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XPhyto Therapeutics (XPHYF-OTC)

XPHYF: Anticipated Benefits of 3a-Diagnostics Acquisition, Upcoming Clinical Trials & Recent Financings

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 (12/22/21) \$0.90
Valuation \$2.00

OUTLOOK

XPhyto recently completed its acquisition of 3a-Diagnostics and believes the transaction will accelerate its growth in the point-of-care biosensor market and facilitate the commercialization of certain products in 3a's development pipeline that are in more advanced stages of development. XPhyto intends to integrate its thin film technology with 3a's biosensor technology; management believes the combination of these technologies position the company for strong growth and market share gains within the biosensor market.

SUMMARY DATA

52-Week High \$3.10
52-Week Low \$0.71
One-Year Return (%) -39.86
Beta -0.18
Average Daily Volume (sh) 8,319

Shares Outstanding (mil) 77
Market Capitalization (\$mil) \$69
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 C\$)

	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	0.1A	0.1E	0.3E
2022					1.2E

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	-0.04A	-0.03E	-0.21E
2022					-0.19E

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

Disclosures on page 15

WHAT'S NEW? ACQUISITION, UPCOMING CLINICAL TRIALS, FINANCINGS

- XPhyto recently completed its acquisition of 3a-Diagnostics and believes the transaction will accelerate its growth in the point-of-care biosensor market and facilitate the commercialization of certain products in 3a's development pipeline that are in more advanced stages of development.
- XPhyto intends to integrate its thin film technology with 3a's biosensor technology; management believes the combination of these technologies position the company for strong growth and market share gains within the biosensor market.
- The company is developing a pipeline of low-cost biosensor screening tests and recently launched a rapid point-of-care COVID-19 PCR system in Europe. 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.
- 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 and is expected to persist for the foreseeable future.
- Separately, the company expects to launch an epilepsy clinical trial in 1Q22. XPhyto expects a European human CBD bioavailability study of treating certain epilepsy using its fast-dissolving CBD oral strips will begin in January 2022. Xphyto believes the study will support that its strips provide efficient and precise dosing and enable the company to move forward with the commercialization of the treatment for patients with certain types of epilepsy.
- In addition, based on the positive results of a human bioavailability pilot study XPhyto completed of its Rotigotine TDS patch for Parkinson's disease in March 2021, the company is advancing the Rotigotine development program to a pivotal human trial. The company expects the study to launch in 2022.
- The company has improved its financial flexibility to support growth with recent capital issuances. Last month, XPhyto closed a private placement and a convertible debenture unit offering, raising combined gross aggregate proceeds of \$7.0 million to support its growth strategy and development efforts, including funding the recent 3a-diagnostics transaction.

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 that recently launched a rapid point-of-care COVID-19 PCR system in Europe and is developing a pipeline of low-cost biosensor screening tests.

The company recently completed its planned acquisition of 3a-Diagnostics. The company believes the transaction will facilitate its expansion into the point-of-care biosensor market and accelerate the commercialization of products in 3a's near-market development pipeline. The company expects the transaction to yield synergies in R&D and manufacturing and contribute to expanding margins for commercial products such as its 25-minute COVID-ID Lab test.

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. XPHYF intends to leverage the transdermal and sublingual delivery technology

of its subsidiary, Vektor, 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.

Strategic M&A Cornerstone of Growth Strategy

The recent acquisition of 3a-Diagnostics is another step in Xphyto’s leveraging strategic M&A to build value for shareholders. Over the past few years XPhyto has completed other transactions to position itself 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.

XPhyto Timeline



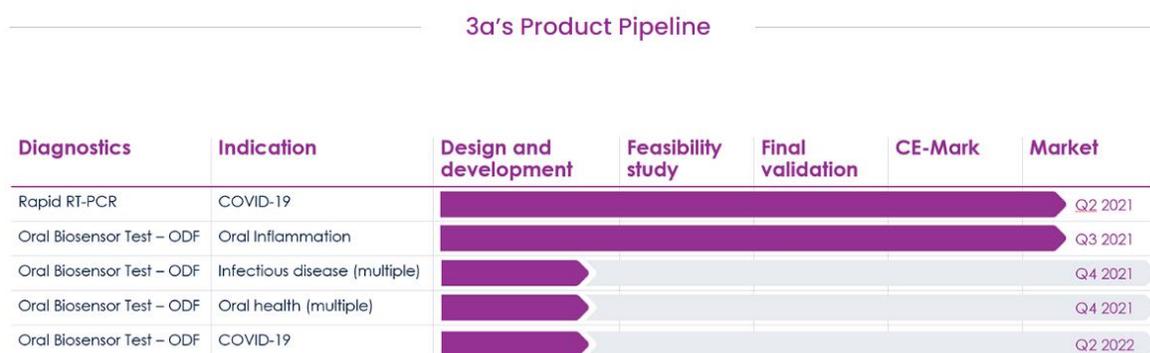
Through M&A and by forging partnerships and supply agreements, XPhyto is assembling the infrastructure and expertise to leverage the opportunities presented by its various target areas. Consistent with these goals, the company appointed Prof. Dr. Thomas Beckert as the managing director of XP Diagnostics GmbH to head XPhyto’s operations in Germany and supervise the integration of 3a-diagnostics. He is the managing director of Vektor Pharma (see below) and, according to management, a well-recognized expert in thin film drug delivery systems. The company’s goal is to combine Vektor Pharma’s thin film technology and 3a-diagnostics biosensors to create an innovative product pipeline.

3a DIAGNOSTICS

Germany-based 3a-diagnostics GmbH is a research-based biotech company that specializes in the development, manufacture and marketing of point-of-care test systems. 3a’s lead product is a rapid point-of-care COVID-19 RT-PCR diagnostic test that Xphyto launched in Europe earlier this year. According to management, 3a developed the first saliva activated “in-mouth” biosensor candidates to detect the COVID-19 infection. 3a’s enzyme-activated biosensors are developed to be rapid, economical and easy

to use for oral screening to detect infectious diseases, including COVID-19, at home or other venues, including point-of-care and high-traffic locations where rapid screening is critical, such as airports and railway stations. Xphyto is leveraging 3a-diagnostics's expertise and technology to develop and launch oral diagnostic products, beginning with a COVID-19 rapid test.

XPhyto currently is in the process of developing and preparing to commercialize diagnostic tests, including for COVID-19, influenza A, and others in the 3a-diagnostics pipeline for the detection of infectious diseases. 3a-diagnostics has an extensive pipeline and operates laboratory facilities in Germany. According to management, 3a-diagnostics has developed a pipeline of peptide-based biosensor screening tests for bacterial and viral infectious diseases. The company believes 3a's approach to diagnostic testing dramatically lowers per unit production cost.



Source: <https://xphyto.com/3a-diagnostics/>

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.

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 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. The company believes this agreement represents an important commercial milestone. 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.

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 ODF sub-lingual strips for immediate bioavailability. The company plans to incorporate the 3a biosensors into Vektor Pharma's ODF delivery platform. 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.

PIPELINE

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.

Certain childhood epilepsies

XPhyto's medical cannabinoid programs are focused on the development of precise and efficient oral dissolvable drug formulations for prescription use. XPhyto's strategy is to develop a portfolio of generic and hybrid-generic drug products.

XPhyto is developing a hybrid-generic CBD prescription drug formulation leveraging its proprietary ODF platform to deliver precise and efficient CBD dosages for the treatment of certain forms of childhood epilepsy. The company expects its European human CBD bioavailability study to begin in January 2022 and demonstrate the efficient and precise dosing of the treatment. According to management, the FDA

and European Medicines Agency have approved other CBD-based medical products for the treatment of severe childhood forms of epilepsy (Dravet syndrome and Lennox-Gastaut syndrome).

Product Pipeline



Source: [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 that the company expects to launch in 2022.

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. Global and European sales of Rotigotine patches in 2019 were approximately \$500 million and \$250 million (CAD), respectively, according to company metrics.

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.

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.

Diagnosics 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

Xphyto continues to advance its psychedelic medicine program. 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

Until this point, most of XPhyto's revenue comes primarily from services Vektor performs for third parties. However, the company recognized product revenue in 3Q21 and expects revenue to begin to ramp up in 2022 and beyond, as it targets product launches in areas with significant market demand.

In 3Q21, the company recorded revenues of \$116,931, including \$90,311 from product sales reflecting the recently launched 25-minute COVID-19 PCR Test, COVID-ID Lab in the European market. In the same period of 2020, revenue was \$84,622.

Operating expenses declined to \$2.5 million compared to \$5.0 million on lower consulting fees and share-based compensation expense, among other factors. Xphyto recognized a comprehensive loss of \$2.6 million compared to \$6.8 million in 3Q20.

Enhanced financial flexibility to support growth

The company has improved its financial flexibility to support growth with recent capital issuances. Last month, XPhyto closed a private placement and a convertible debenture unit offering, raising combined gross aggregate proceeds of \$7.0 million to support its growth strategy and development efforts, including funding the recent 3a-diagnostics transaction. In addition, 3a has also received grant funding from the German Federal Ministry of Education and Research for the development of real-time, low-cost and easy-to-use oral screening tests for the rapid detection of influenza A variants that are high-risk pandemic threats such as H1N1 and H5N1.

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 on December 15, 2021, that its epilepsy clinical trial is planned in 2022 with its proprietary fast-dissolving CBD oral strips.
- XPhyto completed the 3a-diagnostics GmbH acquisition on December 6, 2021.
- On November 29, 2021, XPhyto closed a \$7.0 million private placement.
- The company announced the appointment of a Managing Director, Financing and 3a-diagnostics Development on November 3, 2021.
- XPhyto provided a business update for its drug delivery activities on October 12, 2021.
- On September 8, 2021, XPhyto reported the successful launch and growing demand for its 25-minute COVID-19 PCR test COVID-ID Lab.
- XPhyto announced the EU registration of the first commercial biosensor for oral disease on August 30, 2021.
- XPhyto announced that its rapid Point-of-Care COVID-19 PCR test was offered for sale in Germany on May 20, 2021.
- XPhyto signed a German distribution, storage and logistics agreement for its 25-Minute COVID-19 PCR Test on April 21, 2021.

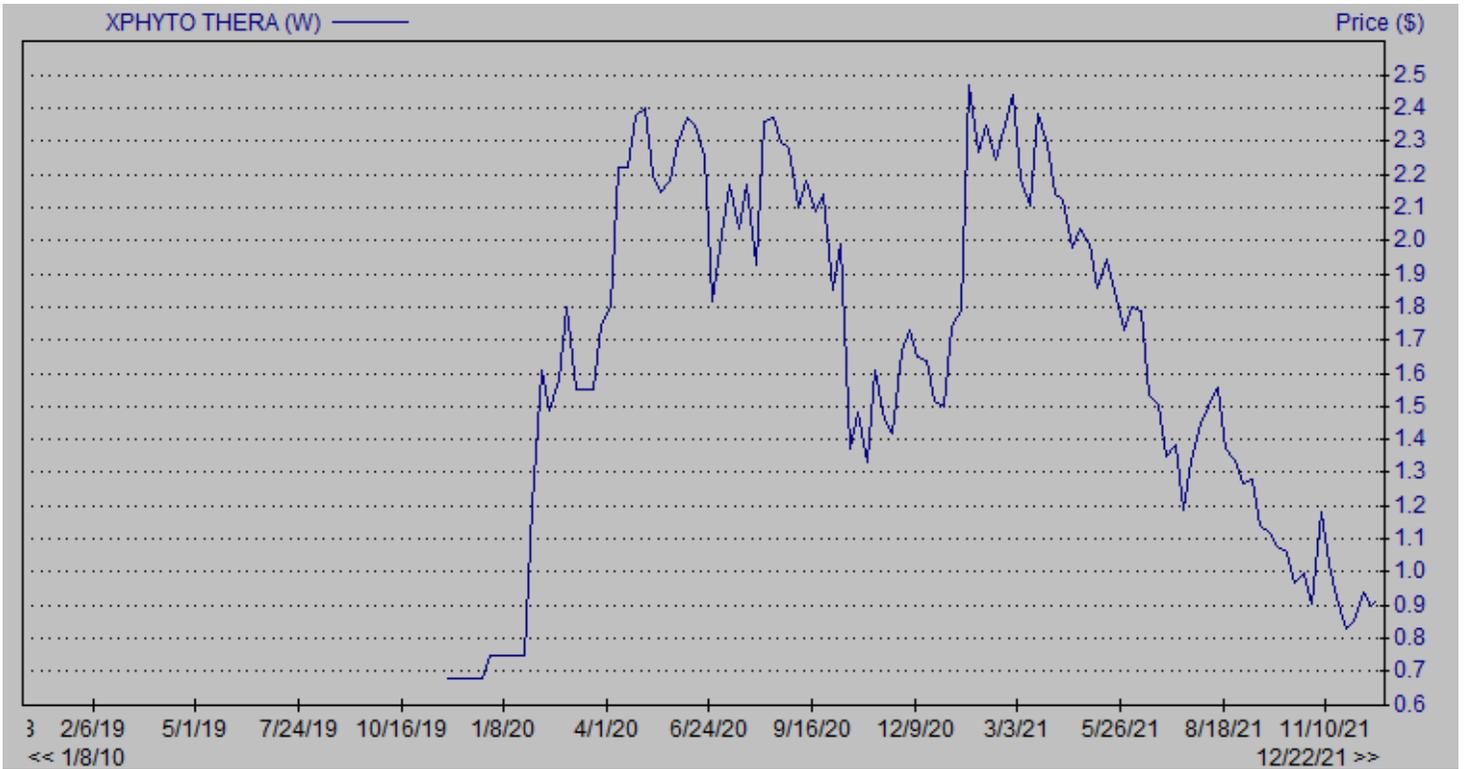
PROJECTED FINANCIALS

XPhyto Income Statement & Projections (C\$)

	2019	1Q20	2Q20	3Q20	4Q20	2020	1Q21	2Q21	3Q21A	4Q21E	2021E	2022E
Revenues	208,119	260,515	(76,813)	84,622	77,330	345,654	3,698	7,685	116,931	142,697	271,011	1,219,551
Cost of sales									66,065	98,891	164,956	939,054
Gross profit									50,866	43,807	94,673	280,497
Depreciation & amortization	945,281	223,650	250,139	211,462	211,219	896,470	210,286	206,367	204,773	208,868	830,294	819,110
Professional fees	600,642	87,096	108,799	40,745	206,566	443,206	80,785	125,833	92,895	94,753	394,266	451,543
Consulting fees	1,063,723	395,158	396,350	647,326	405,890	1,844,724	374,068	265,415	290,162	249,729	1,179,374	1,158,131
Salaries, benefits & other	920,244	194,953	186,932	459,159	(100,875)	740,169	171,973	205,324	218,489	222,859	818,645	777,347
Share-based compensation	1,773,281	886,348	74,497	1,118,074	513,995	2,592,914	896,647	332,151	5,832	5,949	1,240,579	26,769
Regulatory fees	30,716	11,736	27,221	30,350	31,507	100,814	9,602	49,134	42,105	46,230	147,071	154,152
Marketing & advertising	924,742	1,510,960	1,417,775	1,377,823	338,469	4,645,027	1,935,000	2,089,350	919,682	938,076	5,882,108	8,251,858
Office & miscellaneous	284,399	99,021	169,000	99,642	113,179	480,842	155,859	95,856	67,199	68,543	387,457	439,235
Selling and distribution									7,778	9,723	17,501	52,502
Travel & related	160,344	12,076	12,218	10,362	23,207	57,863	7,412	14,195	23,875	24,353	69,835	49,220
Rent	105,180	34,125	30,482	8,842	32,140	105,589	39,967	20,774	35,158	35,861	131,760	184,464
Research & lab fees	515,819	327,561	808,207	927,305	1,178,661	3,241,734	1,343,036	578,164	549,041	543,995	3,014,236	2,305,972
FX	48,096	147,161	(64,771)	102,115	(16,024)	168,481	(16,738)	17,499	21,155	16,465	38,381	34,542
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	2,478,144	2,465,402	14,151,505	14,704,845
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)	(2,427,278)	(2,421,595)	(14,045,449)	(14,424,348)
Other income (expense)	(549,385)	(96,190)	(100,353)	(1,852,819)	(225,710)	(2,275,072)	(162,080)	(170,897)	(171,509)	(157,499)	(661,985)	(699,773)
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)	(2,598,787)	(2,579,094)	(14,707,434)	(15,124,121)
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)	(2,598,787)	(2,579,094)	(14,707,434)	(15,124,121)
Cumulative translation adj	(11,811)	156,287	(46,212)	(37,494)	(9,164)	63,417	(29,349)	1,889	2,282	1,230	(23,948)	(6,422)
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)	(2,596,505)	(2,577,864)	(14,731,382)	(15,130,543)
LPS	(\$0.17)	(\$0.07)	(\$0.06)	(\$0.11)	(\$0.05)	(\$0.30)	(\$0.08)	(\$0.06)	(\$0.04)	(\$0.03)	(\$0.21)	(\$0.19)
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	72,282,830	76,622,830	70,457,341	79,122,830

Source: Company reports & Zacks

HISTORICAL STOCK PRICE



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