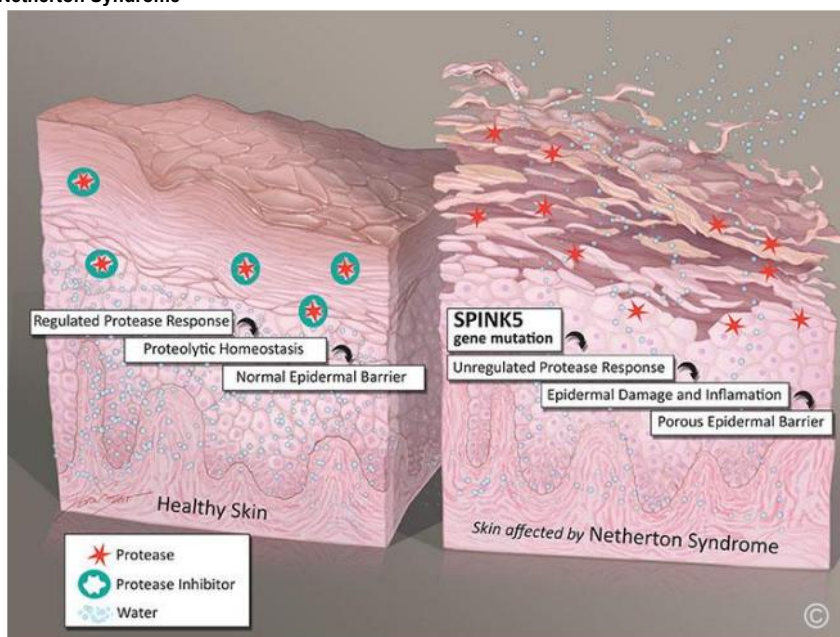
Notably, including the \$16.6 million in upfront funding and \$3.3 million received from warrant exercises in October 2025, the company expects its pro forma cash and equivalent balance to support operations into 2027. Importantly, several healthcare-focused investors participated in the financing, according to Quoin.

Separately, Quoin appointed a new Chief Financial Officer effective immediately, Sally Lawlor. Reflecting her more than 20 years of experience in financial leadership roles in public and private companies including in the pharmaceutical space, as well as a Big Four accounting firm, the company views her as a strong CFO for the next stage in its development as Quoin moves to commercialize QRX003.

NETHERTON NOW CAMPAIGN HAS GAINED TRACTION TO RAISE AWARENESS OF NS

Netherton Syndrome is not widely known among patient populations and even sometimes among non-specialist physicians. For this reason, the disease is sometimes misdiagnosed. QNRX believes there is a need for better awareness of both NS and new treatment options and is trying to raise awareness and understanding of NS. It has launched a campaign, called NETHERTON NOW, designed to boost awareness of NS and its impact and treatment options, including a dedicated website. NETHERTON NOW campaign videos have been viewed by more than 1.5 million since the campaign was launched earlier in 2025.

Netherton Syndrome



Source and copyright: [Quoin Pharma](#)

PIPELINE ASSETS POTENTIAL TO TREAT MULTIPLE INDICATIONS

QNRX is pursuing R&D of its assets for multiple indications and expects to build a database supporting the efficacy and safety of QRX003 as a treatment for dermatological conditions including NS and Peeling Skin Syndrome. Assessing assets for multiple indications can help spread costs over expanded base. Quoin is also evaluating additional opportunities for QRX003 in order to expand potential pathways to regulatory approval and subsequent commercial opportunities. Other indications QNRX believes it might pursue include SAM Syndrome and Palmoplantar Keratoderma.

Therapeutic Development Pipeline

Product Candidate	Indication	Pre-Clinical	Phase 1	Phase 2	Phase 3	Approval
QRX003	• Netherton Syndrome*					
	• Peeling Skin Syndrome**					
	• SAM Syndrome					
	• Palmoplantar Keratoderma***					
QRX008	• Scleroderma					
QRX009	• Microcystic Lymphatic Malformations, Venous Malformations, Angiofibroma and others					

* Pivotal Clinical studies underway

** Clinical trial initiated

*** Clinical testing to commence 1H2026

Source: [Company reports](#)

As Quoin expands its clinical activities and potential applications to other patient populations, this strategy is expected to broaden QRX003's target patient populations and commercial prospects, create operating and cost efficiencies and scale and enhance the commercial opportunities of QRX003 and other drugs in the product pipeline. This strategy is also consistent with recent trends in treatments for

orphan drug disorders. According to NORD, at least 154 orphan products were approved initially to treat a single rare disease and ultimately earned approval to treat one or more additional orphan indications.

Given the company's development progress with QRX003, QNRX has recently fine tuned its pipeline and terminated or possibly paused moving forward on certain assets. The pipeline consists of lead product QRX003 discussed earlier, QRX006, QRX008 and Rapamycin.

QRX003

The company's initial focus is on dermatological indications. Skin is the body's largest organ and first point of contact for microbes and toxins. Demand for products and therapies to treat dermatological disorders has climbed in recent years, driven in part by the aging of the population, and increased awareness of ways to treat and manage symptoms, beginning largely by focusing on products that treat rare skin diseases, as noted. Quoin's QRX003 for Netherton Syndrome (NS) is the most advanced.

QRX003 is a topical lotion that is intended to be applied once daily and, in the case of Netherton Syndrome, to the whole body for the remainder of the patient's life. In addition to assessing QRX003 development for treatment of NS and Peeling Skin Syndrome, Quoin also plans to pursue QRX003 for other rare dermatological indications, including potentially SAM Syndrome, and Palmoplantar Keratoderma. Currently, there are no approved treatments for these diseases.

QRX003 contains a broad-spectrum serine protease inhibitor (SPI), which penetrates into the skin and regulates the hyperactivity of certain skin kallikreins that are responsible for the excessive skin shedding that NS patients suffer from and which leads to the highly porous skin that is indicative of the disease. The SPI also acts as a strong anti-inflammatory and antioxidant. QRX003 is formulated with the patented Invisicare® delivery technology, which Quoin licenses from Skinvisible Pharmaceuticals, Inc. Invisicare enables users to apply the product once daily and the treatment remains active on the skin all day without needing to be reapplied. Quoin has the exclusive right to use the Invisicare technology for all orphan dermatology applications, including QRX003, according to management. QRX003's goal is to reduce the patient's skin shedding and help enhance the protective barrier over the skin.

QRX008

QRX008 is in-licensed from Queensland University Technology. It is being developed to treat scleroderma, which is a rare and sometimes fatal autoimmune disease for which no approved treatments currently exist. Scleroderma is caused by an over production of collagen, which results in hardening of the skin and connective tissue. Quoin's focus is on investigating small molecule inhibition of the VCAM-1: VL-4 interaction; there is an established genetic and clinical link for VCAM1 in scleroderma and the pivotal role VL-4 plays in controlling immune cell migration into inflamed tissue. Therefore, the VCAM-1:VL-4 interaction is an attractive target for therapeutic intervention in scleroderma. Proof of concept has already been established in a mouse model and additional studies are underway to select a candidate for clinical testing.

QRX009 (a proprietary topical formulation of rapamycin)

Quoin's topical rapamycin program is being developed under a research agreement with The School of Pharmacy at University College Cork in Ireland. The program targets rare and orphan skin diseases including microcystic lymphatic malformations, venous malformations, and angiofibromas. Two proprietary delivery platforms are being evaluated including UCC's dissolvable microneedle technology and an in-licensed Quoin technology.

RECENT RESULTS

The company is pre-revenue at this stage of its development. As its clinical activities have expanded, R&D expenses have increased. Quoin reported R&D expenses of about \$2.9 million in 3Q25 compared to \$1.7 million in 3Q24. Quoin reported a net loss of about \$3.9 million compared to a net loss of roughly \$2.3 million for 3Q24.

VALUATION

Given recent milestones and data from clinical activities, we remain optimistic about the chances of QRX003 receiving FDA and other approvals and the subsequent commercial demand, beginning with as NS treatment and potentially for multiple indications. The absence of alternative effective therapies that have the limited side effects, combined with relatively high related healthcare costs of the target patient populations could translate, we believe, into solid demand for QRX003 following clinical studies of its efficacy for a range of indications. Given the early stage of the company's development and the uncertain economic outlook, we assign a 40%-50% confidence multiple to our revenue forecast range at this point. However, depending on clinical efforts, regulatory approval and commercial launches, our confidence multiple might prove conservative. Thus, we might increase / lower our confidence multiple in the future.

Quoin estimates the NS patient population in the U.S. and EU at about 6,000 to 7,000, a noted. It is not difficult to see how revenue for QRX003 could build, depending on the market share the product captures, annual treatment cost and Quoin's retention after revenue sharing with distribution partners and/ or sales commissions. The scenarios presented below represent the potential commercial opportunity for QRX003 for NS alone. Aggregate demand from patients suffering with peeling skin disease and potentially other indications could translate into revenue upside, in our view.

It is difficult to know the revenue arc for QRX003 at this early stage. Nevertheless, with QNRX targeting regulatory approval for NS in 2026, we believe it is reasonable to expect that Quoin could attain product revenue of \$14 million to \$20 million by 2027-29, depending on when / if QRX003 obtains regulatory approval and other factors noted above. We base this range on the company's expected launch timeline and depending on factors noted above, patient population, potential for QRX003 to achieve 15% or greater market share and expected treatment costs. Quoin believes QRX003 represents a strong treatment option. Moreover, it would seem likely that the market can support multiple products, in our view.

Applying a 1.4x to 2x multiple (based on other clinical stage companies, low to mid end of the range) to the above noted possible revenue range and discounting back to the present at 11%/year results in a present value of roughly \$14 million to \$20 million. Applying a confidence multiple at the lower end of the range (we have lowered the factor) on potential timeline delays and / or shareholder dilution yields a mean valuation of about \$27 per ADS. We believe the ADSs can attain this valuation if the company hits certain milestones, although we do not expect the shares to mirror this potential until further advances are made. We also believe current general market conditions and the uncertain economic outlook could continue to overhang the shares. Any delay or failure in clinical development or regulatory approval could cause the share price to decline and represent a potential risk to our valuation but we believe the risk / reward ratio could be attractive for investors who have a higher than average risk tolerance and longer time horizon.

RISKS

Risks to Quoin achieving its objectives, and to our valuation, include the following, among others.

- Quoin might need to raise additional capital earlier than expected.
- Clinical and commercialization timelines could be delayed by factors outside Quoin's control.
- The company might not gain traction as quickly as it expects if/when it commercializes its assets.
- Clinical results might not meet the company's expectations.
- The company might not obtain regulatory approvals in the time expected or at all.
- Competition for QRX003 and other assets could be steeper than anticipated and could also increase.
- Quoin faces going concern risks.
- Quoin shares risk not meeting Nasdaq listing compliance.

RECENT NEWS

- On November 6, 2025, Quoin announced 3Q25 results and provided a corporate update.
- Quoin announced Achievement of Topical Rapamycin Target Loadings for Two Proprietary Delivery Technologies on November 11, 2025.
- Quoin recruited 3 Additional Patients in Investigator Pediatric Netherton Syndrome Study on October 28, 2025, and provided a positive 9-month 'whole body' data update.
- Quoin announced FDA Orphan Drug Designation for QRX003 in NS on October 21, 2025.
- Quoin announced a private placement of up to \$104.5 million on October 10, 2025.
- Quoin's NETHERTON NOW Campaign surpassed 1-million views on August 21, 2025.
- Quoin appointed a new CFO on August 18, 2025.
- Quoin Pharmaceuticals Releases Fourth Episode in NETHERTON NOW Video Series.
- On June 24, 2025, the FDA granted Rare Pediatric Disease Designation for QRX003 in NS.
- Quoin announced EMA grant of Orphan Drug Designation for QRX003 for NS on May 20, 2025.
- May 22, 2025, FDA clearance to initiate a 2nd pivotal whole body QRX003 NS study.
- Positive pediatric Peeling Skin Syndrome study clinical data for QRX003 released on May 14, 2025.
- On April 2, 2025, QNRX announced more positive whole body data from pediatric NS Study, approval to initiate testing of second pediatric patient.

PROJECTED FINANCIALS

Quoin Pharmaceutical Income Statement & Projections (US \$000 except per share data)

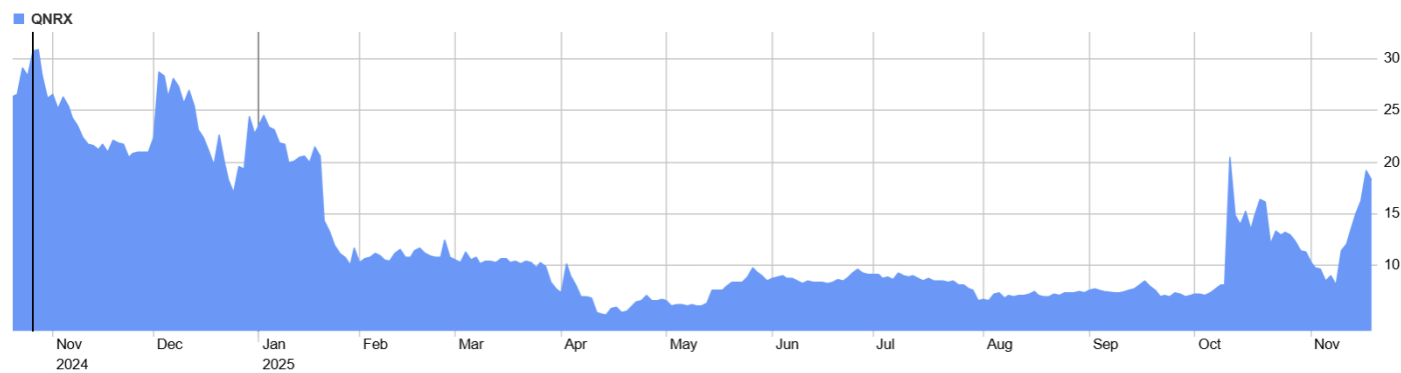
	1Q24A	2Q24A	3Q24A	4Q24A	2024A	1Q25A	2Q25A	3Q25A	4Q25E	2025E
Revenue	-	-	-	-	-	-	-	-	-	-
Operating expenses										
General and administrative	1,573.0	1,617.8	1,357.7	1,377.4	5,925.8	1,583.0	1,742.6	1,738.8	1,744.7	6,809.1
Research and development	885.3	519.3	1,170.3	1,027.7	3,602.6	2,374.1	2,050.6	2,281.2	2,143.8	8,849.7
Total operating expenses	2,458.3	2,137.1	2,528.0	2,405.1	9,528.5	3,957.2	3,793.2	4,019.9	3,888.5	15,658.8
Operating loss	(2,458.3)	(2,137.1)	(2,528.0)	(2,361.1)	(9,528.5)	(3,957.2)	(3,793.2)	(4,019.9)	(3,888.5)	(15,658.8)
Other										
Forgiveness of accounts payable										
Warrant liability (income) expense										
Unrealized loss / inc	6.5	2.2	(31.7)	15.5	(7.5)	(0.1)	6.0	(9.5)		
Interest income	(137.5)	(165.3)	(146.4)	(109.3)	(558.5)	(144.9)	(103.2)			
Other	-	-	-	-	-	-	-	(62.3)	-	-
Total other income	(131.0)	(163.1)	(178.1)	(93.8)	(566.0)	(145.0)	(97.2)	(71.8)	(100.4)	(414.4)
Net loss	(2,327.3)	(1,974.0)	(2,349.9)	(2,250.8)	(8,962.5)	(3,812.2)	(3,695.9)	(3,948.2)	(3,788.1)	(15,244.4)
Dividend on warrant modification					11.0					
Net loss to shareholders	(2,327.3)	(1,974.0)	(2,349.9)	(2,250.8)	(8,951.5)	(3,812.2)	(3,695.9)	(3,948.2)	(3,788.1)	(15,244.4)
Loss per ADS*	(\$38.73)	(\$13.68)	(\$16.29)	(\$15.29)	(\$72.22)	(\$6.50)	(\$6.28)	(\$6.71)	(\$6.42)	(\$25.92)
Weighted avg ADSs outstanding (k)	60.1	144.3	144.3	147.2	124.0	586.3	588.2	588.2	590.2	588.2

Source: Company reports & Zacks

One ADS = 35 ordinary shares

*ADS ratio PF

HISTORICAL STOCK PRICE



Source: Company reports

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