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Zacks Small-Cap Research

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Quoin Pharmaceuticals (QNRX-NASDAQ)

QNRX: Moving QRX003 Forward in Concurrent Studies

Quoin Pharmaceuticals is an emerging specialty pharmaceutical company focused on developing & commercializing therapeutic products for the treatment of rare and orphan diseases that have few or no currently approved therapies. Quoin has three lead products in development, including QRX003 for Netherton Syndrome, its most advanced asset.

Current Price (12/2/22)	$1.75
Valuation	**$7.00**

OUTLOOK

Quoin lead candidate QRX003 is being evaluated in two concurrent clinical studies to assess its safety, tolerability and efficacy in treating patients with NS, including one trial designed to evaluate QRX003 in NS patients currently receiving off-label systemic therapy. Currently there are no approved therapeutic treatments for NS and Quoin is optimistic that, if clinical studies are successful, QXR003 for NS could be approved in the U.S. and EU by 2024-2026. Moreover, given its current focus on rare and orphan dermatological conditions, the company believes that it can attain scale quickly and in an economical way by leveraging QXR003 and other products to treat multiple dermatological conditions when appropriate.

SUMMARY DATA

52-Week High	**$64.38**
52-Week Low	**$1.57**
One-Year Return (%)	**-96.3**
Beta	**N/A**
Average Daily Volume (sh)	**45,068**
ADSs Outstanding (mil)*	**3.5**
Market Capitalization ($mil)	**8**
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 2022 Estimate	**N/A**
P/E using 2023 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)
2020					0 A
2021					0 A
2022	0 A	0 A	0 E	0 E	0 E

Loss / Earnings per ADS

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020					
2021					-$5.42 A
2022	-$2.58	-$3.24	-$0.94 A	-$0.93 E	-$3.22E

Quarters might not sum due to rounding & share counts, ADS ratio

Disclosures on page 15

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KEY POINTS

- Quoin has strengthened its cash position and reached several milestones to continue moving its lead candidates and other assets forward. QRX003, Quoin's investigational product for NS (Netherton syndrome), is being evaluated in two concurrent clinical studies to assess its safety, tolerability and efficacy in treating patients with NS, including one designed to evaluate QRX003 in NS patients currently receiving off-label systemic therapy, primarily biologic therapy.

- There are no currently approved therapeutic treatments for NS and Quoin is optimistic that if clinical studies are successful, QXR003 for NS could be approved in the U.S. and EU by 2024-2026 and potentially become the standard of care for NS patients.

- Given its current focus on rare and orphan dermatological conditions, the company believes that it can attain scale quickly and in an economical way by leveraging its products to treat multiple dermatological conditions when appropriate.

- To prepare for the expect commercialization of QXR003 and other therapies, Quoin is developing an internal sales / distribution infrastructure to cover the U.S. and Europe and has entered into partnerships, for international markets. Quoin has established a global commercialization and distribution network encompassing at least 60 countries across the globe (see below), with additional discussions underway.

- Following an upsized offering in 3Q22 that raised gross proceeds of $16.8 million, Quoin ended September with approximately $15.2 million in cash and marketable securities to advance its strategy.

CLINICAL TRIALS: RECENT MILESTONES

Advancing & expanding clinical studies in the U.S. & Europe

Quoin Pharmaceuticals (QNRX-NASDAQ) continues to move its lead candidate QRX003 forward in clinical studies to evaluate QRX003 for the treatment of Netherton Syndrome (NS). QRX003 is Quoin's investigational product for NS, which is a rare disease that currently has no approved treatment or cure (see below). The company has strengthened its cash position and reached several milestones to continue moving QRX003 and other assets forward.

Quoin reached several milestones for QRX003 over 2022. In April 2022, the company received FDA clearance to initiate clinical testing for its Investigational New Drug (IND) application for QRX003 for NS and launched the first clinical site shortly thereafter in July 2022. The study is a randomized, double blinded, placebo -controlled study designed to assess two different doses of QRX003 topical lotion versus a placebo lotion in NS patients. The test materials will be applied once daily over a twelve-week period, to pre-designated areas of the patient's body. Based on discussions with the FDA, a number of different clinical endpoints will be assessed in the study. In July 2022, Quoin announced that it received constructive and comprehensive Scientific Advice from the European Medicines Agency (EMA) regarding QRX003 as a potential treatment for NS in Europe.

NS patient population

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.

QRX003: Treating NS & other conditions

Quoin intends to pursue approval from the FDA and other international regulatory agencies for QRX003 for NS and potentially other conditions. Quoin is conducting clinical studies designed to evaluate and determine the safety, tolerability and efficacy of QRX003 in patients with NS. In addition to a study launched earlier in 2022, the company is also initiating a second clinical trial to expand recruitment to patients who do not currently qualify for the ongoing trial. Specifically, the second study is designed to evaluate QRX003 in NS patients currently receiving off-label systemic therapy, primarily biologic therapy. The company expects the two trials to run simultaneously. The company has set up a website to facilitate patient awareness and participation.

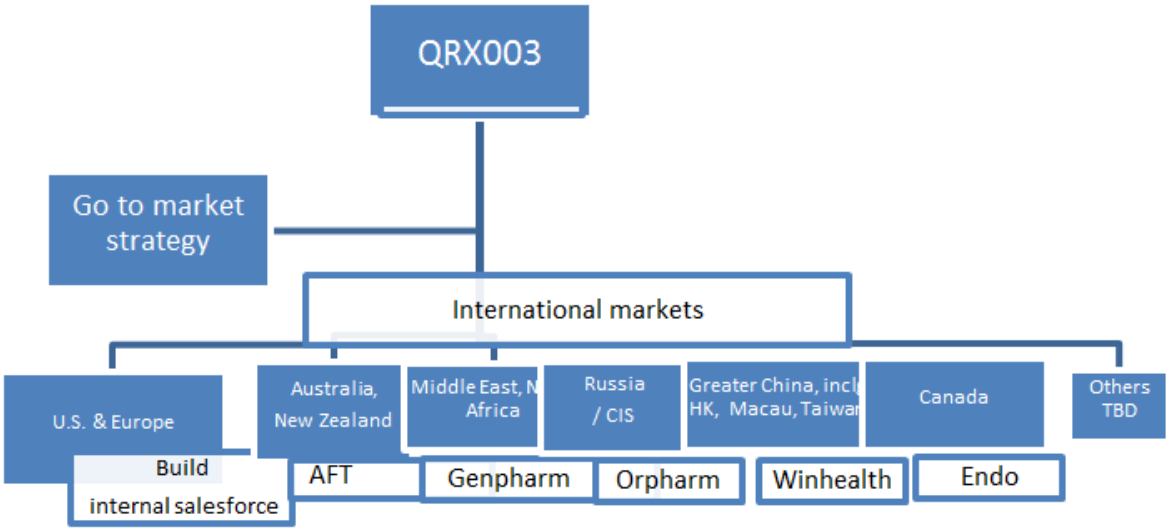
The additional study of QRX003 topical lotion in NS patients who are currently receiving off-label systemic therapy, primarily systemic biologic therapy, is designed as a multicenter open label trial. It will be conducted under Quoin's open U.S. Investigational New Drug (IND) application and, as noted, recruit patients who are currently not eligible for participation in the other trial as a result of being treated with systemic therapy. The company expects to build a database supporting the efficacy and safety of QRX003 as a treatment for NS. We believe two studies underway, as well as multiple target conditions, could also expand the avenues to potential regulatory approval. 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. For example, according to NORD, at January 1, 2020, 564 orphan products were FDA-approved to treat 838 rare diseases, of which some 30% received approval in the three years prior. Quoin expects that initial clinical testing of QXR003 to treat NS will begin in 2022 and

QRX003 will be applied once daily over a twelve-week period, to pre-designated areas of the patient's body. A number of different clinical endpoints will be assessed in the study. The active ingredient in QRX003 is a broad-spectrum serine protease inhibitor, whose mechanism of action is intended to down-regulate the hyperactivity of skin kallikreins, leading to a more normalized rate of skin shedding. If proven to be safe and effective, 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 patients.

There are no currently approved therapeutic treatments for NS, although some patients are being treated off-label with systemic biologics, including systemic therapy, that provide some symptomatic relief but do not address all symptoms or the underlying cause of NS. The company is optimistic that if the studies are successful, QXR003 for NS could be approved in the U.S. and EU by 2024-2026 and potentially become the standard of care for NS patients.

Establishing sales infrastructure for U.S. & EU; Partnerships for other markets

To prepare for the expect commercialization of QXR003 and other therapies, Quoin is developing an internal sales / distribution infrastructure to cover the U.S. and Europe and has entered into partnerships, for international markets. Quoin has established a global commercialization and distribution network encompassing at least 60 countries, including Greater China, the Middle East, Canada, Australia and New Zealand and parts of Latin America, Central and Eastern Europe and Turkey, among other markets, with additional discussions underway to extend the commercial applicability of QRX003 and potentially other products. Quoin also continues to work with its partners to explore potential opportunities for the advancement of QRX003 into local Compassionate Use or Early Access Programs ahead of QRX003 receiving regulatory approval.



Source: Company reports

Enhancing financial flexibility to advance growth strategy, with recent offering upsized …

Following an oversubscribed (and upsized) offering in 3Q22 that raised gross proceeds of $16.8 million, Quoin ended September with approximately $15.2 million in cash and marketable securities to advance its strategy, up from roughly $2.7 million at the end of 2Q22. Quoin intends to use the proceeds of the recent offering for general corporate purposes, including to advance its clinical efforts and growth strategy. Separately, Quoin's board recently approved a change in the ratio of ADS to ordinary shares from 1:400 to 1:5,000 effective August 1, 2022.

QUOIN PIPELINE AND STRATEGIES TO EXPAND PRODUCT PORTFOLIO

Three lead assets; recent licensing deals add new products

Quoin is an emerging specialty pharmaceutical company focused on developing and commercializing therapeutic products for the treatment of rare and orphan diseases that currently have few or no approved therapies. Quoin's goal is to address the unmet medical need of patients suffering from certain rare and orphan diseases, beginning with 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 has three lead products in development; QRX003 for Netherton Syndrome (NS) is the most advanced. Quoin's strategy is to add new products to its portfolio that expand beyond the skincare space, as noted.

Quoin Pharmaceuticals Product Pipeline

Product Candidate	Target Indication	Status
QRX003»	Netherton Syndrome	Clinical/Pre-IND
	Peeling Skin Syndrome	Preclinical
	SAM Syndrome	Preclinical
	Palmoplantar Keratoderma	Preclinical
QRX004»	Epidermolysis Bullosa	Clinical/Pre-IND
QRX006»	Undisclosed Rare Skin Disease	Preclinical

Source: https://quoinpharma.com/pipeline/

QRX003

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. Quoin is targeting initiating the clinical development of QRX003 in 1H22. Quoin also plans to pursue QRX003 development for treatment of other rare dermatological indications, including Peeling Skin Syndrome, SAM Syndrome, and Palmoplantar Keratoderma, among others.

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 QRX0003, according to management. QRX003's goal is to reduce the patient's skin shedding and help enhance the protective barrier over the skin.

Clinical testing has begun, as discussed below. Given regulatory actions to facilitate and expedite approval of drugs to treat orphan and rare diseases, Quoin expects the timeline will be relatively short compared to development timelines of drugs to treat more widespread diseases. QRX003 formulation is fully developed and has been manufactured at commercial scale. The company is working closely with supporting foundations and will have access to patient registries, according to management. Quoin also has QRX007 for Netherton Syndrome in development and believes that patients eventually might be able to use QRX007 in combination with QRX003.

QRX004

QRX004 is a topical lotion that is also utilizes the Invisicare® delivery technology. QRX004 contains two active ingredients and is initially being developed as a potential treatment for RDEB (see below). The primary ingredient in QRX004 helps create robust and sustained type VII collagen that improves wound closure, reduces blistering and generally strengthens the skin.

QRX006

QRX006 is a topical lotion that Quoin is developing to treat a rare disease that the company has not disclosed yet. The existing standard-of-care for this disease generally requires both oral and IV infusion over a prolonged period and many patients have had side effects, according to the company. Quoin believes QRX006 could be a much better treatment alternative that could reduce the side effects and also obviate the need for daily visits to a medical facility for IV infusions. Quoin applied for a patent for QRX006 in mid-2021. We expect the company to provide more color on QRX0006 in the near-term.

Broaden market, spread development, distribution & marketing costs over expanded base

The products in Quoin's pipeline generally are being designed to treat multiple indications. Thus, QRX003 is planned to target NS initially, as noted, and Quoin also intends to expand its use to other patient populations. In turn, 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.

The three lead products in QNRX's development pipeline target a broad number of rare and orphan diseases, focusing on the following illnesses, which we discuss in greater detail below:

Quoin Near-Term Focus

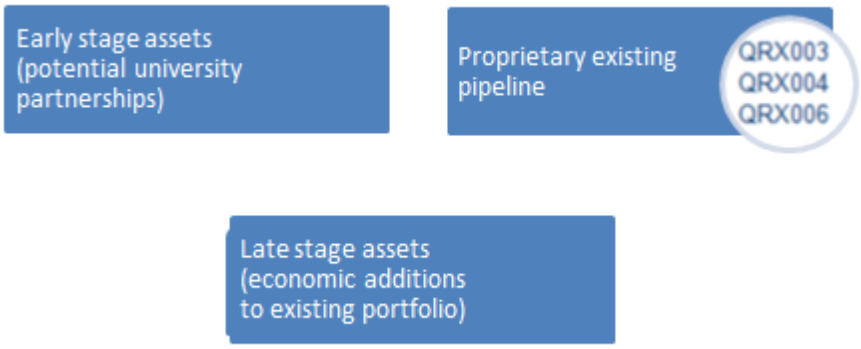
- Netherton Syndrome
- Peeling Skin Syndrome
- Palmoplantar Keratoderma
- Epidermolysis Bullosa

Source: Company reports

Other products in development & strategies to further expand product portfolio

Quoin has licensed two assets for development from Queensland University of Technology: QRX007, also for NS, and QRX008 for Scleroderma. Quoin continues to seek to expand its product pipeline by leveraging relationships with universities and other sources, as well as potentially through M&A. In addition to the three leading candidates discussed above, Quoin has also in-licensed two other assets for development from Queensland University of Technology: Quoin has QRX007 for NS and QRX008 for Scleroderma, as noted. Quoin also seeks to expand its pipeline of products designed to treat rare and orphan diseases. By leveraging relationships with universities and other sources, as well as the M&A market, the company seeks both early-stage and late-stage assets that could enhance its overall portfolio, as noted.

Quoin Pharmaceutical - Strategy Regarding Product Portfolio



Source: Company reports

QRX007

Quoin licensed QRX007 from Queensland University Technology of Australia. QRX004 is active as a dual domain serine protease inhibitor with proven anti inflammatoryactivity and already in use as a biopharmaceutical for the treatment of acute and chronic pancreatitis, Sepsis and toxic epidermal necrolysis. QRX007 is a human protein and Quoin therefore believes it is highly unlikely to provoke an immune response. A pre-clinical program is underway at Queensland University Technology. Quoin did not pay an upfront fee for the licensing right and has global rights in exchange for a mid-single digit royalty on future sales if regulatory approvals are obtained.

QRX008

QRX008 is the second product that Quoin has 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.

Expanding product portfolio

The company's current focus is on rare and orphan diseases beginning, as noted, in the dermatological space. Quoin has signed research agreements with the Queensland University of Technology, Australia for the development of a potential treatment for scleroderma and another for NS. In success, these would fulfill a core Quoin objective, which is to expand the company's product portfolio.

Moreover, the company plans to further expand its existing product portfolio by adding additional assets that address unmet medical needs in other categories beyond skin diseases. Quoin is actively looking to bring in additional rare & orphan assets and also expand beyond skin conditions. The company plans to seek partnerships, licensing opportunities and / or M&A transactions to expand its drug-development pipeline and capabilities. To further this objective and obtain public shares to help finance potential transaction, the company became public via a reverse merger. The shares began trading on the Nasdaq in October 2021.

RARE & ORPHAN DISASES IMPACT LARGE NUMBERS IN THE AGGREGATE

As noted, the FDA defines an orphan disease as one that affects fewer than 200,000 people nationwide. Nevertheless, in the aggregate, many people suffer from various diseases that are categorized as rare and / or orphan. Orphan diseases impact about 25 million people in the U.S. in the aggregate, according to National Institutes of Health (NIH) data. In 1983, Congress passed the Orphan Drug Act, which provided incentives for biotech and pharma companies to develop new drugs and therapeutic treatments to help people suffering from rare and orphan diseases that Big Pharma might not find meets the level of economic return to warrant development. According to the U.S. FDA, sometime in "the late 1970s it became increasingly clear that many citizens were being left out of … [ongoing medical and scientific] advances. One of the key reasons for this neglect was the small size of some patient populations. The relatively limited prevalence of a particular disease acted as a barrier for commercial investment in the research and development required to show evidence of the safety and efficacy of treatments. Ironically, by the early 1980s, these "rare diseases" affected 20-25 million patients who, together, suffered from approximately 5000 rare diseases…"

Regarding rare and orphan diseases:

- There are approximately 7,000-10,000 known rare diseases
- Aggregate U.S. patient population estimated at about 25-30 million
- Generally, they tend to be chronic, serious and frequently life-threatening
- Majority (about 80%) are genetic in origin
- More than 90% have no FDA-approved treatment

Source: NIH, NORD, Company reports

The Office of Orphan Products Development was created to encourage development of products to treat orphan diseases. The Orphan Drug Act was designed to stimulate innovation regarding treatment for rare and orphan diseases. The Orphan Drug Act of 1983 created financial incentives to develop therapies, including a seven-year exclusive period to market a drug approved to treat an orphan disease, even if it was not under patent, and tax credits for R&D and other expenses. The FDA notes that by 1990, it "had designated 370 products for orphan status, and of these 49 were approved for orphan indications. By 2002 the number of orphan designations grew to almost 1100, and approvals to 232, a number that provided treatment to an estimated 11 million patients."

Significantly Higher Cost of Orphan Drugs

The number of diseases designated as orphan diseases has increased geometrically and the number of drugs to treat many of those disorders has also increased as the FDA has sought to accelerate their approval. This gives us confidence of the company's ability to move QRX003 through the approval process domestically and internationally, given the need for novel treatment therapies for the diseases for which it is developing QRX003.

Costs of these treatments generally are significantly higher than costs of treatments for wider spread disorders. According to a study conducted by the National Institute of Health (NIH), "the cost per patient per year for a patient with a rare disease ranged from $8,812 to $140,044, compared to $5,862 for those without a rare disease." This estimate takes into account annual direct medical costs and indirect costs. The estimated direct costs of treating all patients afflicted with a rare or orphan disorder, including drug costs, hospitalizations and other expenses, aggregates to an estimated roughly $400 billion, which is comparable to major diseases such as cancer, heart failure or Alzheimer's.

Other estimates are in-line with NIH's. The United States Government Accountability Office (GAO) found that the "total cost in the United States for the estimated 15.5 million people with these 379 rare diseases was $966 billion. This amount reflects the combination of direct medical costs (estimated about $418 billion) and indirect costs associated with productivity losses ($437 billion), plus direct nonmedical costs.

The company cites estimates that orphan drug sales could reach $242 billion by 2024. In the aggregate, the market sizes and commercial opportunities of treatments that Quoin's products address could represent a sizable market if Quoin can commercialize its product portfolio in an efficient way, as management expects, and address multiple indications with most products. By developing and then launching products centered around dermatological disorders, with treatments that can effectively treat multiple disorders, the company expects to obtain economies of scale on development, distribution and go-to-market costs.

Competition

Several other companies are also developing treatments for NS. Krystal Biotech, for example, has KB104 under development for the treatment of Netherton Syndrome. KB104 is a topical gel formulation designed to deliver two copies of the SPINK5 transgene. BridgeBio Pharma is developing BBP-561, a topical treatment therapy. Novartis had conducted clinical trials for BPR277, a topical treatment for atopic dermatitis and NS, and subsequently licensed the treatment to San Francisco-based LifeMax Laboratories.

In 2020, Toronto Innovation Acceleration Partners (TIAP) and others invested in a drug development project focused on NS. Separately, privately-held Azitra received Rare Pediatric Disease Designation for ATR-12 for the treatment of Netherton syndrome. We would expect multiple products could achieve market if their clinical trials produce effective therapies.

RARE & ORPHAN DISASES QUOIN LEAD PRODUCTS TARGET

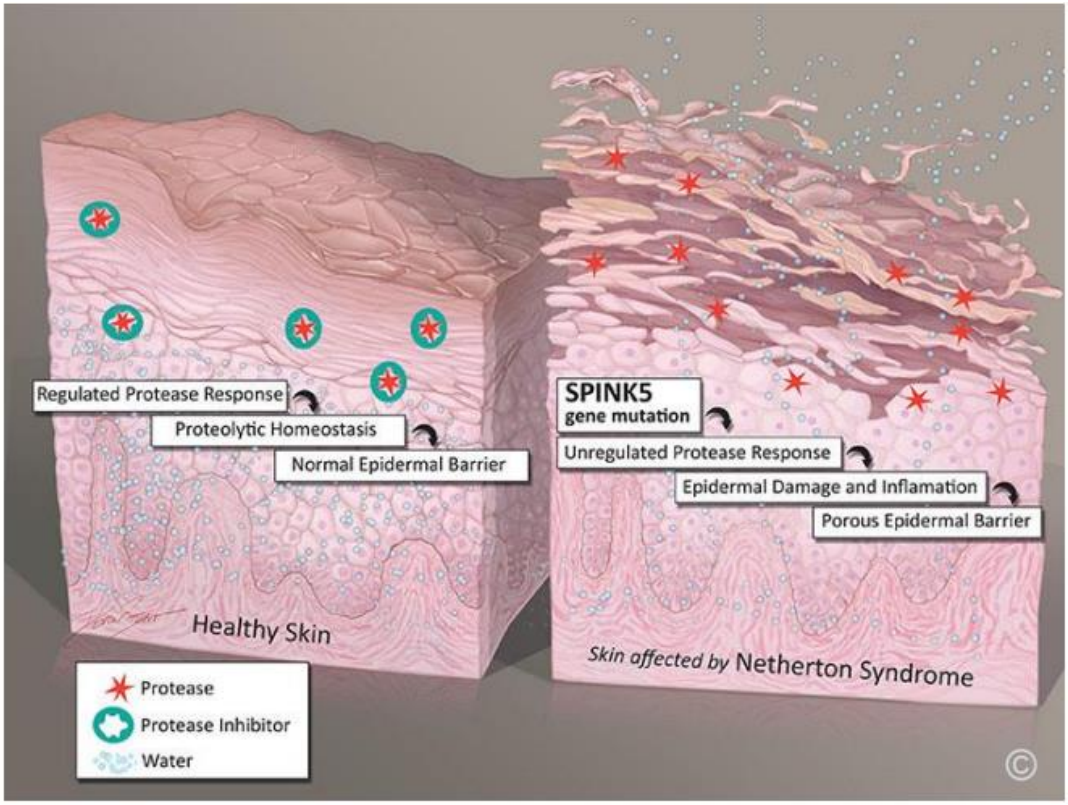
Netherton Syndrome

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 Netherton syndrome do not have as many layers of outer skin (stratum corneum) 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).

Patients can suffer with painful symptoms such as predisposition to allergies, asthma, and eczema, congenital ichthyosiform erythroderma, hair shaft defects and recurring infections, chronic skin inflammation, severe dehydration, and stunted growth, among others. Babies who are born with NS tend to develop slower than others and often gain weight slowly, as well, which can put them at high risk of infection and dehydration. In turn, this can be severe and ultimately life threatening. Severe NS In infants can be associated with failure to thrive, delayed growth, short stature, and recurrent infections. According to the NIH, NS symptoms – including red, scaly skin – generally present at birth. Symptoms could include outbreaks of red, circular scaly rashes, and as noted, thin, fragile hair (bamboo hair), and immune reactions such as hay fever, asthma, itchy skin, and eczema.

Netherton Syndrome



Source and copyright: Quoin Pharma

The NIH notes that "[t]here is no specific treatment" for Netherton syndrome. Current standard of care seeks to manage the associated symptoms and complications. Standard therapies currently include regular use of lotions and emollients. However, because the patient's skin protective barrier is compromised, certain topical ingredients could cause adverse reactions. Because skin inflammation/infection/allergy and skin barrier defect are mutually causal, using one therapeutic strategy generally is not an optimal solution.

Epidermolysis Bullosa

Epidermolysis Bullosa (EB) is a group of rare and genetic skin disorders. A person with EB generally has skin that is so fragile that even minor trauma can result in serious and severe pain, or even blistering, scarring, infections, chronic wounds. If severe enough, the disease could ultimately lead to the patient's immobility, disfigurement, disability and even early death. Recessive Dystrophic (RDEB), a form of EB, is characterized by progressive and increasingly painful blistering. It is diagnosed at infancy and results in a high mortality rate. Some 76% of patients diagnosed with RDEB do not reach the age of about 40. There is no cure or approved treatments.

Peeling Skin Syndrome

The NIH defines Peeling skin syndrome (PSS) **as** "a group of conditions that causes skin to peel and tear easily" and is caused by genetic variants in several genes. In some people with PSS, the skin peeling is limited to the hands and feet. In addition to continuous peeling of the skin, some people who suffer with PSS experience itching, redness, and scarring. Symptoms generally occur by childhood, but can appear anytime from birth to adulthood.

Palmoplantar Keratoderma

The NIH defines Palmoplantar keratoderma (PPK) as “a group of skin conditions characterized by thickening of the skin on the palms of the hands and soles of the feet.” In some rare cases, PPK can also affect organs other than the skin.

Scleroderma

According to the Scleroderma Research Foundation (SRF), Scleroderma is an autoimmune disorder that causes inflammation in the skin and other areas of the body. The inflammation triggers the immune system to over-produce collagen, which in turn leads to the hardening and tightening of the skin and connective tissues (ie: fibrosis). In the most serious cases, there can be complications resulting in damage to the heart, lungs, and digestive system. Scleroderma is “a complex disease that can progress in very variable ways in individual patients,” according to SRF, which frequently makes it difficult to diagnose.

VALUATION

We are optimistic about the chances of QRX003 receiving FDA and other approvals and the subsequent commercial demand, beginning with 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.

Quoin estimates the NS patient population in the U.S. and EU at about 6,000 to 7,000. 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.

While it is difficult to know the revenue arc for QRX003 at this early stage, it is reasonable to expect that Quoin could attain product revenue of $14 million to $20 million by 2027-28, given the company’s expected launch timeline and depending on factors noted above. We base this range on the patient population, potential for QRX003 to achieve 15% or greater market share and expected treatment costs. In terms of market share, although there are competing products under development, Quoin believes the combination of QRX003 and Invisicare technology present a strong treatment option. Moreover, it would seem likely that the market demand can support multiple products, in our view.

Applying a 5x multiple (the low end of the range for other clinical stage companies) to the $14 million to $20 million revenue possibility and discounting back to the present at 4%/year results in a present value of nearly $58 million to $82 million. We believe the ADSs can attain a valuation of about $7 per ADS as 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 uncertain economic outlook could remain an overhang on the shares. Nevertheless, as Quoin moves QRX003 forward towards potential regulatory approval and commercialization and also advances QRX004, QRX006, QRX007 and QRX008 and further expands the number of assets in its portfolio, in success we anticipate share price appreciation.

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.
- COVID-19, monkeypox or other widespread diseases might delay the company's clinical and commercialization timelines.
- The company might not find distribution partners in additional markets to help advance and commercialize 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.
- If the price of Quoin shares fall below the $1.00 level, Quoin might fall out of Nasdaq listing compliance.

RECENT NEWS

- Quoin announced 3Q22 results on November 10, 2022.
- The company closed a $16.8 million public offering on August 09, 2022.
- On July 28, 2022, Quoin announced that it had received constructive scientific advice from EMA for the development of QRX003 in Europe.
- Quoin opened the first clinical site for its Netherton Syndrome clinical study on Jul 06, 2022.
- On Jun 15, 2022, Quoin received a deficiency notice from Nasdaq.
- Quoin announced a new licensing and distribution agreement for Greater China on Jun 15, 2022.
- On May 23, 2022, the company signed an exclusive research agreement with Australian University for the development of a treatment for scleroderma.
- Quoin announced FDA clearance of an IND for QRX003, for NS on April 25, 2022.
- Quoin filed its 20-F on April 14, 2022.
- Quoin signed an exclusive license and distribution agreement for QRX003 with Orpharm LLC on December 15, 2021.
- Quoin Pharmaceuticals and Genpharm Services signed an exclusive license and distribution agreement for QRX003 **on** November 11, 2021.
- Quoin signed an exclusive licensing and distribution agreement for QRX003 with AFT Pharmaceuticals on November 08, 2021.

PROJECTED FINANCIALS

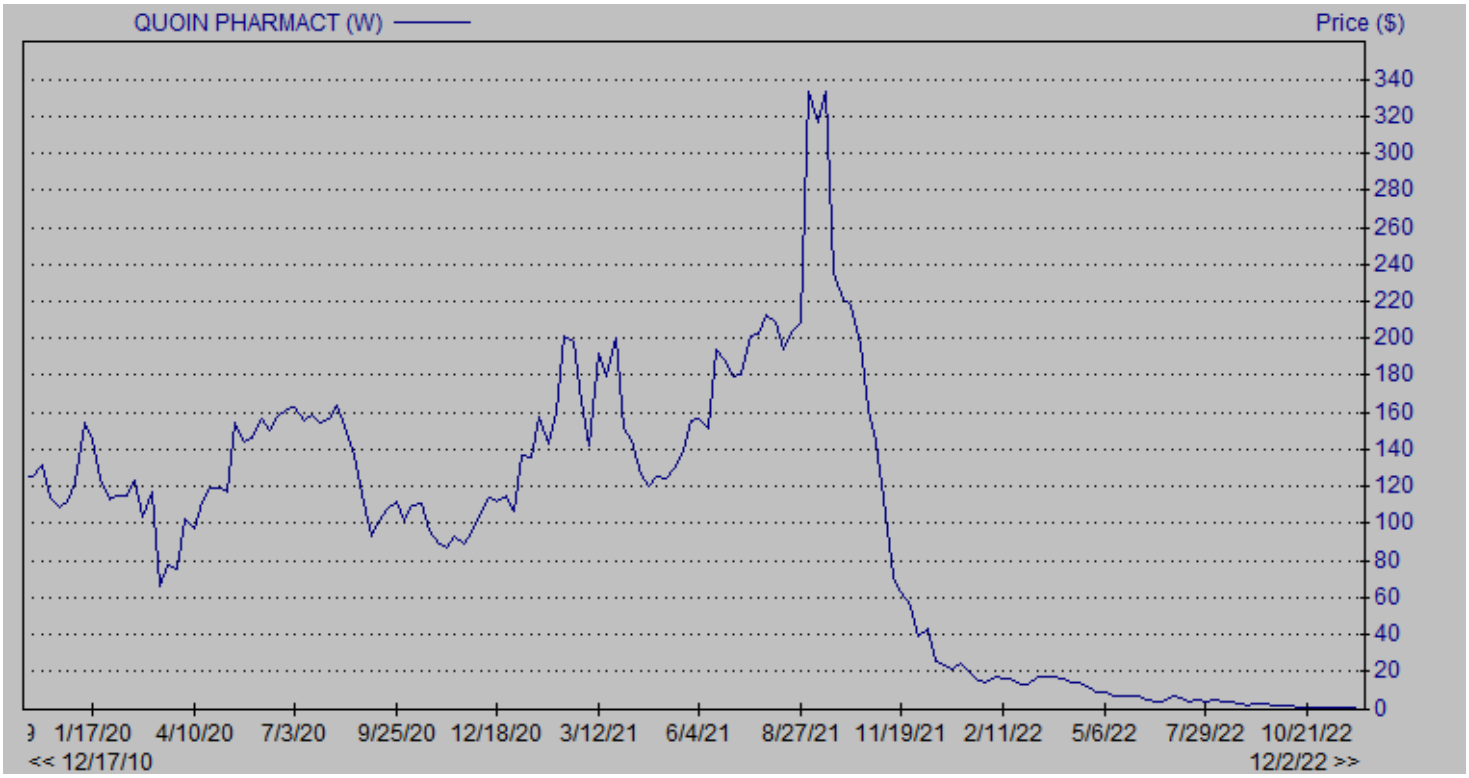
Quoin Pharmaceuticals Income Statement & Projections (US $000 except pe share data)

	PF 2020	2Q21	1H21	3Q21	2021A	1Q22	2Q22	1H22A	3Q22A	2022E
Revenue	-	-	-	-	-		-	-	-	-
Total operating expenses	1,670	976,890	1,779	1,303	6,063	2,176	2,668	4,844	2,328	8,339
Operating income / (loss)	(1,670)	(976,890)	(1,779)	(1,303)	(6,063)	(2,176)	(2,668)	(4,844)	(2,328)	(8,339)
Total other expenses	(425)	-3,360,653	(6,463)	(101)	(15,400)	493	-	493	(702)	(1,280)
Net loss before income taxes	(2,095)	(4,337,543)	(8,242)	(1,404)	(21,463)	(1,683)	(2,668)	(4,351)	(3,030)	(9,619)
Provision for income taxes	-	-	-	-	-		-	-	-	-
Dividend (warrants)				-					(65)	(130.53)
Net loss	(2,095)	(4,337,543)	(8,242)	(1,404)	(21,463)	(1,683)	(2,668)	(4,351)	(3,095)	(9,750)
Loss per share		($18.05)	($34.30)	($5.84)	($89.43)	($2.58)	($3.24)	($5.83)	($0.94)	($2.87)
Weighted avg ADSs outstanding (PF)		240	240	240	240	652	823	747	3,292	3,392

Source: Company reports & Zacks One ADS = 5,000 shares

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