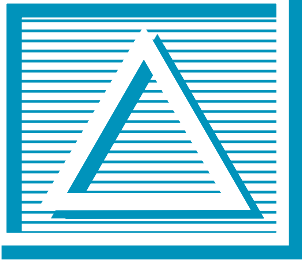


# Late-Stage Product Acquisition Service



The central image is a collage of pharmaceutical and legal-themed elements. At the top left, several white and blue capsules are shown, with one tilted to reveal a pile of small white granules. Below the capsules is a complex chemical structure diagram featuring a central ring system with various functional groups, including a hydroxyl group ( $\text{HO}$ ), an amino group ( $\text{NH}_2$ ), and nitrogen atoms ( $\text{N}$ ). To the right of the chemical structure is a blue CD-ROM case with a white label that reads "CANDA Submission" and a small image of a pill. The CD-ROM is positioned over a background of faint, overlapping legal text, including phrases like "hereby indemnify", "limitation, de", "all provis", "ained", "greeme", "e parties", "parties rig", "aid or shall", "ained shall of", "ovenant, conditi", "negotiations, effe", and "GOVERN". In the bottom right corner, a large, bold, blue stamp reads "CONFIDENTIAL". Below the stamp, there is a small image of a pill and the text "This agr", "in accordance", and "IN WITNESS V".

# Late-Stage Product Acquisition Service

---

Technology Catalysts International (TCI) has created the *Late-Stage Product Acquisition Service* to assist companies in the identification of ethical or OTC (self-medication) pharmaceuticals which are launched or which have pending registrations and can be acquired for **cash and royalties**. Risk factors associated with in-house drug development include:

- Globally, nearly 600 New Drug Applications (NDAs) are filed annually to obtain approval to market pharmaceutical products.
- Current estimates of the cost of drug discovery and development may exceed \$250 million per compound.
- Only 30 percent of all ethical pharmaceuticals launched can be expected to recoup their research and development costs.

Therefore, pharmaceutical companies need techniques to identify and acquire, at minimum risk, ethical pharmaceuticals for which registrations have been filed and which meet the firm's strategic needs. The *Late-Stage Product Acquisition Service* is designed to meet these requirements.

## Types of Deals

In addition to arrangements involving only cash and royalties, other types of deals which may be identified through the service include:

- Manufacturing or marketing rights for specific territories
- Cross-licensing
- Exchange of an over-the-counter (self-medication) pharmaceutical product for an ethical pharmaceutical for which registration has been filed.
- Co-promotion
- Co-marketing
- Joint venture partnerships

## Identification of Opportunities in Ethical Pharmaceuticals

The service provides three reports per year, and the Client can have each one tailored to satisfy a specific strategic need. This focus may take the form of a concentration on a specific therapeutic category, geographic region, market potential, or clinical development stage.

TCI has developed an extensive international network of daily contacts within the pharmaceutical industry based on a long-standing presence in and service to these companies. These are located in:

- Germany
- France
- the Benelux countries
- the United Kingdom
- Scandinavia
- Spain
- Italy
- Japan
- the Visegrad countries
- North American (CAMEUS)
- 15 countries in Southeast Asia

These contacts, when combined with TCI's extensive knowledge of global pharmaceutical product developments, allow for a perfect fit of opportunities to the Client's requirements.

Clients are not limited in the number of requests which can be made for products in different therapeutic categories, geographic regions, or clinical stage of development.

## Low Risk Decisions

Potential licensees will evaluate a registration package that has all the required clinical trials completed. Therefore, the risk in licensing the still unapproved drug is much less than a drug still in clinical trials. The licensee's technical and regulatory evaluation team decides whether the filed registration will be approved. Any incomplete data or poor results can simply provide the licensee with reasons not to exercise options to license or to demand a lower down payment. **At all times, licensees control the decision to license based on the quality of the data in the filed drug registration and the likelihood of approval.**

## Drug Approval Times

This service provides Clients with the ability to launch an approved product in nine months to three years, depending on the country of filing. The ranges of approval times for ethical drug registrations in the last decade are:

- |                                |                                  |
|--------------------------------|----------------------------------|
| • France                       | 9–12 months                      |
| • EC Multi-State               | 12 months                        |
| • Germany                      | 24–48 months                     |
| • Other EC countries           | 11–36 months                     |
| • United States                | 24–36 months                     |
| • Japan                        | 30–48 months                     |
| • 15 Southeast Asian countries | Under influence of U.S. approval |
| • Australia and New Zealand    | Under influence of U.S. approval |
| • Visegrad & CIS countries     | Under influence of U.S. approval |

## Late-Stage Product Acquisition Service Step-by-Step

The service begins with a face-to-face "kick-off meeting" in which the Client identifies its specific areas of interest in ethical pharmaceuticals. This meeting will include confidential discussions covering the needs of the Client regarding its financial and territorial objectives, such as launching a product by a certain date and achieving certain sales, the types of opportunities of interest, therapeutic classes, and geographic regions. Several "product acquisition scenarios" are prepared and sent to TCI staff worldwide. Interviews are held with companies having pharmaceutical products which meet the parameters defined in the scenarios. Client confidentiality is maintained throughout this entire process.

Product descriptions, contacts, and analyses are gathered into one document three times per year. Whenever possible, these analyses will include competitive advantage statements to allow for a more complete understanding of the product position. No brokerage fees or commissions are ever charged by TCI on completed transactions.

## 1. Kick-Off Meeting

In a kick-off meeting with the Client, TCI works to establish a framework and ground rules for the search. There are several ways to approach the acquisition of ethical pharmaceuticals, and an approach or a combination of approaches can be decided on. The "product acquisition scenarios" will be based on Client priorities and interests in areas such as:

### Drug Registration is Filed or Imminent

**Ethical pharmaceuticals for which registration applications are pending or are to be filed in the near future with regulatory agencies.**

### Therapeutic Classes

Products in specific therapeutic classes or for specific indications of interest to the Client. Possible examples include subclasses of these major therapeutic indications:

- Cardiovascular
- Oncological
- Respiratory
- CNS
- Gastrointestinal
- Anti-infective
- Dermatological
- Genitourinary

### Geographic Region

Opportunities in countries into which the Client is interested in expanding or enhancing their current position.

### Types of Deals

The type of deal the Client offers, ranging from cash and royalties to co-marketing.

## 2. Search

A product search and contacts are made by skilled TCI researchers to identify perfect fits based on the "product acquisition scenarios" developed at the kick-off meeting. The global search is made up of large and small companies

that have launched products with acceptable patient data bases, or filed registrations in the areas outlined in the scenarios. Careful screening eliminates imperfect fits: e.g., TCI may screen out  $\beta$ -blockers if the client specifies other cardiovascular products, such as peptidomimetics.

All searches are coordinated through Technology Catalysts' world headquarters in Falls Church, VA. International searches are supported by our on-the-ground staff in the United Kingdom, Germany, Japan, and the Czech Republic. This permits truly global coverage of all activities in the pharmaceutical industry.

## 3. Direct Personal Contact to Determine Type of Deal

Every search includes direct personal contact with the licensor either in person or by telephone/facsimile to determine the type of deal under which the licensor will enter into a strategic alliance. TCI researchers are members of all prominent licensing organizations, such as the Japan Pharmaceutical Licensing Association.

## 4. Technology & Business Analysis

TCI will include relevant patent and commercial data for each opportunity. In some cases, TCI may include a brief competitive analysis of the licensable technology by comparing it to existing ethical pharmaceutical products. TCI's analysis will include information on:

- When the registration was or is to be filed.
- Expected approval date for NDAs or registration packages.
- Indications applied for and under further development.
- Market size.
- Potential patient population in the United States and worldwide.

## 5. Three Reports Per Year

Business opportunities and analyses are presented in three reports prepared for the Client. Each report contains business opportunity summaries which include the source, an abstract of the technology, contact information, and analysis. In addition, each report contains tables summarizing the product opportunities contained in the report and those identified as outside of the Client's interest or not otherwise available. The latter provides a level of competitive intelligence for the Client.

**GLAXO S.P.A.**

**Reference:** 902/TCINL041995

**Title:** A long-acting calcium antagonist

**Technology Description:** Teludipine is a calcium antagonist with vascular-selective calcium entry-blocking activity, and it induces a long-lasting antihypertensive effect. The compound is suitable for once-daily administration. Also, it provides anti-inflammatory effects by interfering with mechanisms underlying the inflammation process. It has been suggested that inflammation is one of the major mechanisms leading to cardiac ischemia and atherosclerosis. The compound also has antioxidant properties. Teludipine can represent a step forward in cardiovascular therapy since it combines favorable hemodynamic and anti-ischemic effects.

**Application:** Teludipine is indicated for the treatment of hypertension and angina.

**Technology Offer:** Glaxo's current product pipeline is well stocked. Therefore, they have decided not to proceed with the development, registration, and worldwide commercialization of this compound. Accordingly, Teludipine is available for license worldwide.

**Patents/Publications:** Teludipine is protected by worldwide patents. In most European countries, patents have been granted and have an expiration date of August, 2006. In the U.S., teludipine is protected by United States Patent 5,162,345, with an expiration date in November 2005.


**Stage of Development:** Phase III trials for angina and hypertension have been completed for teludipine, including dose findings for both indications. The trials were carried out in authorized centers in Italy and standard procedures for European registration were followed. No clinical trials have been conducted in the U.S.

**Competitive Advantage:** Teludipine has the following advantages over other calcium antagonists: slow onset of action, long-lasting antihypertensive effect, once-daily dosage, no reflex tachycardia, high vascular selectivity, and vascular organ protection.

In 1993 the calcium antagonist world market was approximately \$7.48 billion, and it is forecast to reach \$11.9 billion in 1999. If teludipine were developed for all indications, Glaxo estimates that it could obtain a market share somewhere between seven and eight percent.

**Company Information:** Glaxo is an integrated research-based group of companies involved in the discovery, development, manufacturing, and marketing of pharmaceuticals worldwide. Glaxo's main research centers are located in the U.K., U.S.A., France, Italy, Spain, and Japan. With the recent acquisition of Burroughs Wellcome, Glaxo has become the world's largest pharmaceutical company.

**Contact:** Dr. Sergio Re  
Licensing Director  
Glaxo S.P.A.  
Prodotti Farmaceutici Ad Uso Umano  
37100 Verona - Via A. Fleming 2  
Italy  
Telephone: (45) 921 8460  
Facsimile: (45) 921 8387



## 6. Feedback Session: The Most Important Step

At the Client's request, the reports can be discussed in a feedback session at the Client's facility. This meeting can be a means of improving the focus of subsequent searches. It is also done so that Clients do not overlook important opportunities for which TCI may have additional information or intelligence. Feedback sessions are at the Client's request, and travel expenses are extra.

## Advantages of the Service

- Minimum acquisition risk to the Client since late-stage clinical data can be reviewed without obligation
- Provides an exhaustive worldwide overview of specific ethical pharmaceutical products of interest to the Client
- Evaluates opportunities which directly meet the Client's requirements
- Presents competitive advantages on some of the outstanding opportunities
- Eliminates out-of-date opportunities, thus maintaining very current information
- Each opportunity is analyzed to insure a tailored match with the Client's business development needs
- **Excludes published literature sources such as PharmaProjects® or the IMS Newsletter, thereby avoiding duplication of Client in-house searches**
- Locates business opportunities while maintaining the Client's anonymity

- Provides unlimited requests without brokerage fees or commissions on a global basis
- On-time delivery of each of the three reports
- Cost effective, high quality information

## TCI International Offices Positioned to Gather Licensable Drug Registration Information

- Falls Church, Virginia (Washington, D.C. Metropolitan Area, CAMEUS)
- Northwich, Cheshire (France, Italy, Spain, U.K., Scandinavia, and Benelux)
- Bad Soden (Germany, Austria, and Switzerland)
- Tokyo (Far East and the Pacific Rim)
- Prague (Visegrad & CIS countries)