Q-MED

*Q-Med is a rapidly growing and profitable biotechnology and medical device company that develops, produces and markets non-animal hyaluronic acid based medical implants. All products are based on the company's patented technology for the production of NASHA - Non-Animal Stabilized Hyaluronic Acid. Q-Med's operations focus on the areas of Esthetics, Orthopedics and Uro-Gynecology. Esthetics contains the products RESTYLANE, RESTYLANE FINE LINES and PERLANE for facial esthetics. RESTYLANE, for the correction of facial wrinkles and lip enhancement, today accounts for the majority of sales. The development of MACROLANE for breast augmentation is ongoing. Orthopedics is responsible for DUROLANE, the product for the treatment of osteoarthritis in the knee-joint which is under development. Uro-Gynecology contains DEFLUX for vesicoureteral reflux (malformation of the urinary bladder) in children and stress urinary incontinence in women. Q-Med today has 145 employees, with 110 at Q-Med's production facility and head office in Uppsala and the remainder in wholly owned foreign subsidiaries. The Q-Med share has been listed on the O-list of the OM Stockholm Stock Exchange since December 6, 1999.*

PRESS RELEASE
August 8, 2000
Uppsala, Sweden

# Q-MED STARTS CLINICAL TRIALS WITH RESTYLANE IN USA

- **Q-Med has been informed by the FDA, the American regulatory authority, that the company's application to initiate clinical trials within facial esthetics with its product RESTYLANE has been approved.**

**"We aim to launch RESTYLANE during 2002. The American esthetics market is the largest in the world and is also growing appreciably. The market segment in which we are active increased by 85 per cent during last year," says Per Olof Wallström, Q-Med's President and CEO.**

**The US market**
According to the American Society for Aesthetic Plastic Surgery almost 1,000,000 skin injections for the treatment of wrinkles and lips were carried out in USA during 1999, an increase of 85 per cent compared with the previous year. Half of the treatments were performed with collagen and half with botulinum toxin. No hyaluronic acid based products have yet been approved for this use on the American market. The principal collagen products which are approved are Zyderm and Zyplast, which are manufactured and marketed by Inamed Corp./Collagen Aesthetics, Inc. Raw material extracted from cow's hide is used in the products. As approximately 3 per cent of the population are allergic to this type of collagen, pre-testing is required before the implant is introduced, which is not necessary with RESTYLANE. Botulinum toxin, which is sold by Allergan, Inc. under the trademark of Botox, is a biological neurotoxin which blocks muscle activity and thereby prevents the skin from being drawn together into a wrinkle. The product is used primarily for folds in the forehead.

**Study and application for registration**
Approximately 130 patients will take part in the study of RESTYLANE, and they will be treated at five to seven large and leading clinics in USA. The study entails a comparison of RESTYLANE with the today market-leading product Zyplast. The total follow-up time is 12 months and the products are

compared with regard to treatment effect after six months, whereupon data will be compiled and included in an application for the registration of the product. This application is expected to be submitted during 2001. The scrutinization process, which is performed by the FDA (Food and Drug Administration), the American regulatory authority, then normally takes up to one year, but can take longer. Sales of the product may not be begun before it has been approved by the FDA.

**RESTYLANE**
RESTYLANE, which is Q-Med's first and longest used product, is intended for filling out lips and facial wrinkles. So far almost 300,000 patients have been treated since the product was approved for sales in Europe at the end of 1996. In a short time RESTYLANE has become a market-leader in all the markets where the product is sold, either through subsidiaries or distributors. Today RESTYLANE is sold in more than 40 countries, mainly in Europe, South America, Australia and Canada. Like all of Q-Med's products, RESTYLANE is based on the company's unique NASHA (*Non-Animal Stabilized Hyaluronic Acid)* technology. *Hyaluronic Acid (HA)* is a natural substance, identical in all living beings, which is to be found primarily in the skin, but also, for example, in muscles, the skeleton and synovial fluid. The function in the skin is, together with water, to create volume. RESTYLANE and Q-Med's other facial esthetics products are injected into the skin and achieve their effect by providing volume.

NASHA is produced using *non-animal* raw material, which has two advantages compared to animal raw material. First, the product obtains a high level of purity and does not contain infectious substances, for example viruses which can be transmitted to man. Second, the risk of the allergic reactions which can arise when using products of animal origin is eliminated.

The *stabilization* of HA is a prerequisite for the clinical effect and means that the product is degraded slower than naturally occurring HA, which is continuously metabolized in the body. Clinical studies have shown that RESTYLANE is effective up to one year after the treatment of wrinkles and approximately half a year after the filling out of lips.

**Own organization or partnership**
A key factor for Q-Med's continued growth is the securing of suitable channels for marketing and distribution of its different NASHA products. Within the area of esthetics the main strategy is to set up company subsidiaries in the major markets and to take full responsibility for sales and marketing primarily vis-à-vis dermatologists and plastic surgeons. Concerning the American market, different alternatives for establishment, including partnership, are being evaluated.

August 8, 2000
Uppsala, Sweden
**Q-Med AB (publ)**

Per Olof Wallström
President and CEO

Queries should be addressed to Per Olof Wallström, President and CEO, on +46(0)18-474 90 00 or +46(0)70-974 90 70.