September 28, 2021

Zacks Small-Cap Research

Sponsored – Impartial - Comprehensive

M. Marin
312-265-9211
mmarin@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

XPhyto Therapeutics (XPHYF-OTC)

XPHYF: Leveraging an Extensive Portfolio, Including a Recently Launched COVID Test

XPhyto Therapeutics is a next generation biopharma company focused on developing and commercializing next-generation drug delivery platforms, diagnostic tools and new active pharmaceutical ingredients. XPHYF holds a range of products and assets that are under development, with a recently launched COVID test and many others close to expected commercial launch.

Current Price (07/27/21)	$1.12
Valuation	**$2.00**

OUTLOOK

XPHYF recently launched a rapid point-of-care COVID-19 PCR system in Europe and is also developing a pipeline of low-cost biosensor screening tests. The company is acquiring 3a-diagnostics GmbH to commercialize diagnostic tests, with the goal to develop rapid, low-cost pathogen screening tests for pandemic and oral health applications. XPHYF has an extensive pipeline of diagnostic tests and is also focused on high-margin products designed to capitalize on growth in the overall thin film drug delivery market and the rapid growth of cannabis-based therapeutics.

SUMMARY DATA

52-Week High	**$3.10**
52-Week Low	**$1.00**
One-Year Return (%)	-47.94
Beta	**-0.14**
Average Daily Volume (sh)	**16,489**
Shares Outstanding (mil)	**70**
Market Capitalization ($mil)	**$78**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**N/A**
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 2021 Estimate	**N/A**
P/E using 2022 Estimate	**N/A**

Risk Level	**Above Avg.**
Type of Stock	**Small-Growth**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019					0.2A
2020	0.3	0.1	0.1	0.1	0.3A
2021	0.0A	0.0A	0.0E	0.0E	0.0E
2022					0.4E

Per Share Earnings / Loss

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019					-0.17A
2020	-0.07	-0.06	-0.11	-0.05	-0.30A
2021	-0.08A	-0.06A	-0.06E	-0.06E	-0.26E
2022					-0.28E

Quarters might not sum due to rounding & (PF) share counts

Disclosures on page 17

KEY POINTS

- XPhyto Therapeutics is a bioscience accelerator focused on opportunities in the areas of next-generation diagnostics, drug delivery, and drug development. The company recently launched a rapid point-of-care COVID-19 PCR system in Europe and is developing a pipeline of low-cost biosensor screening tests.

- XPhyto is acquiring 3a-diagnostics GmbH to commercialize diagnostic tests in the 3a-diagnotics pipeline for the detection of infectious diseases. The company's diagnostics goal is to develop rapid, low-cost pathogen screening tests for pandemic and oral health applications to launch in European and other markets.

- As the rebound in travel accelerates, the need for reliable and rapid PCR testing to monitor the pandemic is expected to rise and XPhyto believes its COVID test has several competitive advantages compared to others, including rapid turnaround, accuracy throughout the life of the virus with high sensitivity and specificity, notably when the person is pre-symptomatic or asymptomatic.

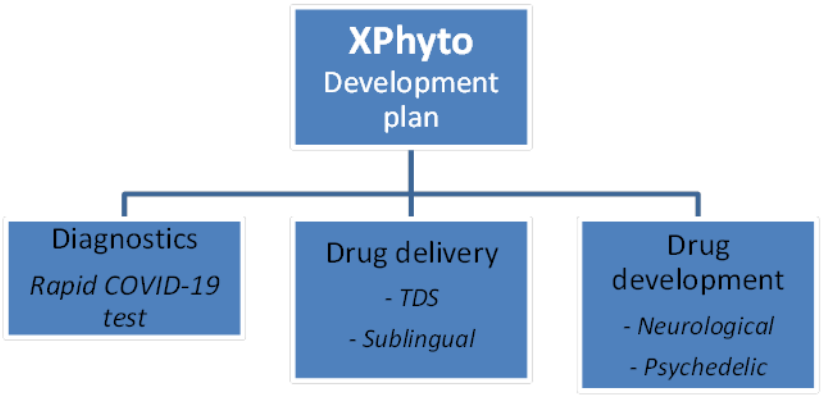
- The company's PCR testing system allows for moderate- to low-volume testing at cost effective price points, which makes XPhyto's test economical for smaller testing centers, as well as for larger venues, as infection rates fluctuate. The company anticipates that its COVID test will have strong adoption.

- Separately, the company also intends to leverage the oral dissolvable drug (ODF) formulations and the cannabinoid and psychedelic expertise and relationships that it has formed to develop and launch innovative medicinal programs. The company also intends to pursue psychedelic drug delivery and API production opportunities and has formed several collaborations towards this goal.

- XPhyto is developing a TDS patch with rotigotine as the active pharmaceutical ingredient, and announced last year that its subsidiary Vektor had finalized the formula for its novel TDS. XPhyto completed a human bioavailability pilot study of its Rotigotine TDS patch for Parkinson's disease in March 2021. Based on the positive results of the study, the company is advancing the Rotigotine development program to a pivotal human trial. Global and European sales of Rotigotine patches in 2019 were approximately $500 million and $250 million (CAD), respectively.

COMPANY OVERVIEW

British Columbia, Canada-based XPhyto Therapeutics Corp. (OTC: XPHYF) is a bioscience accelerator focused on opportunities in the areas of next-generation diagnostics, drug delivery, and drug development. The company recently launched a rapid point-of-care COVID-19 PCR system in Europe and is developing a pipeline of low-cost biosensor screening tests. Among the therapeutic products the company is developing are precision transdermal (TDS) patches and oral dissolvable drug (ODF) formulations, as well as neurological products leveraging cannabinoid and psychedelic compounds. Through an important acquisition, the company's Vektor subsidiary (see below) is focused on supporting XPhyto's growth strategy. XPHYF intends to leverage Vektor's transdermal and sublingual delivery technology to introduce therapeutics for a variety of conditions. Vektor focuses on developing generic and hybrid-generic drug formulations for neurological conditions through its transdermal and oral dissolvable drug delivery platforms. Products in Vektor's development pipeline target large and growing neurological markets. The company also intends to leverage the cannabinoid and psychedelic expertise and relationships that it has formed to develop and launch innovative medicinal programs.

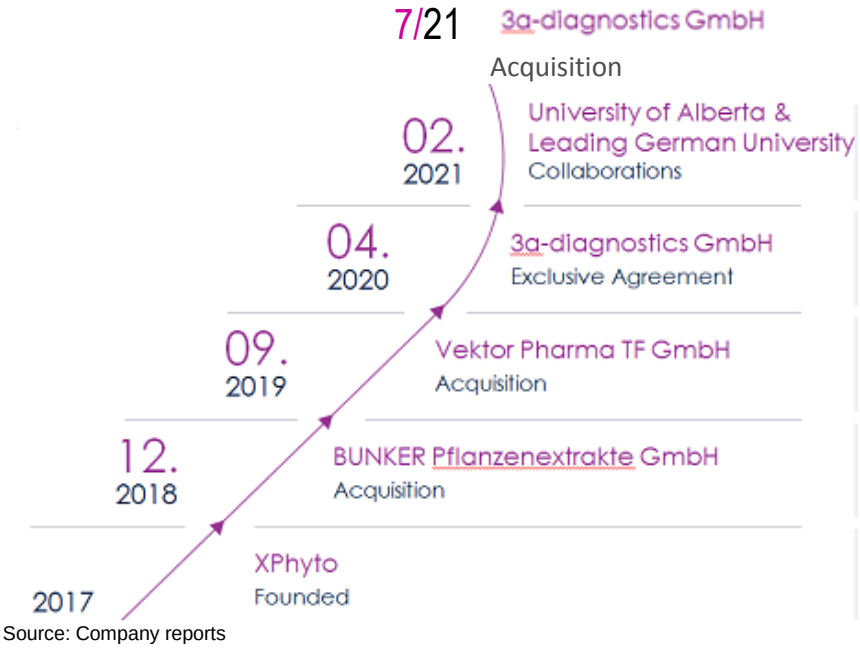


Source: Company reports

Leveraging M&A To Lay the Infrastructure For Growth

The company views strategic M&A as an avenue to build value for shareholders. Since its founding in 2017, over the past few years XPhyto completed transactions that position XPHYF to benefit from the opportunities presented in its target markets. In 2019, for example, the company acquired Vektor Pharma TF GmbH, which forms an integral part of the company's strategy to cross-leverage a growing portfolio of assets. In 3Q21, XPhyto signed an agreement to acquire 3a-diagnostics GmbH.

XPhyto Timeline



Source: Company reports

In addition, the company also formed several important partnerships to advance development and commercialization of its expanding product pipeline. For instance, XPHYF forged a commercial partnership with German-based 3a-diagnostics GmbH to jointly develop and launch oral diagnostic products, beginning with a COVID-19 rapid test. As noted, the company announced that it had signed a definitive agreement to acquire 3a on July 20, 2021. The company also has two psychedelic medicine collaborations underway with leading institutions in Germany and Canada.

With an extensive and growing product pipeline, the products XPhyto has launched or expects to launch near-term are:

- European approved COVID-19 rapid point-of-care PCR system
- European registered oral inflammation rapid biosensor
- Late-stage Parkinson's generic rotigotine transdermal (TDS) patch
- Three late-stage hybrid-generic neurological oral dissolvable (ODF) therapeutics

In some cases, as with its Parkinson's TDS patch (see below), XPHYF's strategy is to launch approved generic drugs once a proven medication comes off patent protection.

DIAGNOSTICS

As noted, XPhyto entered into a strategic alliance with, and currently in the process of acquiring 3a-diagnostics GmbH to commercialize diagnostic tests, including for COVID-19, influenza A, and others in the 3a-diagnotics pipeline for the detection of infectious diseases, under license from 3a-diagnostics. 3a-diagnostics operates laboratory facilities in Germany. Together, the two partners plan to develop and commercialize:

- 3a's COVID-19 RT-PCR rapid test (EU approved)
- 3a's COVID-19 saliva test (in development)
- 3a's biosensor pipeline (oral inflammation biosensor EU registered), and
- incorporate the biosensors into Vektor Pharma's ODF delivery platform (see below)

Developing a Portfolio of Low-Cost Point-of-Care Screening Tests …

The company's diagnostics goal is to develop rapid, low-cost pathogen screening tests for pandemic and oral health applications to launch in Germany and other European markets with 3a-diagnostics. In addition to the COVID-19 tests described below, XPhyto intends to develop a high-throughput biosensor screening platform for rapid identification of new biosensor targets for future pathogen-specific applications. The company is particularly focused on developing low-cost point-of-care screening test systems such as those used for its rapid COVID-19 test, as discussed below.

… Including Important COVID-19 Tests

Tests currently being used to test for COVID-19 generally are either molecular tests that detect the virus' genetic material or antigen tests that detect specific proteins on the surface of the virus, according to the FDA. Until recently, most rapid diagnostic tests have been based on antigen models. These tests rely on a nasal or throat swab, with the sample then used to detect the active presence of a coronavirus protein. Generally, antigen tests are less expensive and provide results faster than molecular tests, but are considered to be considerably less accurate than molecular tests because they cannot determine the presence of antigens unless the test is conducted while the person is at a high viral load, *near peak infection* with a sufficient level of coronavirus protein for the protein to be detected. Up to 20% of antigen tests can return false negative results, according to UC Davis.

Other Tests Often Are Costlier With Longer Turnaround Times & Frequently Inaccurate

XPhyto believes its tests have several competitive advantages compared to others, including rapid turnaround, accuracy throughout the life of the virus with high sensitivity and specificity, notably when the person is pre-symptomatic or asymptomatic. Also, the test is agnostic to PCR test kits, as well as providing ease of use, at point-of-care sites and is competitively priced. Moreover, the company's PCR testing system allows for moderate- to low-volume testing at cost effective price points. This makes

XPhyto's test economical for smaller testing centers, as well as for larger venues, as infection rates fluctuate. The company believes the need for rapid and accurate testing results is growing.

XPhyto's molecular COVID-19 test is a point-of-care reverse transcriptase -polymerase chain reaction (RT-PCR) test that is based on proprietary technology. Reverse transcription-polymerase chain reaction can be used to identify certain changes in a gene or chromosome or activation of certain genes. In turn, this can help diagnose certain diseases such as the SARS-CoV-2 virus.

Importantly, PCR tests are more sensitive and reliable than antigen tests and can detect the presence of coronavirus at earlier stages when the coronavirus material is still replicating within the person's body and the relative viral load is lower. This means that people who are pre-symptomatic and/or asymptomatic but still have been exposed to the virus can test to determine the presence of coronavirus protein in their system. Similar to an antigen test, the sample is collected using a nasal or throat swab. The company notes that PCR tests are the highest standard of COVID testing that have been adopted.

XPhyto's RT-PCR test is rapid, low-cost and disposable. Importantly, it requires no additional equipment other than a small portable proprietary Covid-ID lab and off-the-shelf PCR device, so the test can be conducted almost anywhere. For example, it is relatively easy for personnel to administer the test at high traffic testing locations such as airports, train stations and universities, among other sites. It also yields rapid results. The test takes about five minutes to administer, and the results are available in roughly another 20 minutes. XPhyto believes its test produces accurate results in only 25 minutes and is cost effective.

To perform the test, the Covid-ID lab requires only a 20-minute PCR run time without prior RNA extraction as part of sample preparation. After the RT-PCR, the SARS-CoV-2 virus is detected on a test chip. If the test detects the presence of SARS-CoV-2, the result can be read on-site immediately. XPhyto has addressed the challenges previously associated with PCR tests -- longer time to yield results and generally higher cost – reducing the time involved in obtaining results and also producing a cost effective test.

The company's Covid-ID Lab is the foundation of its COVID testing technology platform, which, as noted, is economical at low to mid-range sample volumes. The portable Covid-ID Lab has the capacity to process up to 96 test samples simultaneously within 20 minutes. By comparison, most other PCR tests are batch shipped to special centralized laboratories and processed there. This takes longer and is generally more expensive. The Covid-ID lab required for XPhyto's test can be installed on-site using relatively inexpensive equipment. Given that the numbers of people who have been exposed to and contracted the virus but are asymptomatic is high, the company believes this test has substantial commercial prospects.

XPhyto recently announced that it has signed a master supply agreement with two German diagnostics, testing, and medical logistics companies that operate ten COVID-19 test centers in Berlin, Germany: Beovita GmbH & Co. KG and Tackleberries GmbH.

As the rebound in travel accelerates, the need for reliable and rapid PCR testing to monitor the pandemic is expected to rise and the company believes this agreement represents an important commercial milestone. The company delivered about 1,000 Covid-ID Lab tests to test centers in Berlin to evaluate XPhyto's new PCR test system. Covid-ID Lab sample processing will occur directly at the sample collection site. By comparison, conventional PCR testing models collect samples, which are then shipped to large centralized and automated labs for processing. XPhyto's decentralized testing model is expected to yield faster results, more versatile test center options, and cost effectiveness at lower testing volumes.

The company anticipates that its test will have strong adoption in densely populated metropolitan areas and at transportation hubs such as train stations and airports where the need for rapid, accurate and cost-effective tests is high. The company has a distribution, storage and logistics partner in Germany, Max Pharma GmbH. Moreover, with cases falling in many markets, test sample numbers are also falling,

which makes it less economic to process PCR tests at large centralized laboratories. Larger labs might have to wait for sufficient samples to be submitted in order to process them in a cost-effective manner, which could, in turn, delay results.

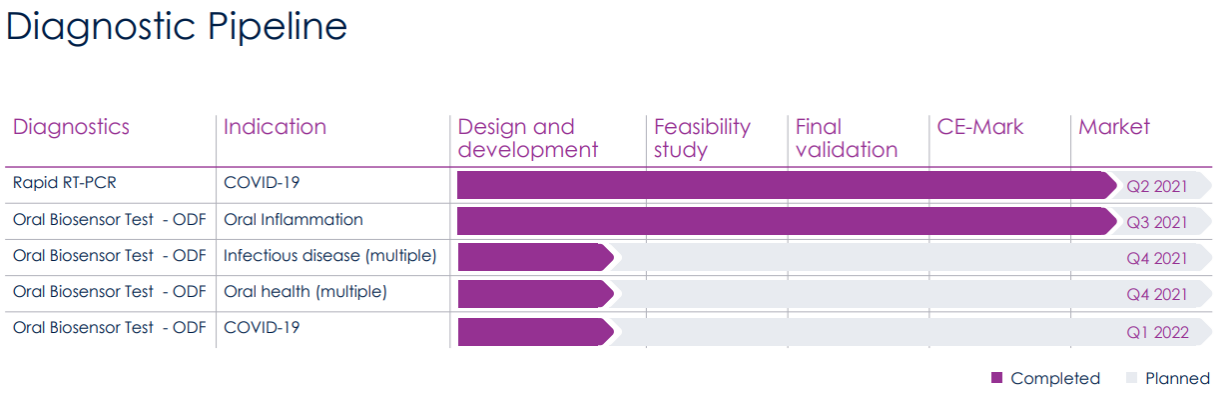
XPHYF is also developing an ultra-rapid oral dissolvable biosensor for COVID-19. Similar to the company's other proprietary biosensor products, the self-administered screening test dissolves in saliva and releases a bitter (but safe) compound within five minutes if exposed to COVID virus. XPhyto's ultra-rapid biosensor test targets home-users and high-volume areas that require immediate results. XPhyto and 3a have registered their first biosensor test in oral inflammation with the German authorities.

With COVID-19 cases spiking in many markets, the need to test for a variety of reasons, such as ahead of travel or to attend school in-person continues to grow. In fact, many port authorities have offered incoming travelers the option to test-out of mandatory extended quarantine requirements that would otherwise be required once they reach their destination. The need for COVID-19 testing is expected to persist for the foreseeable future. XPHYF has a team in Germany working on the COVID-19 test that has extensive experience in the biotech and Big Pharma industries, including product commercialization.

Initial Focus: Germany

The company expects to manufacture the tests in Germany and Austria initially and subsequently, as sales ramp in other markets, to obtain additional manufacturing capability in other markets. XPhyto is also engaged in discussions with potential distribution and wholesale partners for the COVID-19 test in other European markets and the Middle East. For example, the company recently delivered 2,000 Covid-ID Lab tests to an established medical distributor in Israel for clinical evaluation towards commercial regulatory approval and potential distribution. The Israeli distributor's customer base includes government and private institutions such as hospitals, pharmacies and other health care providers in Israel and other Middle Eastern countries.

In addition to the COVID-19 tests noted above, XPHYF has a growing pipeline of proprietary oral tests for the rapid detection of bacterial and viral pathogens, including influenza A, H1N1 (swine flu), H5N1 (avian flu), group A Streptococcus, peri-implantitis, among other disorders.



Source: https://xphyto.com/wp-content/uploads/2021/06/XPhyto-Deck.pdf

On August 30, 2021, XPhyto and 3a announced that they recently successfully registered their first biosensor test in oral inflammation with the German authorities for an easy to use self-check. The biosensor serves as a check to determine if heightened levels of certain bacteria and viruses are present. The thin film dissolves after it is placed on the tongue and after about five minutes, the biosensor releases a bitter taste when oral inflammation is present. The at-home self-check can be performed without the need for specific medical knowledge or training, analytical equipment or a power supply. The company believes that this registration provides proof-of-concept of the prospects of its biosensors technology.

DRUG DELIVERY

Vektor Pharma

XPhyto conducts its drug delivery business through its wholly-owned subsidiary, Vektor Pharma TF GmbH, which designs, tests and manufactures thin film drug delivery systems and transdermal patches (TDS) for slow release and oral dissolvable film (ODF) sub-lingual strips for immediate bioavailability. Vektor operates a testing laboratory and production facility in Germany.

Oral thin films (OTFs), also known as ODFs, are polymeric films designed to deliver therapeutic treatments. As they are absorbed, the active pharmaceutical ingredients are routed directly to the patient's circulatory system directly, bypassing the digestive system. OTFs can rapidly deliver hydrophilic (dissolves when in contact with water) as well as hydrophobic (repels or does not dissolve upon contact with water) active compounds. A hydrophile is a molecule or other molecular entity that is attracted to water molecules and tends to be dissolved by water. Hydrophobicity is the physical property of a molecule that is seemingly repelled from a mass of water (known as a hydrophobe). XPhyto's ODF platform is compatible with most drugs and with 3a-diagnostics GmbH's peptide biosensors.

Vektor is also a narcotics manufacturer, importer, and researcher in Germany. It holds several narcotics licenses, including authorizations related to conventional and cannabis-related prescription medications, related to severe pain, buprenorphine, cannabis, dronabinol, fentanyl, hydromorphone, oxycodone, and THC, among other compounds.

Vektor holds several narcotics import and manufacturing licenses including an import permit for drug dosage forms and cannabis, a manufacturing permit for clinical samples and final drug product release and an analytical permit for chemical and physical testing, as well as a permit to handle narcotic drugs and animal tissue.

Transdermal patches are used widely as a drug delivery mechanism, according to the NIH. Transdermal delivery, a relatively recent innovation, is a technology that enables precise drug administration through the skin for systemic effects. Oral dissolvable films are also a relatively recent innovation and one in which XPhyto has developed expertise. These types of films are designed to dissolve when they come in contact with the tongue. As the film is usually placed under the tongue, it dissolves through the saliva and is absorbed through the oral mucosa. Importantly, this means of deliver means that the drugs do not have to pass through the digestive system in order to enter the bloodstream via the liver, but can be absorbed directly through the oral mucosa without being metabolized first. In turn, this makes the active ingredient significantly more precise to dose because the absorption capacity does not depend on the digestion or the ingested food. Moreover, the active ingredient is available more quickly because it does not first have to be metabolized.

Generic Drug Formulation Strategy

XPHYF's strategy is to launch approved generic drugs once a proven medication comes off patent protection and hybrid-generic drugs that incorporate approved medication into new delivery systems. For example, this is the strategy the company is pursuing with its Parkinson's TDS and cannabinoid ODFs respectively. Vektor has worked for a range of third-party drug companies to develop new and generic dosage formulations based on its sublingual and transdermal drug delivery platforms and has produced generic drug formulations of fentanyl, rivastigmine, and clonidine.

Generic drugs are new formulations of off-patent drugs. They generally are sold by either the manufacturer of the original patent-protected drug or a third-party generic manufacturer such as XPhyto that can replicate the formulation and market a less costly version of the drug, while benefitting from the marketing efforts around the original branded product. The pathway to regulatory approval is generally shorter due to the existing approval for the original product. The pathway to approval with hybrid-generic

formulas are also generally shorter, as they generally can at least partially rely on the existing approval for the active pharmaceutical compound which is delivered in a new form, such as an ODF. The uptake of generic versus branded drugs varies from market to market, according to the International Generics Pharmaceutical Alliance (IGBA). According to Outsourcing-Pharma newsletter, generic drugs account for about 29% of the of the European drug market measured by revenue. XPHYF, through Vektor, is producing a generic Parkinson's topical formulation TDS, as well as three hybrid-generic neurological ODF formulations using approved cannabinoid compounds, as noted.

DRUG & THERAPEUTICS DEVELOPMENT

Including psychedelic medicine …

The company also intends to pursue psychedelic drug delivery and API production opportunities and has formed several collaborations towards this goal. In November 2020, the company expanded an agreement with Prof. Dr. Raimar Löbenberg to commercialize a wide range of psychedelic compounds under testing and research licenses. Under this agreement, the company is developing industrial-scale production of pharmaceutical-grade mescaline, a psychedelic compound which is found in certain cacti. Through its affiliation with Applied Pharmaceutical Innovation (see below), the company intends to focus on the synthesis of pharmaceutical grade mescaline, a plant-based compound that is considered relatively safe as an emerging psychedelic treatment for addiction, depression, PTSD, and substance abuse.

XPhyto recently signed an agreement with Applied Pharmaceutical Innovation, which is a non-profit institution at the University of Alberta, to synthesize pharmaceutical grade psychedelic compounds and develop procedures to obtain regulatory approval for their commercialization. The company continues to expand its portfolio of psychedelic compounds and expects to incorporate these compounds into its thin film drug delivery platforms.

XPhyto expects that its expertise in using sublingual and transdermal therapeutics to deliver precise dosing of very dose-specific drugs will be a strong competitive advantage in the psychedelic industry. XPhyto's psychedelic research is being led by an academic, Prof. Dr. Löbenberg, with strong credentials who founded and directs the Drug Development and Innovation Centre at the University of Alberta and was formerly president of the Canadian Society for Pharmaceutical Sciences. Dr. Löbenberg is a director of XPhyto.

Psychedelic medicine programs moving forward on schedule

The company believes the production of pharmaceutical grade psychedelics, followed by the standardization of dosage formulations with precise, predictable and efficient drug delivery for clinical study and therapeutic use, represents a significant market opportunity (see below). XPhyto recently provided an update on this initiative; its GMP mescaline synthesis program is on schedule, with the completion of initial production batches.

There have been few meaningful advances in the development of psychiatric drugs over the past several decades since selective serotonin reuptake inhibitors (SSRIs) were introduced commercially, despite the many drawbacks of current standard-of-care treatment, including that up to 30% of patients fail to respond and many of the current therapies also can be highly addictive. Standard of care therapies such as SSRIs are frequently prescribed antidepressants, as are MAO (monoamine oxidase) inhibitors and TCAs (tricyclic antidepressants), which have many negative side effects. For example, SSRIs that are widely used for depressive disorders sometimes lead to anxiety, sleep disruptions and weight gain.

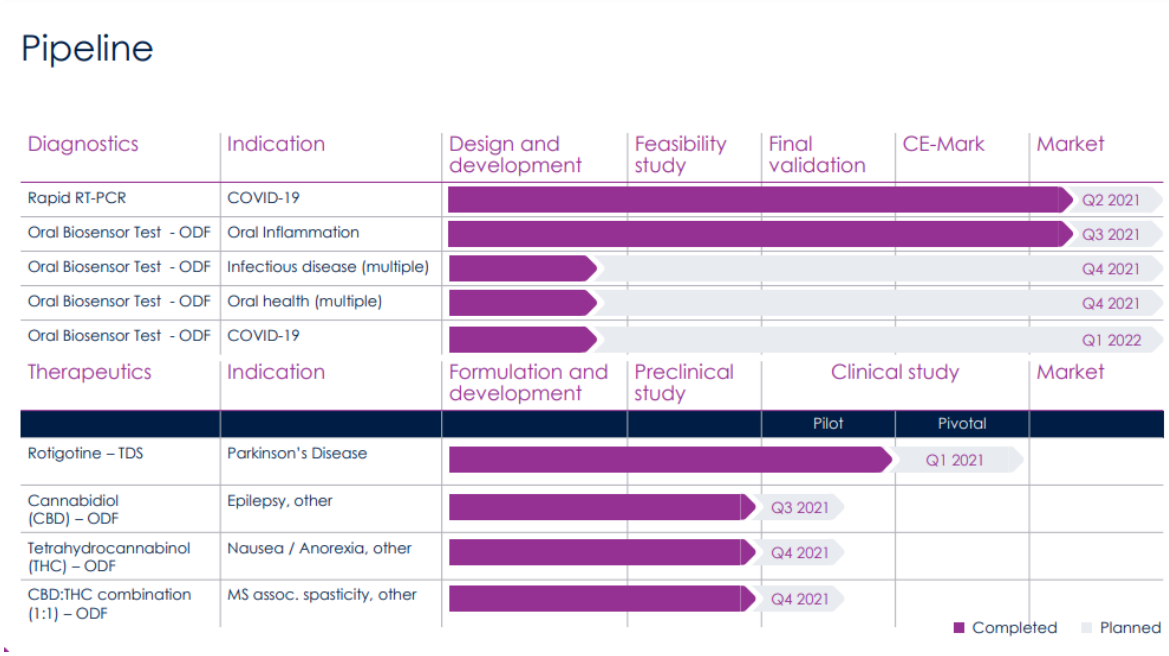
Conversely, the psilocybin in psychoactive mushrooms, mescaline in certain cacti, and the synthesized compounds in LSD and MDMA, have been shown to be much less harmful, with fewer negative side

effects. In fact, a recent study at Johns Hopkins of adults with major depression found that two doses of the psychedelic substance psilocybin, given in conjunction with supportive psychotherapy, "produced rapid and large reductions in depressive symptoms." The company believes that psychedelic medicine program could provide improved treatment compared to what is currently available for treating certain neurological and mental health conditions such as depression, anxiety, addiction, and trauma-related stress disorder.

PIPLELINE

XPhyto's product pipeline is focused on high-margin products designed to capitalize on growth in both the rapid screening test market, overall thin film drug delivery market and the rapid growth of cannabis-based therapeutics.

In addition to its diagnostic pipeline, the company has an ODF development program underway for the delivery of the active pharmaceutical ingredient cannabidiol to treat epilepsy and an ODF development program for the delivery of the active pharmaceutical ingredient THC to treat several conditions.



Source: https://xphyto.com/wp-content/uploads/2021/06/XPhyto-Deck.pdf

In anticipation of strong demand for its growing portfolio of products and delivery systems, XPhyto's Vektor subsidiary expects to begin construction of a new commercial drug production plant in Germany in 2021 and has acquired property near its current laboratory facility. In addition to developing and manufacturing XPhyto products, the plant is also expected to be used for contract development and/or manufacture of products for third-parties.

Parkinson's

Parkinson's is a neurodegenerative disease with symptoms that manifest progressively over the course of several years and differ slightly from one person to another. Many people with Parkinson's experience some form of tremors and many have mobility-related motor and balance issues. According to the NIH, Parkinson's is the second most common neurodegenerative disorder among people over the age of 50. As population age, the number of aggregate Parkinson's cases in Europe, the U.S. and Canada is expected to nearly double by 2050.

There are no medications currently that cure Parkinson's. Researchers are working to identify biomarkers that can lead to earlier diagnosis of Parkinson's, but currently all therapies used for the disease are designed to minimize its symptoms. While there is no standard of care treatment to cure Parkinson's disease, UCB Pharmaceuticals markets Neupro®, a rotigotine transdermal patch that comes out of patent protection shortly. Neupro patches are approved for the treatment of Parkinson's disease in Europe and the United States.

XPhyto is developing a TDS patch with rotigotine as the active pharmaceutical ingredient, and announced last year that Vektor had finalized the formula for its novel TDS. Rotigotine (which is sold under the brand name Neupro) has been approved for the treatment of Parkinson's disease and restless legs syndrome in Europe and the U.S. XPhyto completed a human bioavailability pilot study of its Rotigotine TDS patch for Parkinson's disease in March 2021. Based on the positive results of the study, the company is advancing the Rotigotine development program to a pivotal human trial. Global and European sales of Rotigotine patches in 2019 were approximately $500 million and $250 million (CAD), respectively.

XPhyto's patch will be sold as a generic product, once the patent protection on Neupro® expires in the EU shortly. As a generic "off-patent" drug, it has been formulated as a once daily transdermal patch to provide a slow and constant supply of the drug over the course of 24 hours.

Generic medications can be sold once patent protection on the branded product has ended. They are less costly than the branded product and are designed to work in similar ways as their brand-name patented drugs. In addition to the Parkinsons treatment, Vektor intends to develop other transdermal delivery systems for medications that can be given through patches or sublingual strips.

Clinical Studies

XPhyto expects 2021 to be a transformational year, as the company has assembled the tools and infrastructure through M&A and by forging partnerships and supply agreements to leverage the opportunities presented by its various target areas. Each study is expected to be conducted over roughly a two-week period as an open label, randomized, crossover, two-period, two-sequence, single dose pilot study to assess the relative bioavailability of each product.

XPhyto Clinical Study Timeline

1Q 2021 - Rotigotine - transdermal patch in Parkinson's disease completed;
3Q 2021 - CBD - oral/sublingual strip in treatment resistant Epilepsy;
4Q 2021 - THC - oral/sublingual strip in anorexia/nausea; and
4Q 2021 - CBD:THC (1:1) - oral/sublingual strip in Multiple Sclerosis associated spasticity.

Source: Company reports

If the results of the studies are positive, XPhyto intends to advance the respective products toward a final pivotal study and subsequent application for regulatory approval and is engaged in discussions with potential commercial partners and distributors. With XPhyto optimistic about its COVID-19 tests and other products, the company expects revenue to begin to ramp up in 2022 and beyond, as it targets product launches in areas with significant market demand.

ADDRESSABLE MARKET OPPORTUNITIES

XPhyto holds a range of products and assets that are under development, with many close to expected commercial launch. We highlight some parameters of the various markets XPhyto is targeting below.

Diagnostics Screening Products

The global rapid test market is projected to reach $39.1 billion by 2023 with a CAGR of 8.9%. according to market research firm Allied Market Research. The infectious disease segment of this market is forecast to enjoy double digit growth. Specific to COVID-19 testing, although it is early and forecasts vary, most research suggests significant growth for the COVID-19 diagnostics market. Polaris Market Research forecasts that the COVID-19 diagnostics market could reach $23.67 billion by 2027, with forecasts from other market research firms even higher. These expectations are driven by concerns about increases in COVID-19 cases around the world and the need for testing to help minimize the spread of the disease.

Generic Drug Market

The company has a generic drug delivery strategy whereby approved generic drugs can be delivered using Vektor's novel drug delivery platforms. XPhyto believes its generic drug delivery model is scalable and provides a significant economic opportunity, particularly in Europe, reflecting both transdermal patches and oral dissolvable films.

Generics are off-patented drugs that are bioequivalent to branded medications in terms of dosage, strength, quality, form, effect, intended use, side effects, and route of administration. The global generic drug market reached a value of US$115.2 billion in 2019, growing at a CAGR of 11.7% from 2014 to 2019. Generic drugs have witnessed a substantial rise in production, reflecting their lower cost compared to branded drugs and because they generally do not require extensive R&D and testing because they are based on proven formulations.

According to market research firm IMARC Group, the global generic drugs market size reached $386 billion in 2020 and is forecast to reach $517 billion by 2026, with expected growth driven by the rising Increasing prevalence of chronic diseases, particularly as populations in many markets age.

Psychedelic medicine programs

The mental health market represents a market estimated at about $70 billion per annum worldwide, according to Bloomberg. Annual sales of antidepressants represent more than an estimated $14 billion, according to market research firm Allied Market Research, with estimates from other sources even higher. XPhyto believes that psychedelics are poised to earn a significant share. Anxiety disorders and/or depression affect up to 25% of the respective populations in Europe and the U.S. Market intelligence firm Data Bridge Market Research forecasts that the psychedelic pharmaceuticals market could reach nearly $7 billion by 2027.

RECENT RESULTS

XPHYF is largely pre-revenue at this stage. Most of its revenue comes primarily from services Vektor performs for third parties. In 2Q21, XPHYF recorded revenues of $7,685 compared to higher average quarterly revenue in most periods of 2020. Revenue declined primarily because Vektor's operations focused almost exclusively on R&D related to XPhyto's growth initiatives. The company is optimistic about the recently-launched COVID test. Nevertheless, we believe it will take time before this and other products contribute in a more meaningful way and we do not anticipate much revenue impact in 2021.

Operating expenses in 2Q21 increased to $4.0 million from $3.4 million in 2Q20, primarily reflecting expenses associated with start-up and other new business costs. Operating expenses included marketing and advertising expense of $2.1 million in 2Q21, up about 47% from $1.4 million in 2Q20, as XPHYF expanded its marketing and investor relations efforts in 2Q21 ahead of the anticipated commercial sales launch of products in its pipeline. The net loss of about ($4.2) million compared to a net loss of ($3.6) million recorded in last year's 2Q. On the higher share count, the loss per share of ($0.06) was flat year-over-year.

VALUATION

The company is optimistic about the prospects for the COVID-19 test and other products in its pipeline, as noted. While it is difficult to know the revenue arc for XPHYF at this early stage, just based on the sizable need for COVID testing, we believe the current share price of about $1.10 does not reflect the fundamental value of the company's pipeline and prospects and would anticipate upside if the company continues to advance its candidates. We believe the substantial size of the company's target markets and the company's view of the competitive advantages of its diagnostic and delivery platforms suggest strong revenue growth if the company successfully executes its strategy.

In our view, XPHYF's differentiated products and programs imply that there are no direct publically traded peers. Moreover, we would also expect XPHYF to have a higher growth rate in the early years of commercializing its assets. In addition, other companies that are engaged in introducing new therapies and / or diagnostics and are at a similar stage of development have a wide range of price-to-revenue multiples on forward estimates. Nevertheless, we believe the average price-to-sales multiple of companies in this comparison of 14x provides a valuation benchmark for XPHYF.

Therefore, applying a 14x multiple to our $8 million to $14 million 2025E revenue forecast and discounting back at 3% results in a present value of nearly $102 million to $179 million for XPHYF, or a mean value of about $2.00 per share. As the company advances other assets in its portfolio, our forecast could change.

Any delay or failure in development or regulatory approval could cause the share price to decline and represents 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 XPHYF achieving its objectives, and to our valuation, include the following.

- The company's potential commercialization timelines might be delayed.
- The company's assets might not receive regulatory approval.
- Some of the company's assets might fall short of commercial expectations.
- Competition, including from other companies developing therapies to meet the needs that XPHYF's product portfolio address, could increase.
- The company might need to raise additional capital sooner than management anticipates.

RECENT NEWS

- XPhyto announced the EU registration of the first commercial biosensor for oral disease on August 30, 2021.
- On July 28, 2021, XPhyto announced that its acquisition target, 3a-diagnostics, reported breakthrough identification of COVID-19 biosensor candidates.
- On June 30, 2021, XPhyto announced that it supplies 10 test centers in Berlin with 25-minute COVID-19 PCR test.
- XPhyto provided a progress report on the mescaline program for psychedelic therapies on June 8, 2021.
- XPhyto announced that its rapid Point-of-Care COVID-19 PCR test was offered for sale in Germany on May 20, 2021.
- On April 28, 2021, XPhyto announced its pursuit of market access in Israel for its COVID-19 PCR Rapid Test.
- XPhyto signed a German distribution, storage and logistics agreement for its 25-Minute COVID-19 PCR Test on April 21, 2021.
- On February 22, 2021, XPhyto announced that it has assembled an experienced commercial team to launch the COVID-19 RT-PCR tests.
- On February 3, 2021, XPhyto announced a new psychedelic pharmaceutical production agreement.

MANAGEMENT

CEO & Director

According to the company, CEO Hugh Rogers “is an entrepreneur and lawyer with private and public start-up experience in a range of industries and operational roles.” His recent advisory work has focused on public listings and corporate restructuring in the life science (cell therapy and medical device) and energy (natural gas co-gen and hydroelectric) industries. In addition, he has held several board and executive management positions.

Director

Prof. Dr. Raimar Löbenberg is a member of the company’s board. He joined the University of Alberta in 2000 and is the founder and director of its Drug Development and Innovation Centre, Faculty of Pharmacy and Pharmaceutical Sciences. He is a cofounder of foam-based topical drug delivery company, RS Therapeutics Inc.

Director

Per Thoresen has extensive experience within the pharmaceutical industry, including executive positions with major international European and Asian-based pharmaceutical companies

CFO

Christopher Ross, the company’s CFO, has provided financial accounting, taxation advisory and other financial services to both public and private companies and been involved in a range of debt and equity financings, mergers and acquisitions, corporate re-organizations and divestitures.

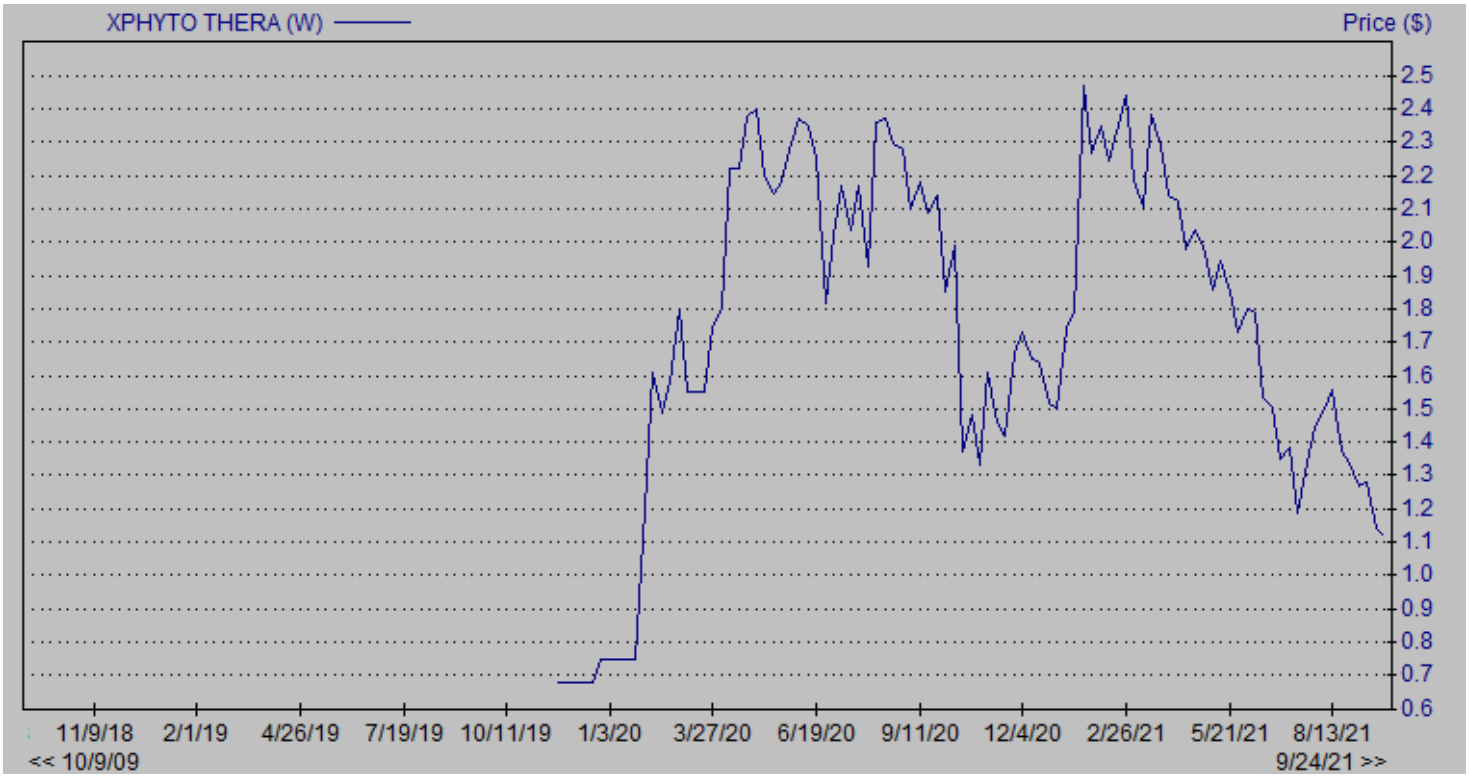
PROJECTED FINANCIALS

XPhyto Income Statement & Projections ($)

	2019	1Q20	2Q20	3Q20	4Q20	2020	1Q21	2Q21	3Q21E	4Q21E	2021E
Revenues	208,119	260,515	(76,813)	84,622	77,330	345,654	3,698	7,685	7,454	7,231	26,068
Depreciation & amortization	945,281	223,650	250,139	211,462	211,219	896,470	210,286	206,367	200,176	194,171	811,000
Professional fees	600,642	87,096	108,799	40,745	206,566	443,206	80,785	125,833	122,058	118,396	447,072
Consulting fees	1,063,723	395,158	396,350	647,326	405,890	1,844,724	374,068	265,415	257,453	249,729	1,146,665
Salaries, benefits & other	920,244	194,953	186,932	459,159	(100,875)	740,169	171,973	205,324	199,164	193,189	769,651
Share-based compensation	1,773,281	886,348	74,497	1,118,074	513,995	2,592,914	896,647	332,151	322,186	312,521	1,863,505
Regulatory fees	30,716	11,736	27,221	30,350	31,507	100,814	9,602	49,134	47,660	46,230	152,626
Marketing & advertising	924,742	1,510,960	1,417,775	1,377,823	338,469	4,645,027	1,935,000	2,089,350	2,026,670	1,965,869	8,016,889
Office & miscellaneous	284,399	99,021	169,000	99,642	113,179	480,842	155,859	95,856	92,980	90,191	434,886
Travel & related	160,344	12,076	12,218	10,362	23,207	57,863	7,412	14,195	13,769	13,356	48,732
Rent	105,180	34,125	30,482	8,842	32,140	105,589	39,967	20,774	20,151	19,546	100,438
Research & lab fees	515,819	327,561	808,207	927,305	1,178,661	3,241,734	1,343,036	578,164	560,819	543,995	3,026,014
FX	48,096	147,161	(64,771)	102,115	(16,024)	168,481	(16,738)	17,499	16,974	16,465	34,200
Total operating expenses	7,372,467	3,929,845	3,416,849	5,033,205	2,937,934	15,317,833	5,207,897	4,000,062	3,880,060	3,763,658	16,851,677
Operating Loss	(7,164,348)	(3,669,330)	(3,493,662)	(4,948,583)	(2,860,604)	(14,972,179)	(5,204,199)	(3,992,377)	(3,872,606)	(3,756,428)	(16,825,609)
Other income (expense)	(549,385)	(96,190)	(100,353)	(1,852,819)	(225,710)	(2,275,072)	(162,080)	(170,897)	(164,061)	(157,499)	(654,537)
Pretax loss	(7,713,733)	(3,765,520)	(3,594,015)	(6,801,402)	(3,086,314)	(17,247,251)	(5,366,279)	(4,163,274)	(4,036,667)	(3,913,926)	(17,480,146)
Deferred tax recovery	45,021	78,451			279,038	357,489					
Net loss	(7,668,712)	(3,687,069)	(3,594,015)	(6,801,402)	(2,807,276)	(16,889,762)	(5,366,279)	(4,163,274)	(4,036,667)	(3,913,926)	(17,480,146)
Cumulative translation adj	(11,811)	156,287	(46,212)	(37,494)	(9,164)	63,417	(29,349)	1,889	1,322	1,230	(24,908)
Comprehensive loss	(7,680,523)	(3,530,782)	(3,640,227)	(6,838,896)	(2,816,440)	(16,826,345)	(5,395,628)	(4,161,385)	(4,035,345)	(3,912,696)	(17,505,054)
LPS	($0.17)	($0.07)	($0.06)	($0.11)	($0.05)	($0.30)	($0.08)	($0.06)	($0.06)	($0.06)	($0.26)
Avg shares out	45,252,733	51,846,877	56,033,761	59,499,641	61,489,145	57,217,356	65,190,837	67,732,866	67,733,866	67,734,866	67,098,109

Source: Company reports & Zacks

HISTORICAL STOCK PRICE



DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, M. Marin, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer. Therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.