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Quoin Pharmaceuticals (QNRX-NASDAQ)

QNRX: Planned Protocol Modifications Might Accelerate QRX003 Regulatory Approval

Positive clinical data from the first 6 patients in Quoin's QRX003 open-label trial for treatment of NS has led to planned protocol amendments, including eliminating the lower 2% dose in the double blinded study based on the clean safety profile observed for the 4% dose, increasing dosing frequency to twice-daily & increasing the number of subjects in both studies.

Current Price (11/10/23)	$3.71
Valuation	**$6.94**

OUTLOOK

Quoin believes planned protocol modifications could accelerate & possibly expand regulatory approvals for QRX003. As Quoin continues to seek assets to complement & enhance its current product pipeline, the company hopes to close at least one M&A transaction as quickly as it can, but noted that current market and economic uncertainty might delay a potential – or even result in not closing – a potential deal. Quoin's goal is to conserve cash to advance clinical efforts for its ongoing programs. The company therefore would not expect to close a transaction unless it can raise funds to support expanded clinical development activities. With about $14m in cash & investments, Quoin believes it has sufficient capital to maintain its growth strategy through the end of 2024.

SUMMARY DATA

52-Week High	**$33.84**
52-Week Low	**$3.64**
One-Year Return (%)	**-83**
Beta	**N/A**
Average Daily Volume (sh)	**21,046**
ADSs Outstanding (mil)*	**1.0**
Market Capitalization ($mil)	**4**
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 2023 Estimate	**N/A**
P/E using 2024 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)
2021					0 A
2022	0 A	0 A	0 A	0 A	0 A
2023	0 A	0 A	0 A	0 E	0 E
2024	0 E	0 E	0 E	0 E	0 E

Loss / Earnings per ADS

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021					-$5.42A
2022			-$11.28A		-$70A
2023	-$0.34 A	-$2.13 A	-$1.95A	-$2.37E	-$9.09E
2024					-$9.36E

Qs might not sum due to rounding, shr counts, ADS ratio 3Q22 PF

Disclosures on page 17

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POSITIVE QRX003 CLINICAL TRIAL DATA; MIGHT ACCELERATE APPROVAL

Positive data from clinical study leads to protocol modifications…

Quoin Pharmaceuticals (QNRX-NASDAQ) reported positive clinical data from the first six subjects enrolled in its ongoing open-label study of QRX003 as a treatment for Netherton Syndrome patients (NS). The company has two active NS studies that are being conducted concurrently. As both trials utilize the same investigators and clinical sites, Quoin expects to garner substantial operational synergies and cost savings. Quoin believes it is the only development company conducting dual NS studies concurrently under an open IND application. To-date, no safety concerns have been reported for any patient enrolled in either study.

One 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, with the test materials applied once daily over a twelve-week period to pre-designated areas of the patient's body. Quoin announced the dosing of the first patient in this clinical trial in December 2022 and has subsequently enrolled and dosed additional patients. Following recent results from the open label study (see below), the number of subjects to be enrolled will be increased from the original 18 to 30. In addition, this will now be a two-arm study with QRX003 at a 4% dose tested against a placebo. Both QRX003 and placebo will be applied twice daily.

The second study is investigating the safety and efficacy of QRX003 in NS patients currently receiving off-label systemic therapy, primarily biologic therapy. The trial is a single arm, open label study investigating the safety and efficacy of QRX003 in these Netherton Syndrome patients, who will continue to receive the treatment throughout the trial. This study is not placebo-controlled. All the patients participating in the trial will be tested with a 4% dose of QRX003 applied once daily every day over 12-weeks to pre-designated areas of the patient's body. Based on results reported last month, the number of subjects in this study will be increased from ten to 20. All new subjects will be tested with QRX003 dosed twice daily.

Last month Quoin announced positive clinical data from the first six patients in the open-label trial. Five of the six subjects evaluated had negligible or absent pruritus (itch) following treatment with QRX003, which represents a substantial improvement for these patients compared to before the study even though all of the subjects enrolled have received off-label systemic treatment for at least one year and/or multiple years. In terms of the Investigator assessed skin scoring system, all six subjects showed improvement. Of the six, three exhibited improvement throughout the study and three at various times over the course of the study. Moreover, all six subjects had positive impressions of QRX003 on multiple metrics that were assessed.

… that might accelerate and possibly expand regulatory approvals for QRX003…

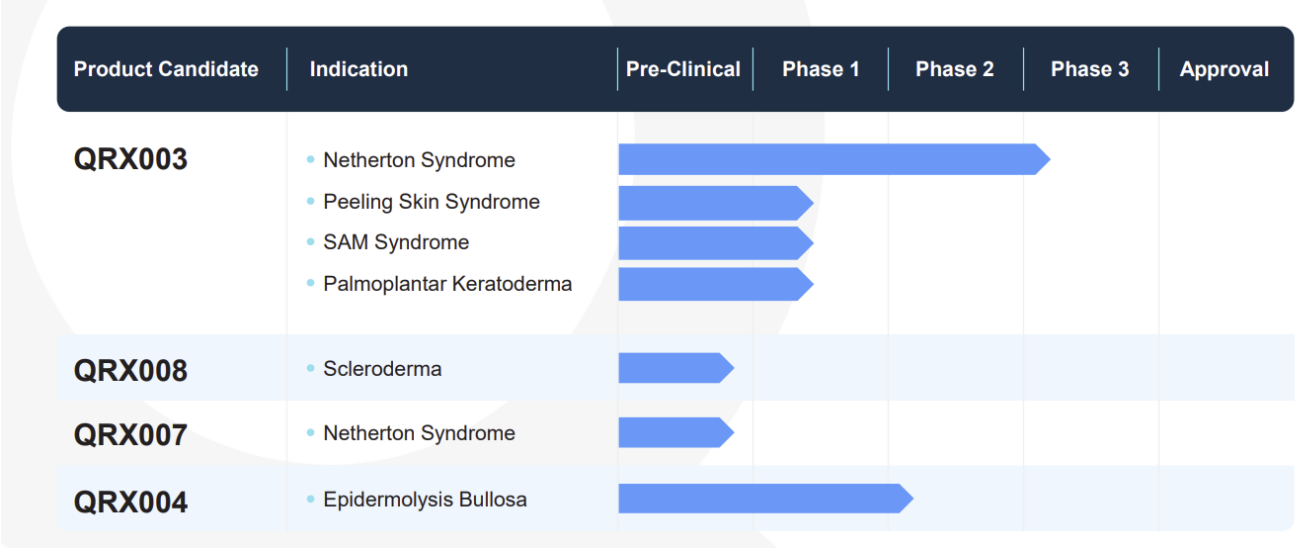
As a result of these early outcomes, the company intends to implement several protocol amendments to its clinical program, including: eliminating the lower 2% dose in the double blinded study based on the clean safety profile observed for the higher 4% dose across both studies to-date, changing the dosing frequency to twice-daily from once-daily and increasing the number of subjects in both studies. Quoin expects these modifications can further optimize its clinical effort. The company believes these protocol modifications could potentially result in accelerating and/or expanding regulatory approvals for QRX003.

Both studies will each have a cohort of subjects dosed once daily and a second cohort dosed twice daily. The company expects this will enable Quoin to assess whether increasing the frequency of dosing can lead to incremental therapeutic benefit.

Importantly, working with its CMO (contract manufacturing organization) has resulted in successfully scaling up a new GMP manufacturing process for the active ingredient in QRX003, the source of which is available exclusively to Quoin, according to the company.

Assets expected to address multiple indications, which might enhance regulatory prospects…

Quoin is optimistic that if the studies are successful, QRX003 for NS could be approved in the U.S. and EU by 2025 and potentially become the standard of care for 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. Other development companies have assets that are expected for evaluation in treating NS, including Azitra, Inc., which submitted an investigational new drug application, or IND, for a Phase 1b clinical trial of its drug ATR-12 in NS patients and received notification from the FDA on January 27, 2023, that it could proceed with the study. However, it is unclear based on government sources whether the ATR-12 study has commenced.



Source: Company presentation

According to the company, the FDA has indicated that about 20 patients tested with QRX003 at the commercial dose might be sufficient for the therapy to attain approval. Quoin also believes that European regulators might view a similar number as sufficient to obtain regulatory approval for QRX003. In addition, the company is working with regulatory consultants to see if QRX003 could qualify for conditional marketing approval in Europe. Conditional marketing approval, which allows for the commercialization of a medical product in advance of formal regulatory approval, is sometimes granted by the EMA when there is no other available treatment for a particular disease when a clearly defined medical need exists.

Potential for additional QRX003 studies, including testing pediatric NS patients…

Moreover, Quoin has also started to assess several other potential studies internationally for QRX003 in NS, including a possible study in pediatric patients. FDA guidelines indicate that developmental treatments should first be studied in adults before being assessed in pediatric populations. Treating pediatric patients is important for a variety of reasons, including that early diagnosis and treatment are important to managing the disease. Moreover, according to NIH, life-threatening complications such as severe cutaneous infections up to sepsis and hypernatremic dehydration “are frequent in infancy.” Quoin notes that newborns with NS have skin that is “red and scaly all over” and “trouble gaining weight in infancy and childhood is common and can be severe.”

Quoin is also evaluating another international study in pre-identified patients in the Middle East. The company has also indicated that it is making progress in providing proof of concept for clinical testing for QRX003 in other indications, including SAM Syndrome, Peeling Skin Syndrome and Palmoplantar Keratoderma.

Australia offers favorable economics for clinical efforts…

The company is optimistic that it will initiate clinical testing of pipeline products with Queensland University of Technology for treatment of Scleroderma and / or NS by year-end 2023. 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. Quoin has licensed two assets for development from Queensland University of Technology: QRX007, also for NS, and QRX008 for Scleroderma. Both of Quoin's dermatological rare disease research programs with Queensland University of Technology for treatment of Scleroderma and Netherton Syndrome continue to move forward and the company is optimistic about launching clinical testing in Australia for at least one of these programs in 2H 2023. Clinical testing in Australia has the dual benefit of lowering costs via economic incentives and usually generating data that is viewed positively by U.S. and other regulators. Quoin expects to benefit from a 43.5% rebate on all research dollars spent in its Australian clinical testing programs.

Cash position expected to support clinical efforts through YE24

The company ended September 2023 with about $14 million in cash and investments. In 1Q23, the company conducted a capital raise that generated net proceeds of about $6 million. Quoin believes its cash position provides sufficient capital for Quoin to maintain its growth strategy through the end of 2024.

Quoin continues to seek to expand its product 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 and is especially interested in acquiring derisk late-stage assets.

Quoin is currently looking at several potential opportunities, having evaluated more than 20 different potential opportunities in 3Q23. The company has narrowed its potential M&A list down to three products for which the company has reached agreement on key financial terms in order to move forward towards a possible transaction of a rare disease asset that management believes would complement its existing product portfolio. Management noted, however, that current market and economic uncertainty, as well as the interest rate environment, might cause delays in consummating a potential transaction or even result in not closing a deal at all. Nevertheless, the company hopes to close at least one transaction as quickly as it can. The company reiterated its goal of conserving its current cash position to advance its clinical efforts for the ongoing programs and therefore would not expect to close a transaction unless it can raise funds to support expanded clinical development activities.

NS: no approved treatments, sizable 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.

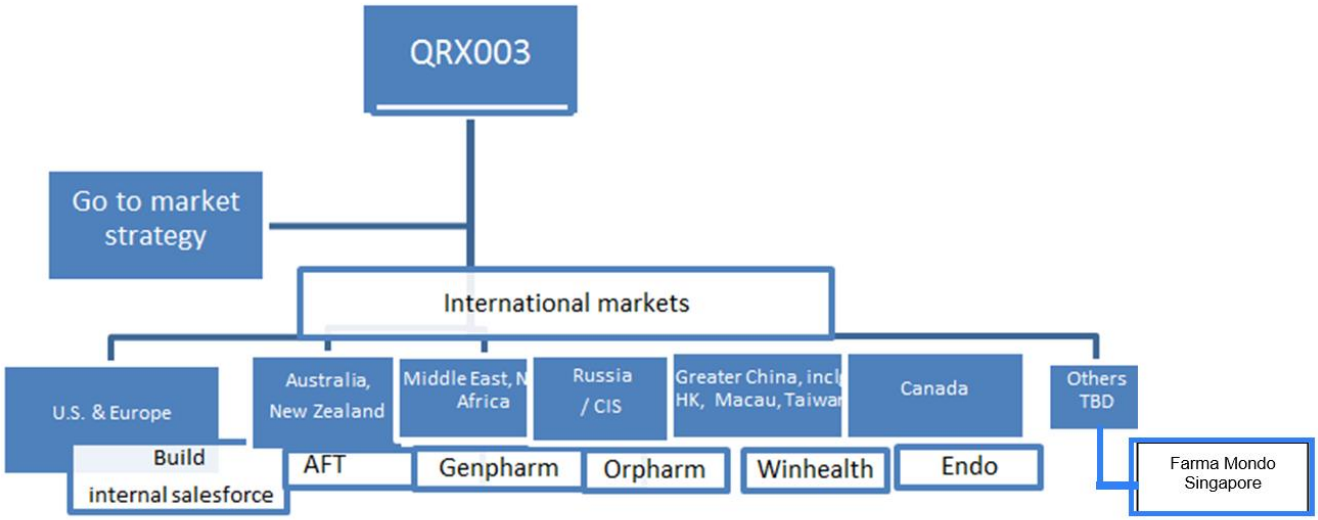
Moreover, in addition to studying QRX003 to evaluate its safety and efficacy in treating NS patients, Quoin intends to study QRX003 for other conditions, as noted, such as peeling skin syndrome and SAM syndrome, among other conditions.

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 and potentially other patients.

U.S. & EU internal sales infrastructure; international Partnerships; Latest for Singapore

To prepare for the expect commercialization of QRX003 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. Earlier this month, Quoin entered into an exclusive license and distribution agreement with Switzerland-based Farma Mondo SA, granting Farma Mondo an exclusive license to commercialize QRX003 in Singapore, once regulatory approvals have been attained.

Over the past several quarters, 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 in some markets ahead of QRX003 receiving regulatory approval. The company is optimistic that generating clinical data can facilitate this.

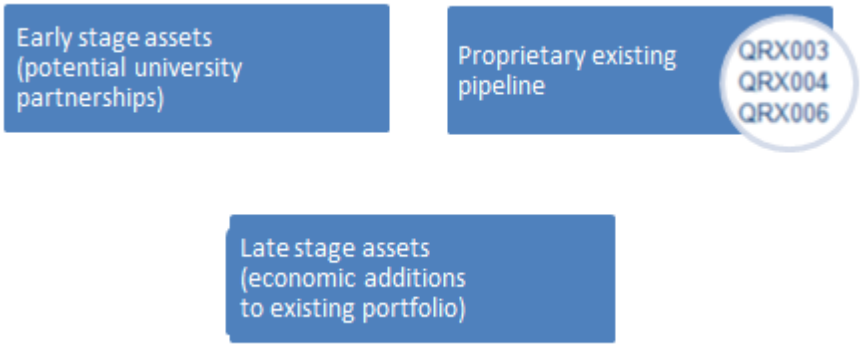


Source: Zacks from Company reports

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 PRODUCT PORTFOLIO & PIPELINE

Quoin Pharmaceutical - Strategy Regarding Product Portfolio



Source: Company reports

QRX003 expected as treatment for multiple indications

The products in Quoin's pipeline generally are being designed to treat multiple indications and 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.

As Quoin's products are being designed to treat multiple indications, lead asset 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.

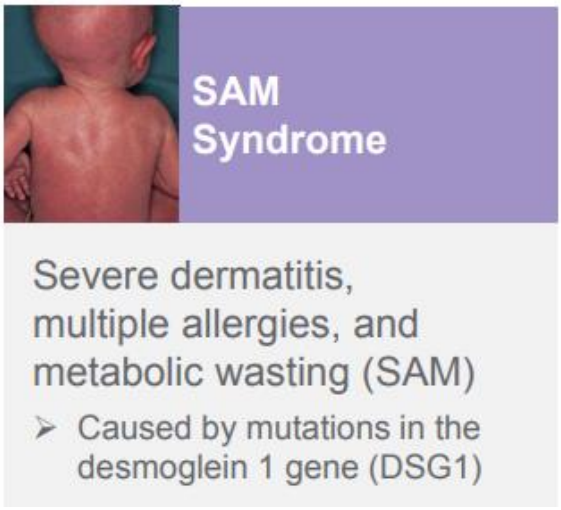
QRX003

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. 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 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 for NS has begun, as discussed above, with Quoin expecting to expand clinical efforts for multiple indications per its overall strategy for the various assets in it product pipeline. 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.



Source: Company presentation

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

As 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 has three lead products in its development pipeline. These assets target a broad number of rare and orphan diseases, focusing on the following illnesses:

Quoin Near-Term Focus

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

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.

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. As noted, however, the company believes it is the only pharmaceutical company conducting dual clinical NS trials under an open IND application. 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 and an IND for ATR-12 for the treatment of Netherton syndrome, as noted, although they do not seem to have commenced clinical trials. We would expect multiple products could achieve market if their clinical trials produce effective therapies.

RARE & ORPHAN DISASES QUOIN LEAD PRODUCTS TARGET

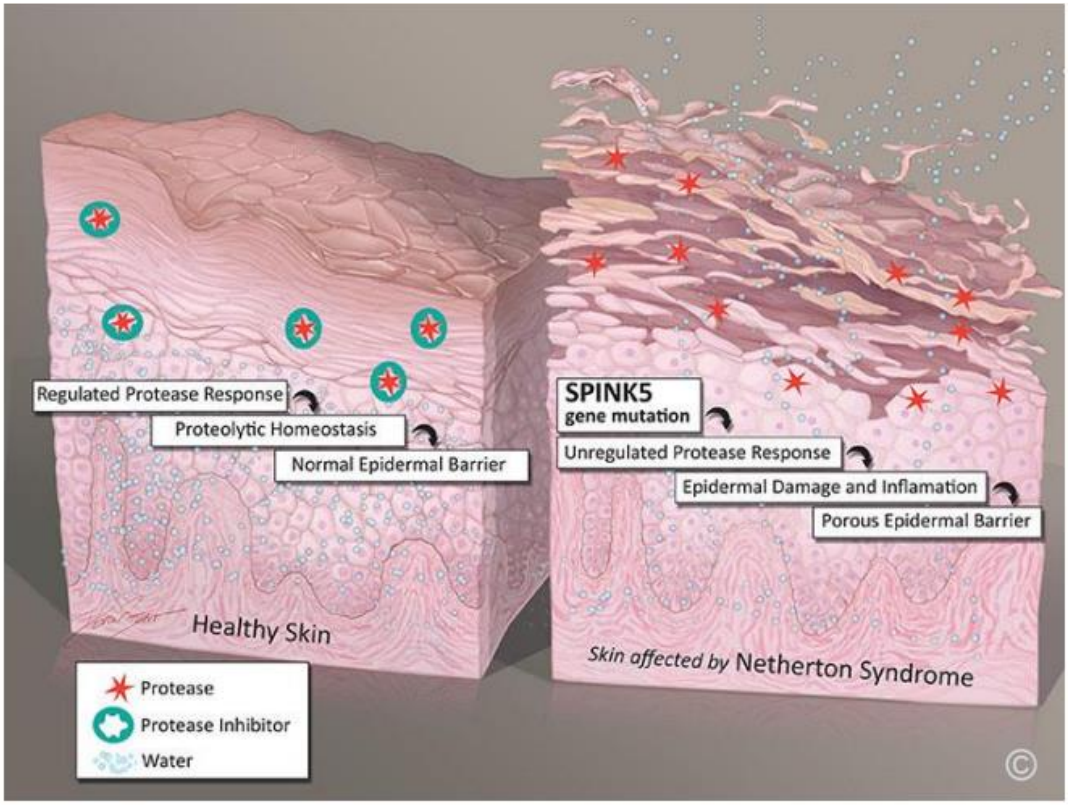
Netherton Syndrome

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.

RECENT RESULTS

Quoin incurred R&D expense of about $759,000 and $746,000 in 3Q23, up about 2% year-over-year. The increase primarily reflects ongoing development efforts principally related to clinical studies for the development of QRX003, as well as the company’s work with Queensland University of Technology in Australia. R&D activities are expected to increase, as Quoin continues to advance the development of QRX003 and other products.

Separately, as of November 8, 2023, Quoin completed a 1 for 60,000 reverse stock split. This resulted in the ratio ADSs to ordinary shares changing from 1 ADS representing 60,000 ordinary shares to 1 ADS representing one ordinary share.

VALUATION

QNRX shares fell steeply in late 2021 amid the general market volatility and rising interest environment that has hurt many emerging microcap companies. The impact was likely exacerbated because Quoin is pre-revenue; the shares have remained under pressure subsequently. Moreover, after the company modified the ADS ratio in July 2023 in order to remain compliant with Nasdaq listing requirements, the shares came under further pressure.

Nevertheless, we remain 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. Given the early stage of the company’s development and the uncertain economic outlook, we assign a 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, depending on these factors, 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. 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, we believe it is reasonable to expect that Quoin could attain product revenue of $14 million to $20 million by 2027-28, 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.

Following the recent ADS ratio revision and reflecting current interest rates and applying a 1.4x multiple (based on other clinical stage companies, low end of the range) to the above noted possible revenue range and discounting back to the present at 8%/year results in a present value of roughly $14 million to $20 million. Applying the above noted 50% confidence metric yields a valuation of $6.94 per ADS. We believe the ADSs can attain this valuation 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 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 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.
- Quoin shares risk not meeting Nasdaq listing compliance.

RECENT NEWS

- Quoin announced 3Q23 results & provided a corporate update on November 8, 2023.
- On October 24, 2023, Quoin announced additional positive clinical data from its open-label trial in Netherton Syndrome.
- On May 24, 2023, Quoin announced that it had achieved 50% enrollment in the open label NS trial.
- Quoin announced that it had dosed the first patient in its open label NS study on March 21, 2023.
- The company closed a $7 million public offering on February 22, 2023.
- Quoin dosed the first patient in its first clinical trial for NS on December 13, 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.
- 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.

PROJECTED FINANCIALS

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

	1Q22	2Q22	3Q22	4Q22	2022	1Q23	2Q23A	3Q23A	4Q23E	2023E	2024E
Revenue	-	-	-	-	-	-	-	-	-	-	-
Operating expenses											
General and administrative	1,588.5	1,941.5	1,582.1	1,472.9	6,584.9	1,683.8	1,635.0	1,366.5			
Research and development	587.6	726.7	745.5	613.1	2,672.8	1,091.7	625.1	758.8	-	-	-
Total operating expenses	2,176.0	2,668.2	2,327.6	2,085.9	9,257.7	2,775.6	2,260.1	2,125.2	2,491.7	9,652.6	9,749.1
Operating loss	(2,176.0)	(2,668.2)	(2,327.6)	(2,085.9)	(9,257.7)	(2,775.6)	(2,260.1)	(2,125.2)	(2,491.7)	(9,652.6)	(9,749.1)
Other											
Forgiveness of accounts payable	(416.0)	-		-	(416.0)	-	-				
Warrant liability (income) expense	(77.2)	-		-	(77.2)	-	-				
Unrealized loss / inc	-	-	3.1	-	(1.3)	(20.4)	-				
Interest income	-	-	(15.1)	(4.4)	(95.7)	(152.1)	34.5	(2.1)			
Other	-	-	714.1	(80.6)	714.1	-	(187.6)	(196.4)	-	-	-
Total other income	(493.2)	-	702.0	(85.0)	123.8	(172.5)	(153.1)	(198.5)	(152.8)	(677.0)	(500.9)
		-									
Net loss	(1,682.8)	(2,668.2)	(3,029.6)	(2,001.0)	(9,381.5)	(2,603.1)	(2,106.9)	(1,926.7)	(2,338.9)	(8,975.6)	(9,248.1)
Dividend on warrant modification			(65.3)		(65.3)						
Net loss to shareholders	(1,682.8)	(2,668.2)	(3,094.8)	(2,001.0)	(9,446.8)	(2,603.1)	(2,106.9)	(1,926.7)	(2,338.9)	(8,975.6)	(9,248.1)
Loss per ADS*	($2.51)	($38.91)	($11.28)	($0.41)	($3.90)	($0.34)	($2.13)	($1.95)	($2.37)	($9.09)	($9.36)
Weighted avg ADSs outstanding	670.9	68.6	273.3	4,846.6	2,421.9	7,646.6	987.2	987.2	987.6	987.6	998.6

Source: Company reports & Zacks One ADS = 1 ordinary share as of 11/23 *3Q22 pro forma for ADS ratio

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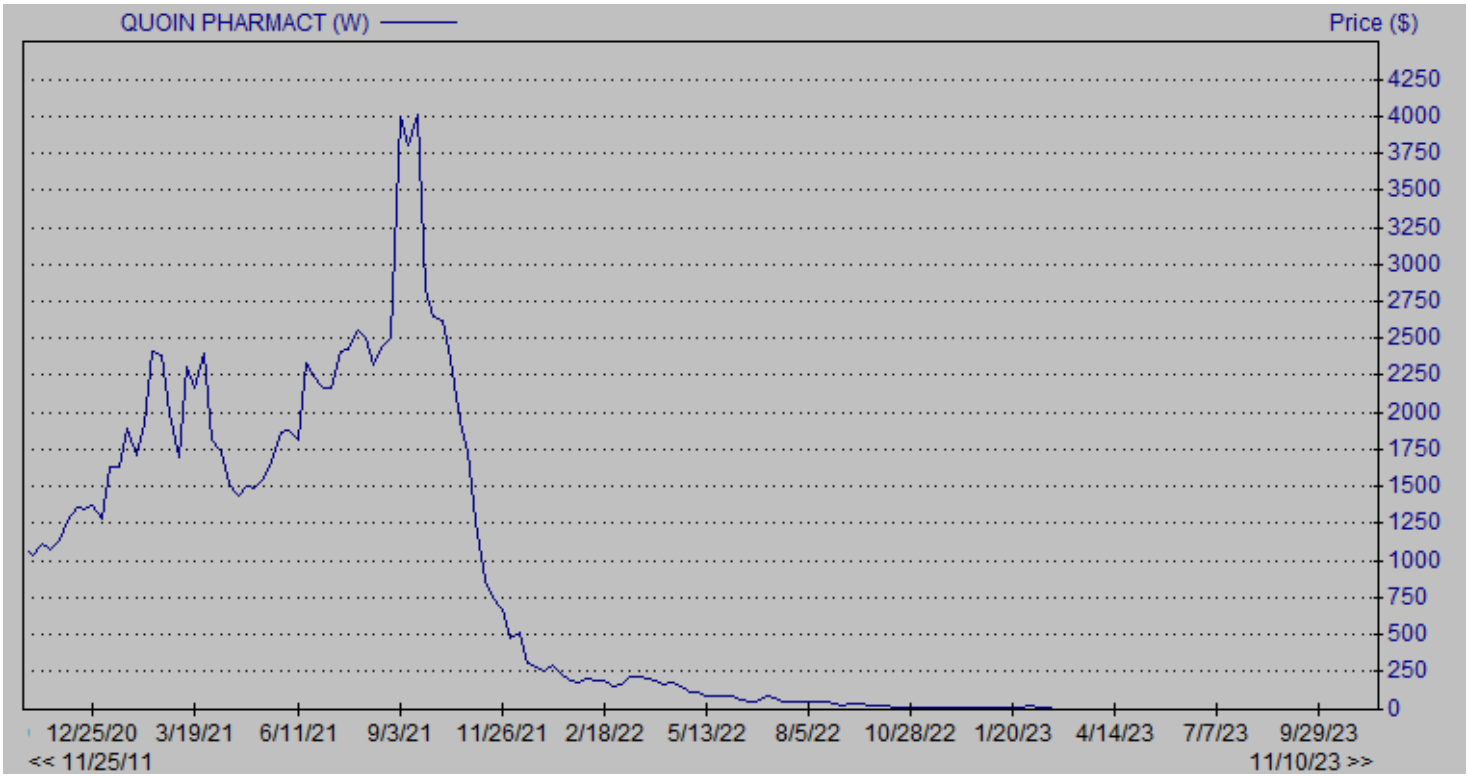
HISTORICAL STOCK PRICE



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