

## Outsourcing Chemistry – Organix Can Provide the Synthetic Chemistry Services That You Need

a report by

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*President, Organix, Inc.*

Organix, Inc. is a privately held custom synthesis and contract research company that conducts research and development in organic and medicinal chemistry. The company, managed by four experienced scientists, owns a modern facility designed specifically for synthetic organic chemistry. Organix is located in the Boston area, close to Logan International Airport in Massachusetts, and is easily accessible to local clients as well as those utilising air travel. Clients of Organix include pharmaceutical companies, diagnostic companies, government agencies, biotechnology companies, polymer companies and fine chemical houses.

### Capabilities

Organix' unique capabilities address the following:

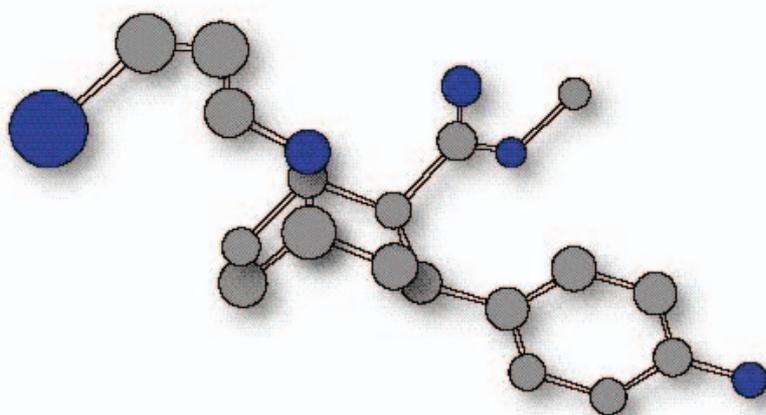
- custom synthesis;
- contract research and development (R&D);
- optimisation of synthetic methods;
- structure activity relationship studies;
- discovery and synthesis of new chemical entities;
- characterisation of components of complex organic mixtures; and
- preparation from milligram to subkilogram quantities of compounds.

Your compound may be a dream on paper or a reality in your laboratories. It may require one step or 20 synthetic transformations. It may be optically active with many chiral centres, it may be racemic or it may have no chiral centres at all. It may require the use of unstable intermediates, it may require careful characterisation of every step along the way or its synthesis may be quite straightforward. You may need 10 milligrams or 1,000 grams. Organix can design a synthetic route to obtain your compound or can use routes that have already been developed.

### Organix Can Synthesise It

Organix can assist you in achieving your R&D goals in a timely, cost-effective, professional and confidential manner. A particular strength of the company is its ability to integrate on-going work with the client's own R&D efforts. This facilitates

Figure 1



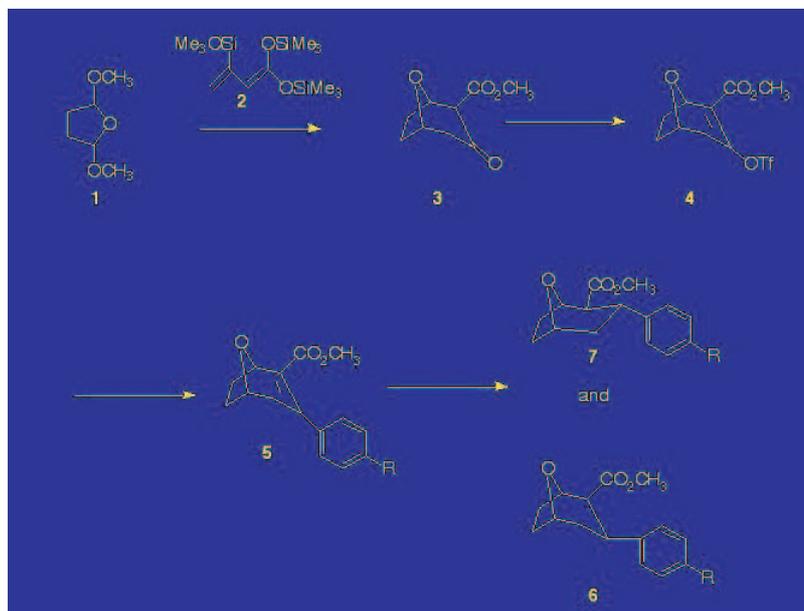
rapid introduction of any necessary changes and redirection as work progresses. This approach is designed to incorporate and rapidly take into account any new information that the client may obtain during the course of the work. The focus of the work may therefore be redirected by the client as the project goals demand.

### We Work Hand-in-hand With You

#### *Confidentiality and Record-keeping are a Number One Priority at Organix*

Confidentiality of proprietary information is an overriding concern of pharmaceutical and biotech companies as they consider the benefits and risks of outsourcing sensitive discovery functions. Clients entrust Organix with their most valuable assets – their intellectual property. Organix takes confidentiality very seriously and has taken all steps to ensure the complete and total confidentiality of all client intellectual property. Organix scientists are instrumental in enhancing and creating new intellectual property and all intellectual property developed during the course of the work for a client resides with that client. Organix conducts any necessary reporting that may be required to perfect the clients' ownership of their intellectual property.

Figure 2



To ensure additional client protection, Organix does not accept conflicting contracts. Once Organix is engaged by a client to conduct certain chemistry, Organix will not accept an identical project from any other client.

Modern drug discovery has ushered in an era that has favoured the outsourcing of essential chemistry programmes. It makes economic and scientific sense to retain the services of independent contract research organisations (CROs) for support of in-house drug discovery programmes. While such CROs have long been contracted for the production of large amounts of materials and for current Good Manufacturing Practice (cGMP) supplies of clinical materials, Organix was one of the first companies to offer contract facilities for research at the starting line of drug discovery: support of structure activity studies and provision of critical standards, building-blocks and intermediates for discovery programmes.

Many large and small pharmaceutical and biotech companies have discovered that contract synthesis companies provide accessibility to cost-effective and efficient resynthesis and custom synthesis. The best of these companies provide specialised expertise to design and develop new compounds, novel analogues and new patentable intellectual property. This value-added contract work provides the client company with access to valuable discoveries that might not otherwise have been made. For the small pharma or biotech company that may not have in-house chemistry facilities, contract research with a competent and efficient CRO is clearly the only way to go.

Organix, a well-established synthetic organic chemistry powerhouse, pioneered contract small-scale synthesis and discovery chemistry. In fact,

Organix provided the paradigm for many subsequently established CROs that have emerged since the mid 1980s. Many CROs moved toward larger-scale chemistry and cGMP manufacture while a few, including Organix, have committed to provide the essential services of relatively small-scale and highly sophisticated synthetic organic chemistry. The numerous reorganisations and mergers of 2000–2004 have resulted in increased demand for Organix' services and the company lists most of the large pharmaceutical companies and increasing numbers of biotech companies among its clients. Organix is extremely proud of its client list, which includes over 100 companies.

### Organix' Success

Organix' success has resulted from its promise: *"We carry out projects efficiently, on time, and at a reasonable cost."*

Organix is situated in the midst of the vibrant and booming biotechnological and pharmaceutical area that is home to companies such as Aventis, AstraZeneca, Wyeth, Arqule, Amgen, Biogen, Genzyme, Merck, Millennium Pharmaceuticals, Novartis and Vertex. World-renowned academic institutes such as Harvard University, Massachusetts Institute of Technology, Boston University, Tufts University, Brandeis University, Harvard Medical School and The Whitehead Institute provide a window on the latest research in all fields of interest to pharmaceutical sciences and drug discovery. These institutes also provide access to one of the most talented pool of scientists in the world.

Boston offers an exciting and stimulating environment for chemistry. Situated in one of the most scientifically exciting and popular cosmopolitan regions of the US, Organix easily attracts outstanding PhD-level scientists with exceptional skills and state-of-the-art capabilities to join its staff. Organix has assured that it is at the cutting edge of synthetic organic chemistry by providing multiple opportunities for its scientists to learn, to develop their skills and to acquire new synthetic skills and methodologies. This approach has allowed the company to prosper and grow since its establishment in 1986. Organix' exceptional staff has assured that, over the past 18 years, the company has provided outstanding services to its clients in North America and Europe.

### The Staff of Organix

Organix is a chemistry-based company, owned, managed and directed by internationally recognised and widely published organic chemists who have a passion for organic chemistry. There are few service companies that can match the expertise and experience in synthetic organic chemistry of

Figure 3



Organix. Organix' staff comprises, almost exclusively, PhD-level synthetic organic chemists. Many have obtained their PhD degrees or postdoctoral training under the guidance of the world's best-recognised and most-respected academic scientists. Organix' chemists have therefore gained invaluable experience in demanding laboratories in an extremely broad array of synthetic areas. Most have completed one or two postdoctoral placements before joining Organix. Consequently, the company enjoys the benefit of an unusually talented and experienced pool of scientists.

Organix provides a competitive compensation package to encourage staff continuity. Staff attend professional meetings, lectures and conferences. The company's cultural philosophy encourages close collaboration and co-operation in order to take advantage of the unusually broad array of skills, knowledge and experience of its scientists. This synergistic work environment has proved a major attraction to highly talented scientists. This company culture is outstanding and has resulted in one of the lowest staff turnover rates in the industry. Once scientists join Organix, they stay with Organix. Their commitment to the company and to client projects is long term and sustained. The investment that Organix makes in its staff is rewarded by the quality and quantity of work that emerges from our skilled and highly satisfied personnel.

Organix staff also conduct non-proprietary basic research that maintains Organix at the cutting edge of organic and medicinal chemistry. This research is widely published in peer-reviewed journals and provides a window for prospective clients into Organix' synthetic and medicinal chemistry-based strengths.

#### Instrumentation and Capabilities

Organix' facility houses five wet laboratories, an nuclear magnetic resonance (NMR) and mass spectral facility, research, administrative and support functions, as well as a conference room, library and computer facilities. The design, layout, cleanliness and efficiency of the facility has been admired by clients.

The five synthetic chemistry laboratories house 40 fully equipped workstations, each having bench space and storage and state-of-the-art fully serviced six- or eight-foot Kewaunee hoods equipped with individual Phoenix variable-frequency drive control systems for control of incoming and outgoing air. Two walk-in hoods are available for larger-scale work. Each scientist is assigned a single workstation. Each laboratory is fully and independently equipped with the appropriate equipment and glassware to carry out organic and inorganic reactions from milligram to subkilogram scale.

Organix utilises all modern techniques and

instrumentation. A Jeol 300MHz NMR spectrometer, a Perkin Elmer FTIR 1,720x infrared spectrophotometer, an Agilent 1100 LC/MS with electrospray and atmospheric pressure chemical ionisation capabilities, a Jasco polarimeter, a Perkin Elmer 5200 gas chromatograph, equipped with capillary and packed columns and a Waters high-performance liquid chromatography system, equipped with both normal and reverse-phase capability and variable and monochromatic wavelength detectors, are situated in the analytical laboratory. An atmospheric pressure hydrogenator, two Parr hydrogenators (500ml and 2-litre), high-pressure (3,000 pounds per square inch) reaction vessels, photolysis equipment, high vacuum lines, lyophiliser, ozonator are located in rooms adjacent to the laboratories. Organix utilises Macintosh, personal computer and Unix-based computer systems interconnected through the company local access network. Glass-blowing and maintenance electronic services are available locally.

Organix subscribes to around 15 chemistry and medicinal chemistry journals and Beilstein's CrossFire. The company accesses CAS Online, PubMed, and STN databases and has a corporate literature search and retrieval agreement with NERAC and CISTI.

### Safety

Organix places an extremely high priority on safety. The company Safety Officer is Vice-President of Organix. The safety programme, guided by the rules set by the Department of Labor's Occupational Safety and Health Administration (OSHA), is closely monitored and carefully enforced. A Safety Manual and quarterly company-wide meetings ensure on-going compliance. The Safety Officer discusses safety issues with personnel on a day-to-day basis. Senior staff who have the most in-depth knowledge of safety issues are interspersed among all employees and work alongside less-experienced personnel. Extensive safety equipment is situated in all laboratory spaces.

### Licences

Organix has been licensed by the Drug Enforcement Agency (DEA), US Food and Drug Administration (FDA), US Environmental Protection Agency (EPA), Massachusetts Department of Environmental Quality Engineering, Massachusetts Water Resources Authority (MWRA) and the Woburn, Massachusetts Fire Department.

### Scheduled Compounds

Organix is licensed to conduct research and manufacture of classified drugs in Schedules 1 and 2-4. Security and record-keeping comply fully with the regulations of the DEA. The premises are protected by an alarm system and laboratory work hours are restricted. Guests sign in and out at the reception desk and are met by their Organix hosts at the reception desk. Only authorised visitors are allowed in the laboratories.

The synthesis bottleneck that so often hampers the rapid advancement of vibrant discovery programmes can be overcome. A visit to Organix will convince you that the best interests of pharmaceutical and biotechnology companies can be served by a state-of-the-art, efficient and independent, high-quality CRO. ■

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