

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549



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FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13a-16 OR 15d-16 OF  
THE SECURITIES EXCHANGE ACT OF 1934

May 21, 2002

Provalis plc  
(Translation of Registrant's Name into English)

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FINANCIAL

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Newtech Square  
Deeside Industrial Park  
Deeside  
Flintshire  
CH5 2NT

(Address of Principle Executive Offices)

(Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.)

Form 20-F  Form 40-F

(Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.)

Yes  No

(If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-\_\_\_\_.)

**Provalis plc**

**Provalis signs agreement with Cholestech Corp. for the Distribution of Glycosal®  
in the USA and other major markets**

**Provalis plc (LSE: PRO and NASDAQ:PVLS)**, is pleased to announce that its Medical Diagnostics division, Provalis Diagnostics Ltd, has signed a semi-exclusive distribution agreement with Cholestech Corp. for Glycosal®, its leading diabetes A1c diagnostic product. Under the terms of the agreement, Cholestech will promote, distribute and sell Glycosal, under its trademark Cholestech GDX™, in the major diabetes markets of the USA, Japan and Europe, as well as in much of the rest of the world. Provalis has retained the right to sell Glycosal through its own sales division in the United Kingdom.

Commenting on the announcement, John Curtis, Managing Director of Provalis Diagnostics, said, "Cholestech, which is based in Hayward, California, is a point of care diagnostics company which had sales of approximately US \$50 million in its last financial year. Cholestech focuses on providing diagnostic tools to doctor's offices and a broad range of healthcare professionals. In addition, it has a number of marketing relationships with Pharmaceutical companies, through its' WellCheck™ business unit, which supports patient screening events. We believe that Cholestech is ideally positioned to exploit the growing opportunities for Glycosal in the point of care market, particularly in the USA which represents around 40% of the worldwide diabetes testing market".

Phil Gould, CEO of Provalis plc, added, "The worldwide commercialisation of Glycosal, which now benefits from the recently announced CLIA waiver and NGSP certification, through strong sales players is crucial to the development of our Medical Diagnostics division. In partnership with Cholestech, which has an established position in the point of care market through its worldwide distribution network, and Bio-Rad Laboratories Inc, our other distributor, we are now in a position to fully capitalise on the leading position Glycosal has given Provalis in the diabetes A1c testing market"

Warren E. Pinckert II, President and Chief Executive Officer of Cholestech, said "Our agreement with Provalis is an important step in our effort to broaden Cholestech's product line and expand our presence in both the professional and health promotion markets. We plan to introduce the product at the American Diabetes Association's annual meeting in San Francisco in June."

- END -

For further information: -

Dr Phil Gould, Provalis plc, Tel: 01244 833463

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**Provalis' Internet Website ; <http://www.provalis.com>**

**"Safe Harbor" Statement under the US Private Securities Litigation Reform Act of 1995:** Statements in this announcement that relate to future plans, expectations, events, performances and the like are forward-looking statements as defined in the US Private Securities Litigation Reform Act of 1995. Actual results of events could differ materially from those described in the forward-looking statements due to a variety of factors. Such factors include, among others: the success of the Group's research and development strategy; uncertainties related to future trial results and the regulatory process; the execution and success of collaborative agreements with third parties; the impact of future laws, regulations and policies; the Group's intellectual property position and the success of patent applications for its products and technologies; stock market trends in the Group's sector; the Group's dependence on key personnel; general business and economic conditions; and other factors beyond the Group's control that may cause the Group's available capital resources to be used more quickly than expected. These and other factors that could affect the Company's future results are more fully described in its filings with the US Securities and Exchange Commission, in particular the latest 20-F filing, copies of which are available from the Company Secretary at the Company's registered address.

#### **Notes to Editors**

**Provalis plc** (LSE.PRO and NASDAQ.PVLS) is a healthcare company with three separate divisions:-

- **Medical Diagnostics** – develops and sells to world markets medical diagnostic products for chronic disease management. The division's principle products are Glycosal® and Osteosal® in the areas of diabetes and osteoporosis respectively.
- **Healthcare** – sells and markets its own, and third party, branded, prescription medicines in the UK to GPs and hospitals through its own regionally managed sales force. The division sells products in the areas of muscular-skeletal disorders, gastroenterology, osteoporosis, migraine and dermatology.
- **Therapeutics R&D** – develops a range of vaccine candidates for the prevention of infectious diseases through a network of research collaborators.

**Cholestech** is committed to enabling people to lead longer, healthier and more active lives. Cholestech's Diagnostic Products and WellCheck™ business units provide easy to use, accessible diagnostic tools and information to health care practitioners in over 35 countries around the world. Cholestech offers efficient and economic diagnostic testing for cholesterol and related lipids, blood glucose and

glycemic control, and liver function at the point of care. Health care providers can use the CLIA-waived Cholestech LDX<sup>®</sup> and GDX<sup>™</sup> Systems to initiate and monitor the progress of patient therapy. By providing effective disease management solutions, Cholestech's goal is to be a leading provider of diagnostic tools and information for immediate risk assessment and therapeutic monitoring of heart disease and diabetes.

### **Glycosal<sup>®</sup>**

Providing accurate, real-time results outside of the laboratory, Glycosal is suitable for point-of-care use in the physician's office or diabetes clinic, as well as for home testing by prescription. Glycosal eliminates the need for expensive laboratory instruments or tedious training procedures, removing cost and complexity as barriers to decentralized A1c testing and monitoring. The key facts are:-

- Glycosal is a simple, four minute, test for A1c
- Glycosal can be used by diabetic clinics, G.P.s and nurses at the "point-of-care"
- Glycosal is certified by the European Reference Laboratory
- Glycosal is CLIA waived in the USA, and has NGSP certification
- The current global clinical laboratory market for A1c testing is approximately US\$800 million
- The tighter control of diabetes is associated with the reduction of risk of debilitating long term complications
- Glycosal is now distributed throughout the world by Cholestech Corp. and Bio-Rad Laboratories Inc.

### **A1c**

A1c, or HbA1c as it is also known, is formed when haemoglobin in red blood cells binds glucose over the cells' typical 90-day life span. The quantitative measure of A1c has been well established as a way to determine a patient's long term glycemic control profile. Unlike daily glucose monitoring, which provides a 'snapshot' of a patient's glucose level at the time of testing, A1c provides an average level over the previous 90 days and therefore indicates the long-term progress of a diabetes disease and therapy management.

The American Diabetes Association (ADA) recommends that an A1c test be performed every three-to-six months in all diabetes patients to determine how well glucose has been controlled over that period of time. The objectives are to document blood glucose control at the initial assessment and to assess the effectiveness of continuing care. As a percentage of total blood haemoglobin, the goal is to maintain an A1c level of 7% or lower. Owing in part to infrequent testing, the vast majority of diabetic patients have an A1c level well in excess of

the recommended 7% and are at a higher risk of developing serious complications.

## **Diabetes**

Diabetes mellitus is a group of diseases characterized by high and fluctuating levels of blood glucose. It results from defects in insulin secretion, insulin action, insulin resistance, or a combination of all three. The disease can lead to serious complications and premature death. People with diabetes can reduce such occurrences by maintaining proper blood glucose levels through diet, exercise, medication and monitoring. Type 1 and Type 2 diabetes are the most common forms. Type 2 constitutes 90 percent to 95 percent of all cases; type 1 is an autoimmune disease in which the body makes no insulin. Type 2 diabetes is a metabolic disorder usually found in people over the age of 30. In the United States, it is recognized that nearly half of all people with Type 2 diabetes remain undiagnosed.

Products used in testing patients with diabetes, which affects about 6 percent of the world's population, have a compounded annual revenue growth rate of 15 percent, making them the fastest growing product segment in the in vitro diagnostic (IVD) industry. Diabetes continues to reach epidemic proportions, with nearly 150 million suffering worldwide (10 million Americans) with direct and indirect costs in the United States alone of almost \$100 billion annually. Indirect costs of \$55 billion include disability, work loss and premature mortality. At about \$3 billion per year, glucose-monitoring products represent a large percentage of direct expenditures.

Diabetes can lead to complications including heart disease, stroke, high blood pressure, blindness, nerve damage, kidney damage, periodontal disease, amputation, congenital malformations incurred during pregnancy and diabetic coma. People with diabetes are more susceptible to many other illnesses, such as pneumonia and influenza. The risk of death from these illnesses and complications is significantly greater than that for the general population.

According to the ADA, the death rate from diabetes has increased by 50 percent since 1985, while death rates from heart disease and stroke have been declining. Some population groups are at higher risk for diabetes as they age. The risk factors are family history, age, sex and ethnic background. Obesity, unhealthy diet and a sedentary lifestyle increase disease prevalence.

## **CLIA**

In the USA, Congress passed the Clinical Laboratory Improvement Amendments (CLIA) Act in 1988, establishing quality standards for all laboratory testing to ensure the accuracy and reliability of all laboratory tests, regardless of where the test was performed. The CLIA regulations are based on the complexity of the test method, and the more complex the test method, the more stringent the requirements are for the laboratory which carries out the test. Test methods are assessed by the FDA and the Centers for Medicare & Medicaid Services and

assigned one of three complexity ratings, namely, waived test, moderately complex test and highly complex test. For a test to be designated as waived it must be so simple and accurate as to render the likelihood of obtaining an erroneous result as negligible.

### **The National Glycohemoglobin Standardisation Program (NGSP)**

The National Glycohemoglobin Standardisation Program is an independent quality assessment of the performance of any test for the analysis of A1c. The program is run by the University of Missouri and compares the results from the manufacturer's method with a reference method. Manufacturers meeting the exacting standards of the NGSP are certified by the University and may advertise their products as conforming to NGSP during the period of certification.

The assessment is carried out each year and determines precision of the test over a 20 day period and the accuracy as compared to a reference method carried out by a national reference laboratory. Standards are extremely tight the precision pass criteria being a 5% coefficient of variation over the entire 20 day period.

The importance of the certification is demonstrated by the fact that the American Diabetes Association only recommends, and many health care providers will only use, tests that are NGSP certified.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Provalis plc

Date: May 21, 2002

By: 

Name: Lee Greenbury

Title: Secretary