EXECUTIVE INFORMATIONAL OVERVIEW

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Novel Drug Delivery Platforms for Injectable Medicines

Snapshot

November 10, 2008

The Medical House PLC ("TMH" or "the Company") designs drug delivery platforms for the pharmaceutical and biotechnology industries. Employing the right delivery device can be critical for determining treatment adherence and efficacy. The Company's primary product line is a family of devices known as the AutoSafety Injector (ASI™) **autoinjector**† platform that is intended to offer patients an easier, safer, and more convenient self-injection method. The ASI™ autoinjector is entirely automated—from needle insertion and medication injection to needle withdrawal and full retraction back into the device. When the shot is completed, the entire unit is disposable. With an ASI™ autoinjector device, patients never see or handle a needle, thereby reducing the anxiety that many people have about self-injections and eliminating the risk of accidental **needlestick** injuries. The ASI™ autoinjector technology also removes guesswork about dosing. Its prefilled syringes and automated delivery process ensure that patients receive accurate and consistent doses—a feature designed to improve treatment compliance and efficacy as well as reduce users' dependence on their clinicians. The Company has also developed a second delivery platform, reusable **needle-free jet injectors**. TMH has received Europe's **CE Mark** and the U.S. Food and Drug Administration's (FDA) **510(k)** clearance for versions of the ASI™ autoinjector family and the reusable needle-free jet injectors. In addition, several entities have licensed TMH's platforms as a means to deliver proprietary medications. TMH has partnerships for its ASI™ autoinjector platform with Dr. Reddy's Laboratories Ltd. (RDY-NYSE), Catalent Pharma Solutions, Inc. and Stallergenes SA (GENP-EPA), a European government agency, and an undisclosed global pharmaceutical partner that licensed an ASI™ autoinjector system in an agreement valued at up to £34 million over its first six years. Further, TMH anticipates the future launch of its needle-free jet injector technology for injection of **human Growth Hormone (hGH)** in collaboration with Merck Serono International S.A.

Recent Financial Data

Ticker (Exchange)	MLH (LSE)*
Recent Price (11/07/2008)	£0.17
52-week Range	£0.13 - £0.32
Shares Outstanding	60.1 million
Market Capitalization	£10.2 million
Average 3-month Volume	65,851
Insider Owners +3%	33.90%
Institutional Owners	31.64%
EPS (6 mos. ended 06/30/2008)	(£0.17)
Employees	25

* Share information in British pound (£).
On 11/07/2008, £1 = ~US$1.57.

Key Points

- ASI™ autoinjector technology is applicable to many elective and emergency therapies, including the long-term treatment of chronic **autoimmune diseases** like **rheumatoid arthritis (RA)** and **multiple sclerosis (MS)**, delivery of morphine to wounded military personnel, or use with adrenaline for the treatment of **anaphylaxis**. As technologies advance and chronic diseases become more prevalent, the medical community is favoring self-injection over products that require physicians' office visits.
- The ASI™ autoinjector platform is highly customizable, including modification for **subcutaneous** or **intramuscular** injection. Versions of the platform are designed to inject liquids, sustained-release **viscous** medicines, and dry **biologics** that the device reconstitutes with a **diluent** before injecting.
- TMH believes that its user-preferred autoinjector represents a solid marketing tool for its licensees' products, as patients are likely to view the ASI™ autoinjector device as the therapeutic product, rather than focusing on the medicine within the device. Under its licenses, TMH retains ownership of the technologies and related intellectual property. The core ASI™ autoinjector technology is patented in the UK and EU, with further patents pending in Europe and the U.S.
- In 2006, the implantable/injectable drug delivery market had revenues of $9.8 billion worldwide and is forecast to reach $12.6 billion by 2010, driven by patients' demand for improved injection systems, drug manufacturers' realization that novel devices can extend the life of products nearing patent expiration and provide a competitive edge, and growth of new biologic therapies that require long-term injections.
- At June 30, 2008, TMH had cash and cash equivalents of (£284,000).

†**BOLD** WORDS ARE REFERENCED IN THE GLOSSARY ON PAGES 45-47.

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Executive Overview

The Medical House PLC ("TMH" or "the Company") supplies medical devices for the pharmaceutical and biotechnology industries. At present, the Company's lead initiative is its AutoSafety Injector (ASI™) autoinjector family, which is a patented disposable autoinjector platform technology. TMH is presently licensing versions of this technology to third parties that require a novel method to deliver new injectable medicines or enhance existing injectable drug products. The Company has also designed a second delivery platform, needle-free jet injectors, that is available for licensing as well. By offering easy to use, safe, comfortable, and economical delivery systems that do not require the involvement of a clinician to administer an injection, TMH aims to enable its pharmaceutical and biotechnology partners to increase sales of their medications.

TMH's current license agreements include partnerships with Dr. Reddy's Laboratories Ltd., which seeks to combine the ASI™ autoinjector platform with a generic product; Catalent Pharma Solutions, Inc. and Stallergenes SA, with which TMH has entered into a joint development, license, and supply relationship for the Adreflex™ **epinephrine** autoinjector; Catalent, which also helps TMH identify new business opportunities and offers the ASI™ autoinjector device as its in-house autoinjector; a European government agency that is evaluating the ASI™ autoinjector technology for emergency applications; a global pharmaceutical company that intends to employ the ASI™ autoinjector platform for a new medicine; and Merck Serono International S.A. (a division of Merck KGaA [MRK-Frankfurt]), which seeks to market a human Growth Hormone (hGH) product using TMH's reusable needle-free jet injectors.

For its partners, TMH's drug delivery services include conceptual product design, development and customization, filing for the necessary patents and regulatory approvals, and managing product manufacturing and supply. The Company is experienced at obtaining international regulatory approval for medical devices and believes that it can bring these systems to market in a relatively short period of time. Moreover, all of TMH's systems enable the injection of a partner's medication in its existing formulation and primary packaging systems (such as glass syringes)—features that the Company believes can facilitate rapid, cost-effective development programs and fast-tracked product launches.

Injections

Traditionally, delivering medications via injections has been avoided by physicians and pharmaceutical companies wherever possible due to the required clinical expertise, inconvenience, high healthcare costs, safety concerns, and needle aversions that are associated with this delivery technique. It is estimated that up to 22% of the general population has an injection phobia that makes injecting treatments very difficult or even impossible (Source: the *Journal of Neuroscience Nursing* 2006). Through TMH's 20-year history of supplying medical devices, the Company has concluded that many patients who do not like injections or who fear needles frequently opt to not take their medications at all, which leads to ineffective therapies and worsening conditions. In addition, the conventional needle and syringe method that has been used for over a century subjects individuals to accidental punctures by the used needles that result in contact with another person's blood or other bodily fluids. In the U.S., there are between 385,000 and 600,000 needlestick wounds annually. The diseases most commonly transmitted by needlestick injuries are **hepatitis B**, **hepatitis C**, and the human immunodeficiency virus (HIV).

Despite the drawbacks of injections, this route of drug delivery is expanding—in large part due to the use of new biologic therapies to treat chronic diseases. Unlike traditional synthetic pharmaceutical products, biologics are typically derived from naturally occurring therapeutic proteins, which often cannot be orally delivered as the gastrointestinal system begins to break down proteins before they can reach the desired site of action. As of 2007, there were over 400 biologics in clinical development in the U.S. for more than 200 disease targets, and over 1,700 biologics at either preclinical or clinical stages in Europe. TMH believes that injection may likely be the most viable method of administration for a large percentage of future biologics. In August 2008, the *Seattle Times* reported that the market for bioengineered and specialty medications was nearly $59 billion, forecast to reach $98 billion by 2011 as the pharmaceutical industry continues to focus its research in this area.

As a result, there may be considerable opportunity for medical device entities that can provide drug manufacturers with a preferred injection platform. To this effect, TMH believes that its delivery systems reduce patients' dependence on clinical expertise by offering a self-injection option, improve treatment convenience and therapy management, enhance compliance with optimal therapy, overcome needle aversions, eliminate needlestick injuries, and potentially benefit large-scale, rapid or emergency injection programs.

TMH's Lead Product Line: the AutoSafety Injector (ASI™) Autoinjector Platform

Autoinjectors are devices that automatically inject a needle and deliver the desired amount of medication. Several studies have suggested that autoinjectors can reduce pain and anxiety in patients versus conventional syringes and may also help defray treatment costs, as most individuals can use the device at home and do not require the assistance of a skilled professional. The Company's ASI™ autoinjector device is easy to use, with few components. Unlike some competitive products, the ASI™ autoinjector does not require the activation of triggers, buttons, or similar mechanisms in order to function. Patients merely remove the safety cap and press the autoinjector against their skin. The spring-loaded ASI™ autoinjector platform does the rest—automatically injecting the patient, delivering the medication, and (unlike some competing technologies) retracting the needle back into the autoinjector after the completion of an injection. Audible and visual signals indicate to the user when the injection is complete. After an indicator window turns a different color, signaling that the injection is complete, the patient can dispose of the entire device. The patient never sees the needle.

In addition, the patient is given a consistent, accurate dose each time—a critical feature of efficacious treatments. TMH believes that its simple design offers several advantages over competing devices. Most notably, these include ease of use, patient convenience, improved reliability as there are fewer components that can malfunction, and reduced manufacturing costs because the device does not require complicated or numerous parts. Figure 1 summarizes the features and benefits of TMH's ASI™ autoinjector family, with greater details provided on pages 21-26.

Figure 1
The Medical House PLC
FEATURES AND BENEFITS OF TMH'S AUTOSAFETY INJECTOR (ASI™) AUTOINJECTOR

Cost Effectiveness
- No Need for a Clinician to Administer
- Minimal Number of Device Components
- Simple Production Processes

Patient Comfort
- No Visible Needle

Convenience
- Simple Two-step User Process with "On-board" Drug
- Automated Needle Insertion, Drug Delivery, and Needle Retraction

Safety
- Needle Automatically Retracted and Secured After Injection
- Disposable Device with No Exposed Sharps
- Drug Inspection Window

Reliability
- Reproducible Injection Results without a Specialist's Expertise
- Audible and Visual Indicators of Injection Completion

Rapid Commercialization
- Incorporates Drugs in Existing Syringe or Cartridge Presentations
- Avoids Long and Costly Repackaging Projects

Versatility
- Choice of Dosing Options
- Suitable for a Wide Range of Compounds

Sources: The Medical House PLC, Catalent Pharma Solutions, Inc., and Crystal Research Associates, LLC.

Customized Autoinjectors

TMH possesses comprehensive development capabilities for off-the-shelf product designs as well as for more unique solutions tailored to its customers' specific requirements, whether the licensee seeks to launch a new product, extend an existing product line, or market a generic medicine. The ability to customize its autoinjectors is a vital factor for TMH, as licensees often have unique delivery needs ranging from injection duration (e.g., rapid or slow) and dose volume to medication viscosity and depth of injection (e.g., subcutaneous or intramuscular). The ASI™ autoinjector platform is capable of injecting standard non-viscous liquid compounds and sustained-release (viscous) formulations, as well as reconstituting and injecting dry (e.g., freeze-dried) formulations. Typically, a licensee funds the device customization process, which may entail new production tooling and testing for regulatory purposes, among other activities.

Regulatory Clearances

In Europe, four ASI™ autoinjector device versions (subcutaneous, intramuscular, viscous, and non-viscous) are covered by the CE Mark, a regulatory approval indicating conformity to European directives. In the U.S., the Food and Drug Administration (FDA) granted a viscous drug version of the ASI™ autoinjector family a 510(k) medical device clearance in March 2008, which represented the first U.S. approval for the Company's disposable autoinjector technology. In October 2008, TMH received a second 510(k) clearance for the use of its technology with non-viscous medicines as well.

TMH's Needle-free Jet Injectors

TMH has also designed a reusable needle-free platform. The reusable needle-free jet injectors have received both Europe's CE Mark and the FDA's 510(k) clearance. Due to the chemical composition and required dose volumes as well as the likely need for extensive clinical evaluations, there are presently few products for which needle-free delivery is deemed to be commercially appropriate; however, both **insulin** and hGH can be delivered through jet injectors. Needle-free drug delivery is forecast to reach $3 billion by 2010, in part due to growth in the needle-free administration of vaccines (Source: Kalorama Information, a publisher of research for medical markets, 2007). TMH is partnered with Merck Serono for the delivery of hGH to children and adolescents via a reusable needle-free jet injector.

Roughly 1 in every 10,000 children is born with an hGH deficiency, and some countries report rates as high as 1 in 4,000. The Human Growth Foundation, Inc. estimates that 10,000 to 15,000 children and approximately 70,000 adults in the U.S. have growth failure due to hGH deficiency.

Market Opportunity

In 2006, the implantable/injectable drug delivery market reported revenues of $9.8 billion worldwide, forecast to reach $12.6 billion in 2010 driven by demand for new delivery technologies. Factors fueling market expansion include an aging global population that values easy to use, safe, and low-cost medications; the pharmaceutical industry's realization that novel delivery methods can extend the life of products nearing patent expiration and provide a competitive edge; and generic manufacturers desire to incorporate novel devices that supply their **bioequivalent** products with distinct, differentiating features. Kalorama's *Drug Delivery Markets, Edition 2 Volume II: Implantable/Injectable Systems* (2007) postulated that drug delivery techniques could continue to be a focal point of competition in the pharmaceutical industry—determining a product's success versus failure for the next decade.

The autoinjector sector in particular is expanding. Of the currently commercialized therapeutic proteins for chronic diseases, more than two-thirds are supplied in an autoinjector or **injection pen** format (Source: Greystone Associates, a provider of pharmaceutical market reports, May 2008). Growth drivers include legislation requiring the use of safer injection products, and trends toward patients taking an active role in their treatments (i.e., refusing to use antiquated, uncomfortable, or inconvenient devices).

Autoinjectors are also beneficial for medications that are losing patent protection and are likely to be subject to intense generic competition (Source: *Innovations in Pharmaceutical Technology* 2007). By 2012, generics are expected to replace approximately $70 billion in annual sales in the U.S. alone as more than 36 medicines go off-patent. TMH believes that companies with products losing patent protection could use its patented ASI™ autoinjector device to extend sales of their medications. Additionally, the growth of generic competition presents further opportunities for autoinjectors, as many of these entities may seek to incorporate a novel delivery device to create more competitive generics that can command a higher price than they might without an accompanying self-injection system.

Anti-tumor Necrosis Factor Alpha (TNFα) Application

Potentially one of the largest upcoming applications for disposable autoinjectors is the delivery of anti-TNFα products. TNFα is a protein produced by white blood cells that has an important role in the body's inflammatory processes. Two of the primary products in the anti-TNFα market already employ disposable autoinjectors: (1) Amgen, Inc.'s (AMGN-NASDAQ) ENBREL®, which uses the ENBREL® Single-use Prefilled SureClick™ Autoinjector; and (2) Abbott Laboratories' (ABT-NYSE) HUMIRA®, which uses the HUMIRA® Pen. Both ENBREL® and HUMIRA® are approved to treat rheumatoid arthritis (RA), chronic moderate-to-severe plaque **psoriasis**, juvenile arthritis, and **psoriatic arthritis**, among other conditions. In 2007, ENBREL® generated global sales of approximately $5.3 billion and HUMIRA® had worldwide sales of roughly $3.1 billion. By 2012, the total global market for anti-TNFα products could exceed $20 billion (Source: Arana Therapeutics Ltd. [AAH-ASX]).

TMH believes that because both Amgen and Abbott use disposable autoinjectors, any other company seeking to enter the anti-TNFα market will likely also need a disposable autoinjector in order to be competitive. The disposable autoinjector sector is estimated to contain only a relatively small number of active companies (roughly half a dozen established competitors) and is believed to be largely defined by intellectual property barriers and the regulatory status of devices. As such, TMH views itself as well positioned to capitalize on entrants to this space that may have not yet selected a delivery device for their anti-TNFα pipeline products.

History, Headquarters, and Employees

TMH, a holding company, was founded in 1998 and admitted to the London Stock Exchange's (LSE) Alternative Investment Market (AIM) in 2000. Prior to this, the Company had operated as Eurocut Ltd. since 1987. Eurocut, which subsequently became a wholly owned subsidiary of TMH, specialized in product development, engineering, and contract manufacturing for the orthopedics industry—ultimately developing over 1,000 devices for medical companies. During this time, the Company did not own any of the intellectual property related to these devices; it only manufactured complex orthopedic components for which there were few other manufacturers. Management believes that Eurocut was one of Europe's leading orthopedic contract manufacturers during the 1990s.

However, over time, India and China began to emerge as regions with considerable low-cost production capabilities. Given that Eurocut did not own the intellectual property and theoretically its customers could relocate to manufacturers in India or China at any time, the Company opted to begin evaluating diversified business opportunities where it could leverage its design skills and attain ownership of intellectual property. Thus, in 2001, TMH created a drug delivery division based on management's market research into the drug delivery arena during the 1990s, its designers' skill with medical devices, and the Company's connections and reputation within the medical industry. This division is now called Medical House Products Ltd. (www.tmh-drugdelivery.com), a wholly owned subsidiary of TMH.

In December 2007, following a slowdown in the Company's orthopedic businesses, Eurocut and its related subsidiary Medical House Orthopaedics Ltd were sold to Semes Ltd. Semes was formed by Eurocut's managing director, Mr. Stephen Shaw, to acquire Eurocut in a leveraged buyout transaction. This transaction represented the elimination of the Company's orthopedic manufacturing division, thereby allowing TMH to channel resources toward continued market adoption of its drug delivery devices, believed to be an expanding business area.

TMH is incorporated and headquartered in Sheffield, UK. The Company's functional currency is the pound sterling. TMH presently employs approximately 25 individuals.

Quality Standards

The Company's quality management systems have been certified as being compliant with **International Organization for Standardization (ISO)** standards 9001:2000 and **ISO 13485:2003**. Businesses that adopt these voluntary international standards can develop and market products and services meeting specifications that have wide international acceptance. **ISO 9000** pertains to quality management and quality assurance and ISO 13485 specifically governs quality systems relating to medical devices.

Growth Strategy

Due to the wide array of potential uses for a needle-based disposable autoinjector, the Company has positioned the ASI™ autoinjector system as its lead technology, centering its resources primarily in this area. In contrast, needle-free jet injectors, while beneficial in certain scenarios, have fewer commercial opportunities.

License-based Business Model

TMH has completed the development of its patented ASI™ autoinjector and needle-free jet injector systems, and thus, no longer requires funding for the creation of these technologies. Rather, the Company has transitioned to a business model that revolves around a license-based revenue stream, where TMH outlicenses the use of its delivery platforms to pharmaceutical and biotechnology companies, government agencies, and other entities. Under its license agreements, the Company retains ownership of the technology and associated intellectual property and is typically entitled to either cash, revenue or profit sharing, or technology access fees (e.g., royalties) on product sales. In addition, the licensee funds any technology customization that may be required to meet the particular needs of the licensee's drug formulation, therapy, or patient population. The licensee also finances certain activities undertaken by TMH on the third party's behalf, such as obtaining regulatory approvals and establishing commercial-scale supply chains. Lastly, the partner finances certain capital investments that may be required, such as manufacturing systems. TMH's long-term income is primarily generated through licensing payments, but also through the supply of devices and development fees. Manufacturing is outsourced (as addressed on page 25).

Marketing Strategy

To identify, pursue, and obtain new business, TMH's marketing strategy entails entering into collaborative arrangements with third parties that have established sales and marketing operations. In particular, the Company focuses on entities that have experience supplying to global pharmaceutical, medical device, and biotechnology markets and that currently offer products that are complementary to TMH's. TMH believes that this approach for increasing its worldwide presence is faster, more direct, and more economical than hiring, training, and deploying its own global sales organization. As fully detailed on pages 29-30 of the Partnerships section, the Company's first sales and marketing partner under this strategy is Catalent, formerly the Pharmaceutical Technologies and Services (PTS) division of Cardinal Health, Inc. (CAH-NYSE).

Table 1 summarizes some of the new business opportunities that TMH is pursuing for its ASI™ autoinjector platform. Each additional license agreement that the Company enters into establishes greater market credibility for TMH and its ASI™ autoinjector family.

Table 1
The Medical House PLC
ASI™ AUTOINJECTOR: POSSIBLE NEW BUSINESS AREAS

- *Global Outlicensing*: Outlicense and customize the ASI™ autoinjector for licensees to incorporate with proprietary drug products
- *Drug Life Cycle Management*: Adapt the ASI™ autoinjector to existing blockbuster biologics
- *Generics*: Customize, license, and supply the ASI™ autoinjector to international generics companies
- *Big Pharma*: Provide broad licenses for new biologics drug pipelines
- *Government*: Continue to pursue opportunities with governmental and civilian agencies

Sources: The Medical House PLC and Crystal Research Associates, LLC.

Intellectual Property

The Company believes that the most significant barriers to entry for potential new competitors to the disposable autoinjector space include existing intellectual property rights, the requisite device regulatory approvals, and experience managing customization and industrialization projects on behalf of licensees. Furthermore, TMH views itself as one of only a handful of companies that possesses both the requisite intellectual property and the capability and experience to customize and commercialize a drug delivery project, including achievement of international regulatory approvals.

TMH's primary patent for its core ASI™ autoinjector technology was granted by the UK Intellectual Property Office in 2006 under the title "Injection Device" and the patent number GB2410188. The core technology was patented at the European Patent Office in 2007 and the patent validated extensively across Europe. Certain claims associated with this patent family have been agreed upon with the U.S. Patent and Trademark Office (USPTO). TMH expects that these claims may lead to a **Notice of Allowance** in the U.S. There are also pending patent applications for this technology in other countries.

At the time of publication for this Executive Informational Overview® (EIO®), TMH had six additional patent applications pending in the UK that related to variations of its core ASI™ autoinjector technology, such as the mixing of a dry drug with a diluent and the inclusion of a syringe protection system (SPS) to protect the glass syringe from breakage that can occur as a result of elevated forces required in viscous drug injection. Additional patent applications are also pending under the **Patent Cooperation Treaty (PCT)**, a vehicle that enables an entity to seek patent protection simultaneously in 139 countries. The PCT does not grant an "international patent," which does not exist, but rather facilitates the process of obtaining a patent in each member country and bestows additional benefits to the applicant, including priority over more recent third-party applications. TMH's PCT applications are currently moving through various national phases in jurisdictions around the world. They entail enhancements to the ASI™ autoinjector that could provide advantages in relation to specific uses. Table 2 (below and continued on page 10) summarizes TMH's intellectual property in the UK as well as some of its global patent applications.

Table 2
The Medical House PLC
A SELECTION OF TMH'S INTELLECTUAL PROPERTY PORTFOLIO

Title	App. Date	Pub. or App. Number	Status
ASI™ Autoinjector Devices			
Injection Device	1/27/2004	CA2455937	Pending in Canada
Injection Device	1/23/2004	GB2410188	Granted in the UK
Injection Device	1/28/2004	US10/767860	Pending in the U.S.
Injection Device	1/24/2005	PCT/GB2005/000223	Granted in Europe; Pending in Canada, China, India, Israel, Japan, New Zealand, Russia, South Africa, South Korea, U.S.
Injection Device	1/24/2005	EP1715903	Granted and validated in 29 European countries
Improved Autoinjector	10/12/2006	GB0620163.6	Pending (UK)
Improved Autoinjector	3/22/2006	US11/387645	Pending (U.S.)
Improved Autoinjector	1/17/2007	PCT/GB2007/000141	Pending in Canada, China, Europe, India, Israel, South Korea, U.S.
Improved Autoinjector	4/15/2006	GB0806814.0	Pending (UK)
Improved Autoinjector	12/18/2007	PCT/GB2007/004870	Pending (International phase)
Improved Autoinjector	12/18/2007	GB0724567.3	Pending (UK)
Improved Autoinjector	8/18/2008	GB0814985.8	Pending (UK)
Improved Autoinjector	3/20/2008	PCT/GB2008/001015	Pending (International phase)
Improved Autoinjector	3/20/2008	GB0805269.8	Pending (UK)
Improved Autoinjector	3/4/2008	PCT/GB2008/000741	Pending (International phase)
Improved Autoinjector	3/4/2008	GB0804021.4	Pending (UK)

Source: Harrison Goddard Foote.

Table 2 cont.

The Medical House PLC

A SELECTION OF TMH'S INTELLECTUAL PROPERTY PORTFOLIO

Title	App. Date	Pub. or App. Number	Status
Needle-free Injection Devices			
Needleless Injection Device	10/20/2003	PCT/GB2003/004532	Granted in South Africa; Pending in Australia, Canada, China, Europe, Japan, Poland, U.S.
Needleless Injection Device	10/21/2003	PK138714	Granted (Pakistan)
Needleless Injection Device	10/20/2003	PCT/GB2003/004528	Expired (no national phase entries)
Needle-free Injection Device	1/27/2004	CA2455930	Pending (Canada)
Needle-free Injection Device	1/11/2005	PCT/GB2005/000063	Pending (Europe)

Source: Harrison Goddard Foote.

Company Leadership

TMH supports the concept of an effective Board leading and controlling the Company, including approving strategy and policy. Table 3 summarizes TMH's key management and Board members, followed by detailed biographies. TMH's Board of Directors includes two subcommittees: (1) an Audit Committee composed of Mr. Ian Townsend, Mr. Bryan H. Bodek, and Mr. John K. Pool; and (2) a Remuneration Committee composed of Mr. Bodek and Mr. Pool.

Table 3
The Medical House PLC
COMPANY LEADERSHIP

Ian Townsend, FCA	Chairman
Bryan H. Bodek, LLB	Deputy Chairman
David Urquhart	Managing Director of the Drug Delivery Division (Medical House Products Ltd.) and Director
Margaret Scott, FCMA	Financial Director and Company Secretary
John K. Pool	Non-executive Director

Sources: The Medical House PLC.

Ian Townsend, FCA, Chairman

Mr. Townsend qualified as a chartered accountant in 1976 and worked for KPMG International until 1979, when he established his own practice in Harrogate and York, UK. In 1986, he formed Townsend Management Consultants Ltd, specializing in corporate recovery. He became finance director of Conrad PLC in 1993, until the reversal of Sheffield United PLC (SUT-LSE) into Conrad, when he became finance director and the chief executive of Sheffield United. Mr. Townsend was a founding member of Eurocut Ltd. in 1988 and, until the formation of TMH, served as chairman. He was chief executive of TMH from January 2000 to January 2005, when he became chairman. Mr. Townsend has also served on the Members Committee of Yorkshire County Cricket Club since 2003, and is a fellow of the Institute of Chartered Accountants (FCA).

Bryan H. Bodek, LLB, Deputy Chairman

Mr. Bodek is a lawyer and vice chairman of the Company. He is also chief executive of Airline Services Ltd, a supplier of aircraft presentational services and products to airlines. Prior to joining Airline Services in January 2000, he was the managing partner and head of corporate finance of Kuit Steinart Levy LLP solicitors in Manchester, UK, where he had 25 years of experience advising corporate transactions. He is also a director of the University of Manchester Intellectual Property Ltd., the University of Manchester's managing agent for intellectual property commercialization. Until recently, he was a director of the Manchester City Football Club as well.

David Urquhart, Managing Director of the Drug Delivery Division (Medical House Products Ltd.) and Director

Mr. Urquhart is a qualified engineer, having studied at the University of Dundee before embarking in 1985 on a career in sales with Pall Europe Ltd (part of the Pall Corp. [PLL-NYSE]), a supplier of fluid processing equipment for the pharmaceutical and biotechnology industries. In 1990, he joined Haemonetics Corp. (HAE-NYSE), initially holding positions in sales and product management with this manufacturer of specialist medical devices used in the collection and processing of human blood components and in surgical blood recovery. In 1997, Mr. Urquhart assumed the role of general manager of Haemonetics' UK subsidiary. He joined TMH in 2002 and now has responsibility for the Company's operations in relation to the design, development, and marketing of drug delivery systems. In January 2005, he became the managing director of Medical House Products Ltd.

Margaret Scott, FCMA, Financial Director and Company Secretary

Ms. Scott joined TMH in April 2008, having spent three years working in the aviation sector as a business controller with Mytravel Airways Ltd (acquired by the Thomas Cook Group plc [TCG-LSE]) and also as finance director with Airline Services. Previously, she culminated a 13-year career with Alstom SA (ALO-EPA), a French engineering company, holding finance director roles both in the UK and the Far East. Ms. Scott is a fellow of the Chartered Institute of Management Accountants (FCMA) and has received institute awards for examination achievements during her student years.

John K. Pool, Non-executive Director

Mr. Pool has extensive experience in establishing companies in the medical sector. In 1981, he instigated and was program manager for the flotation of the first private hospital in the UK, the West Yorkshire Clinic (which subsequently became part of Community Hospitals Group PLC). In 1987, he founded a private company exploiting computer-aided molecular design in drug discovery, which became a subsidiary of Proteus International PLC in 1990 (now Protherics PLC [PTIL-NASDAQ]). Having led the successful flotation of Proteus on the Unlisted Securities Market of the LSE, Mr. Pool served as managing director and subsequently as deputy chairman. Mr. Pool is currently a director of several emerging medical companies in the UK.

Core Story

The Medical House PLC ("TMH" or "the Company") specializes in the design, development, licensing, and supply of self-injection medical device platforms for the pharmaceutical and biotechnology industries. By leveraging the expertise of its drug delivery division—Medical House Products Ltd.—the Company aims to provide innovative, cost-effective drug delivery solutions that have a reduced time to market. At present, TMH is focused on supplying its AutoSafety Injector (ASI™) autoinjector and reusable needle-free jet injectors, for which the Company's services range from conceptual design to managing manufacturing and device supply.

By offering easy to use, safe, comfortable, and economical delivery systems that do not require the involvement of a clinician to administer an injection, TMH aims to enable its pharmaceutical and biotechnology partners to increase sales of approved medications. The Company designs, develops, patents, and seeks regulatory approval for customized devices based on input from its partners and proceeds to license the customized autoinjector to the partner.

DRUG DELIVERY DEVICES

As pharmaceutical companies are faced with the effects of ever-rising healthcare costs and greater competition from generic products, these entities are becoming more proactive at seeking out ways to differentiate their products, increase profitability, and add depth and diversity to their product lines. One widely used technique is to incorporate the drug product into a novel delivery system that is preferred by patients and physicians. Drug delivery devices use one or more technologies to create a system or vehicle that facilitates the entry of a therapeutic substance into the body. In general, next-generation delivery systems are intended to demonstrate enhanced performance, fewer side effects, greater efficacy, and less wasted product than prior systems. Traditional methods of delivering medications include pills, liquids, or injections given at a physician's office, while newer delivery forms involve high-tech versions of these traditional systems, such as automated injections that patients can administer themselves ("autoinjectors"). Certain drug delivery methods may also be able to lengthen a product's lifecycle in the face of generic competition by offering enhanced performance or a reduced side effect profile.

A critical objective for any pharmaceutical company is to identify the most appropriate drug delivery system to optimize the therapeutic benefits of a medicine and to minimize any potential adverse events. The mission of a drug research program does not end with the discovery of a viable new chemical entity, as the compound will not likely command market success until it can be made available in a dosage form or delivery system that is superior in both therapeutics and pharmacoeconomics to competing products. Careful consideration of delivery systems is an increasingly important factor in overall drug development as the intensity of competition in the pharmaceutical industry continues to grow.

TMH believes that its delivery systems offer a way for pharmaceutical manufacturers to reduce patients' dependence on clinical expertise, improve treatment convenience and therapy management, enhance compliance, overcome needle aversions, eliminate needlestick injuries, assist in large-scale or rapid injections, and save lives in emergencies.

Conventional Injections

The first needle and syringe combination fine enough to pierce the skin was developed in 1853. Currently, due to requirements for drug product compatibility with primary packaging materials, glass is overwhelmingly the material of choice for manufacture of pre-fillable syringes. Such pre-fillable syringes are used mainly for products to be self-injected or for vaccines. Figure 2 illustrates a typical glass syringe with a pre-attached needle. Beginning in the 1990s, pharmaceutical companies and medical device companies began incorporating safety mechanisms onto needles.

Figure 2
NEEDLE AND SYRINGE

Source: The Medical House PLC.

Despite over a century of progress, the conventional syringe and needle design is still associated with significant drawbacks, namely those listed below:

- need for clinical expertise to administer the injection with related cost implications and inconvenience;
- being prone to accidental needlestick injuries;
- although unintended by product manufacturers, single-use injection devices being reused in developing countries that have limited resources to purchase new sterile needles; and
- patients' aversions to injections due to the pain, discomfort, inconvenience, fear, and high costs typically associated with this delivery method.

Risks of Needlestick Injuries

Needlestick wounds entail any accidental punctures by exposed needles or other like **sharps** that result in contact with blood or other bodily fluids. Inherently, even the smallest needle prick that contacts bodily fluid carries the risk of transmitting dangerous infectious diseases. The most common pathogens contracted by individuals who have been accidentally stuck with an exposed sharp are hepatitis B, hepatitis C, and the human immunodeficiency virus (HIV), although it is possible to transmit more than 20 known infections through unsafe injection practices (several of which are summarized in Figure 3). A study of 19 of Australia's Queensland Health hospitals from February 2002 to December 2005 found that of the more than 5,300 occupational exposures to blood and bodily fluids, approximately 68% were due to percutaneous (through the skin) sharps injuries. Roughly 55% of these sharp injuries were caused by hollow-bore (**hypodermic**) needles.

Figure 3

INFECTIONS TRANSMITTED VIA SHARPS INJURIES DURING PATIENT CARE (PC) AND/OR LABORATORY/AUTOPSY (L/A)

Infection	PC	L/A	Infection	PC	L/A
Blastomycosis		○	Herpes	●	
Cryptococossis		○	Leptospirosis		○
Diphtheria		○	Malaria	●	
Ebola		○	M. tuberculosis	●	○
Gonorrhea		○	Rocky Mountain spotted fever		○
Hepatitis B	●	○	Scrub typhus		○
Hepatitis C	●	○	Strep pyogenes		○
HIV	●	○	Syphilis		○
			Toxoplasmosis		○

Source: the U.S. Centers for Disease Control and Prevention (CDC) 2004.

In the U.S. annually, there are approximately 385,000 sharps-related injuries to hospital-based healthcare personnel, which represents an average of 1,000 punctures per day (Source: the Centers for Disease Control and Prevention [CDC] 2004). These numbers do not include needlestick injuries to patients or to healthcare workers at non-hospital institutions, such as home healthcare, long-term care, and private practice. In addition, the CDC estimates that as much as 50% of healthcare personnel do not report their occupational percutaneous wounds. Additional estimates place the number of needle injuries in the U.S. each year at approximately 600,000, with as many as 2,000 of these resulting in the transmission of bloodborne viruses. Injection devices that require manipulation or disassembly after use are associated with the highest rates of injury. One of the primary features of TMH's ASI™ autoinjector technology is its ability to automatically and securely retract the needle from the skin directly back into the device, without the user/administrator ever having to see or handle the needle.

As early as November 1999, the U.S. Occupational Safety and Health Administration (OSHA) agency issued a Bloodborne Pathogens Compliance Directive mandating the use of safer needles and requiring

that healthcare facilities perform annual reviews of safety and compliance programs. Furthermore, Australia's Queensland Government's Centre for Healthcare-Related Infection Surveillance and Prevention (CHRISP) undertook a study in 2004 to evaluate the safety impact of replacing the conventional syringe and needle appliance with retractable needles. The two-year study documented a reduction in needlestick injuries by 50% versus the pre-trial period. CHRISP now recommends a variety of safety procedures for Queensland's healthcare industry, which include replacing the needle and syringe for intramuscular and subcutaneous injections with retractable devices that come with a pre-attached needle as well as using more needle-free intravenous systems.

The direct costs associated with treatment of needlestick injuries are approximately $500 and $3,000 per patient depending on the treatment (Source: CDC). There are also non-monetary impacts that are harder to quantify, such as the emotional burdens of fear and anxiety that result from worrying about disease exposure, the social stigma associated with contracting one of these infectious pathogens, lost time from work, and litigation expenses.

Unsafe Reuse of Injectable Devices

In countries such as the U.S., immunization processes are well established and advanced, and safe injection systems are generally available. However, the majority of the developing world cannot afford enough needles, especially not the newer, more costly needles that prevent reuse. As a result, healthcare workers are reusing unsterilized needles and syringes to immunize local populations. Considerable problems are arising in developing countries where vaccines and other treatments are administered with "dirty" unsterilized needles. The World Health Organization (WHO) estimates that unsafe injections account for 33% of new hepatitis B and 42% of new hepatitis C cases in developing and transitional countries, and 2% of new HIV infections globally each year. The supply of a cost-efficient injection device that does not require skilled administration and does not allow reuse may be able to help improve the safety of injections in developing countries, thereby also helping to reduce disease transmission.

Needle Phobias and Patient Anxieties

While many patients dislike needles, with reactions including anxiety, fear, and avoidance, between 7% and 22% of the general population actually has an injection phobia that makes injectable treatments very difficult or even impossible (Source: the *Journal of Neuroscience Nursing* 2006). Phobias and needle anxiety are more common in pediatric patients and those individuals whose therapy requires frequent shots.

Through TMH's history of supplying medical devices (in particular, needle-free insulin injectors for diabetic patients), its management has concluded that many patients who do not like injections or who fear needles may frequently opt just to not take their medications at all, which can lead to worsening conditions and ineffective therapies. A report of the American Association of Diabetes Educators (AADE) released in August 2008 found that 20% of diabetic patients surveyed had skipped insulin injections and 43% of individuals had altered their eating schedules in order to avoid injections. A selection of physicians were also interviewed, with 79% of healthcare providers acknowledging that their patients skip insulin injections (Source: *Injection Impact Report* 2008). For this patient population, non-compliance to insulin injections can lead to severe and costly complications, including heart disease, blindness, renal failure, and hypertension (high blood pressure), among many other conditions. Most complications arise from extended periods of elevated, uncontrolled blood glucose levels, and each year, roughly four million adults die of these side effects (Source: International Diabetes Federation [IDF]).

As many as one-third of patients questioned reported experiencing dread about daily injections, 14% felt insulin injections negatively impacted their life, and 29% viewed the injections as the hardest aspect of diabetes care. Altogether, 47% of respondents to the AADE's survey said they would be more adherent to a treatment regimen if it was associated with less pain and discomfort than their current injections. While these data were specific to diabetes patients, it may be representative of the larger issues surrounding most injectable medicines today—pain, inconvenience, and fear—that keep people from seeking or complying with treatment. As addressed in greater detail on page 26, TMH recently sold its needle-free insulin delivery business. However, the Company remains committed to the provision of safe, convenient, comfortable, and cost-efficient forms of drug delivery, believing that the right device can improve patient compliance and thus the therapy's effect as well as increase demand for the pharmaceutical products that incorporate TMH's systems.

Some Alternatives to Standard Needle Techniques

There are several methods to enhance injections that are either presently employed or are being researched for potential future application, including autoinjectors (described below and on pages 17-19) and variable-dose injection pens. Unlike the syringe and needle technique, injection pens are easier and safer to transport. At present, one of the most common applications of injection pens is insulin administration. Yet, these devices are not as widely used in the U.S. as they are in Europe, in part due to differing treatment plans, poor marketing of the delivery method, and an initial reluctance of health insurance providers to reimburse the pens. This trend may change if thinner, smaller, and easier-to-use pens reach the market in the future, as expected (Source: Global Insight, Inc., an economic forecaster and financial analyst, 2007). Future development may also include microneedle technologies (which center on using great numbers of microscopic needles) and expansion of external infusion pumps.

In addition, needle-free jet injectors can be used to administer insulin and human Growth Hormone ([hGH] addressed in greater detail on page 27). Jet injectors, which produce a narrow, pressurized stream that is capable of permeating the skin without puncturing it, provide an alternative for patients who fear needles. Needle-free injection is an emerging form of **parenteral drug delivery** that is gaining general acceptance among the medical community. Encompassing a wide variety of sizes and designs, the technology operates by using pressure to force the drug, in solution or suspension, through a minute perforation, creating an ultra-thin stream that penetrates the skin and deposits the medicine into the subcutaneous tissue. This technology may increase patient comfort (and in turn compliance), as well as eliminate needlestick risks. TMH's advances in needle-free injection are described on pages 26-27.

To further address the market's need for an improved injection technique, TMH has designed the AutoSafety Injector (ASI™) autoinjector technology that is licensed to pharmaceutical and biotechnology companies requiring a novel method to deliver new medicines or enhance existing products. The ASI™ autoinjector platform (fully detailed on pages 21-26) entails a proprietary autoinjector that is customizable for an array of applications.

AUTOINJECTOR OPPORTUNITIES

Autoinjectors, essentially spring-loaded devices that are prefilled with a medication contained within a syringe/needle, are expanding in popularity because they offer greater ease of use, improved compliance, and the potential for reduced costs since healthcare professionals are often no longer required to administer the injection. Several studies have also suggested that autoinjectors reduce pain and anxiety in patients versus conventional syringes. Table 4 summarizes some of the benefits that autoinjectors offer, as noted in the November 2007 edition of *Innovations in Pharmaceutical Technology*.

Table 4

BENEFITS OF AUTOINJECTORS THAT COULD FUEL MARKET ADOPTION OF THIS DELIVERY SYSTEM

For the User
▪ Simplifies self-administration
▪ Creates a self-injected option for patients who may suffer from impaired vision, dexterity, or other challenges
▪ Reduces costly clinic visits and home visits by clinicians
▪ Reduces anxiety as users do not need to see or manually insert the needle
▪ Improves safety by decreasing needlestick injuries
▪ Improves compliance due to controlled, consistent drug delivery
For the Business
▪ Enables drug manufacturers to meet customers' needs and preferences, which is important as patients may request a change of treatment if they do not like their current method of drug delivery
▪ Provides a safe needle device that meets legislative requirements mandating injection safety
▪ May create and protect market share for key drug products
▪ Offers protection from counterfeit medications

Sources: "Auto-Injectors: Technology Advances and Market Trends" (Innovations in Pharmaceutical Technology) and Crystal Research Associates, LLC.

The market for autoinjectors is believed to be experiencing rapid growth (Source: *Innovations in Pharmaceutical Technology* 2007). Some contributing factors include legislation, such as OSHA's standards governing the use of safer injection products, and trends toward patients taking an active role in treatment management. Additionally, as the problem of counterfeit medications is pervasive—worldwide sales of fake drugs are expected to reach $75 billion by 2010 (Source: WHO 2008)—employing single-use, disposable autoinjectors that are considerably more difficult and costly to counterfeit could offer an extra layer of protection for pharmaceutical products.

Trend Toward Self-administration

The self-injection market is estimated to be growing at 15% compounded annually due to increasing disease incidence and prevalence, patient preference, efforts to control spiraling healthcare costs, and technology advances (Source: *Drug Delivery Technology* 2006). Disorders currently treated with self-administered injections include multiple sclerosis (MS), rheumatoid arthritis (RA), hepatitis, **Crohn's disease**, migraines, blood clotting, allergic reactions, and infertility, among others. Self-administration is also expanding as more studies document the critical role of the delivery device in determining treatment adherence. Compliance to the therapy regimen is mandatory for therapeutic success. A 2007 study published in *Gastroentérologie clinique et biologique* found that use of a self-injection device to treat hepatitis C was associated with easier, faster, and less painful shots as well as a greater assurance of exact dosing versus the conventional needle and syringe method. Compliance was greater than or equal to 80% in more than 80% of participants.

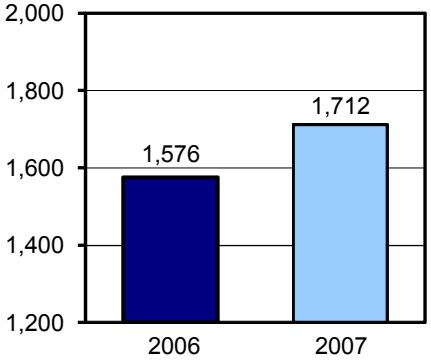
The ASI™ autoinjector incorporates prefilled syringes, which are a standard technology and a low-risk option for achieving formulation stability. TMH believes that two billion pre-fillable glass syringes are produced annually, 900 million of which are for self-injection products. Some estimates value the prefilled syringe market at $1.5 billion per year, with 10% to 20% annual growth (Source: Unilife Medical Solutions Ltd.).

Expansion of Injectable Biologic Products

One of the primary factors fueling the need for enhanced injection devices is the growth of biological products to treat chronic diseases. Whereas traditional drugs are synthetic compounds, biologic medicines are typically derived from naturally occurring therapeutic proteins and are very specific in how they work on the underlying causes of disease. Gene-based and cellular biologics are often at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available (Source: the U.S. Food and Drug Administration's [FDA] Center for Biologics Evaluation and Research [CBER]).

The number of biotechnology-based products now in development far exceeds the number of conventional drugs being tested. For example, as of 2007, there were over 400 biotechnology molecules and vaccines in clinical development in the U.S. for more than 200 disease targets (Source: the Biotechnology Industry Organization [BIO]). Likewise, in Europe in 2007, the number of biotechnology products in the preclinical and clinical pipeline increased by roughly 9% to more than 1,700, as illustrated in Figure 4. Concurrently, in 2007, the pharmaceutical industry's pipeline had fewer products in development in the top 10 therapeutic areas than it did in 2006—propelling pharmaceutical companies' acquisitions of the smaller biotechnology firms in order to bolster pipelines and capitalize on growth in biologics. From 2005 to 2007, large pharmaceutical entities spent over $76 billion to buy biotechnology firms. During 2007 alone, there were 417 new partnerships between biotechnology and pharmaceutical companies (Sources: *Wall Street Journal* and BIO).

Figure 4
BIOLOGIC PRODUCTS AT THE CLINICAL TRIAL STAGE IN EUROPE



Sources: Ernst & Young Global Ltd. and Crystal Research Associates, LLC.

In August 2008, the *Seattle Times* reported that the market for bioengineered (created by genetically modified living cells) and specialty medications was nearly $59 billion, forecast to reach $98 billion by 2011 as the pharmaceutical industry continues to focus its research in this area.

Most Biologic Products are Injected

The most significant challenge beyond discovery of such biologic molecules is how to effectively deliver them. At present, more than two-thirds of all therapeutic proteins for chronic diseases are supplied in an autoinjector or injection pen format (Source: Greystone Associates, a provider of pharmaceutical market reports, May 2008). TMH further believes that approximately 70% of biologic products will likely require injection as the means of administration due to the harsh environment that stomach acids present for therapeutic proteins. When administered orally into the human body, most proteins are broken down in the gastrointestinal system before they can reach the desired site of action, resulting in decreased drug efficacy. This effect, called first-pass metabolism, occurs after a medication is swallowed. Once ingested, the drug is absorbed by the digestive system and is carried into the liver, which metabolizes the compound. In some cases, treatments are so extensively broken down by the liver that only a small amount of medication enters the systemic circulation, reducing the bioavailability of the drug. As a result, patients must consume larger doses of medication in order for the required amount to reach the affected area.

In addition, certain biologics could also become sequestered in the stomach or another organ, or be deactivated or altered by the gastrointestinal tract due to the tract's acid environment, digestive enzymes, and permeable membranes that generally hinder the delivery of protein drugs. Efficiently transporting large proteins across membranes to the target tissues can be challenging, and thus result in fundamentally poor absorption. However, issues relating to absorption can be circumvented with injections. Medications destroyed or metabolized in the gastrointestinal tract or poorly absorbed in the body when taken orally may instead be administered intravenously or subcutaneously. Intravenous administration offers systemic dose accuracy and immediate onset of action, which is not possible with traditional oral systems. High concentrations of a medication can rapidly access the blood system and targeted tissues. As a result, many biologics are and will likely continue to be injected, further contributing to the market's demand for efficient, convenient, safe, and cost-effective injection systems.

Anti-tumor Necrosis Factor Alpha (TNFα) Indications

Potentially one of the largest upcoming applications for autoinjectors are anti-TNFα products. TNFα is a protein produced by white blood cells that has an important role in the body's inflammatory process. This therapeutic protein promotes the creation of new blood vessels, thus it is important to healing. However, it also contributes to numerous inflammatory pathologies, including RA, psoriasis, psoriatic arthritis, Crohn's disease, and other autoimmune diseases. According to the U.S. Department of Health and Human Services and the National Institutes of Health's (NIH) Office of Technology Transfer (OTT), over 5% of the U.S. population presently has an autoimmune condition. Medications that block TNFα (called anti-TNFα products or TNFα blockers) have been proven to be beneficial in reducing the damage that the body's immune system causes in many inflammatory diseases. By 2012, the market for anti-TNFα products could exceed $20 billion (Source: Arana Therapeutics Ltd.).

The dominance of biologic TNFα inhibitors as the **first-line treatment** for RA is expected to continue and possibly expand over the next two years, with 99 of 100 surveyed rheumatologists prescribing these products (Source: Decision Resources, Inc., a market research publisher, 2008). Expansion of the global market for anti-TNFα products is expected to be fueled by increased sales of existing products as well as new products becoming available, in part to address the drug-specific resistance that patients may develop after prolonged use of an anti-TNFα product.

Two primary products in the anti-TNFα market already employ autoinjectors: (1) Amgen's ENBREL®, which uses the ENBREL® Single-use Prefilled SureClick™ Autoinjector; and (2) Abbott Laboratories' HUMIRA®, which uses the HUMIRA® Pen. Both ENBREL® and HUMIRA® are approved to treat RA, chronic moderate-to-severe plaque psoriasis, juvenile arthritis, and psoriatic arthritis, among other conditions. ENBREL® was the first FDA-approved drug to block TNFα. Its SureClick™ Autoinjector requires patients to first remove a white safety cap, and then unlock a safety guard. After waiting until the guard is fully retracted, patients press a purple activation button. Patients then count slowly for 15

seconds until the end of the injection. Abbott's HUMIRA® Pen is more complex, requiring a four-step injection process. The HUMIRA® Pen has a needle that is not visible during the injection process. Patients place the HUMIRA® Pen against the skin, press a button, and wait for the medicine to inject. In 2007, ENBREL® generated sales of approximately $5.3 billion and HUMIRA® had worldwide sales of roughly $3.1 billion.

TMH believes that because both Amgen and Abbott use autoinjection devices, any other company seeking to enter the anti-TNFα market will likely need an autoinjector as well in order to be competitive. For example, Schering-Plough Corp. (SGP-NYSE) and Centocor, Inc. (a Johnson & Johnson [JNJ-NYSE] company) are working toward the launch of a next-generation anti-TNFα therapy called golimumab, which is in the final stages of development. The companies submitted a **Marketing Authorization Application (MAA)** to the European Medicines Agency (EMEA) in March 2008 and a **Biologic License Application (BLA)** to the FDA in June 2008. Cilag GmbH International (also a Johnson & Johnson company) is providing an autoinjector for the subcutaneous self-injection of golimumab. Development costs for the autoinjector are being shared by Centocor and Schering-Plough, with the latter holding rights to the device following an upfront payment of $20.5 million in the fourth quarter 2007.

With its patented ASI™ autoinjector technology, existing regulatory approvals, and experience, TMH believes that it is well positioned to capitalize on entrants to this space that may have not yet selected a delivery device for their anti-TNFα pipeline products.

Growth of Generic Competition

Pharmaceutical markets are competitive, and companies seeking to create or increase market share must be able to offer a differentiated product that patients and physicians prefer. Novel autoinjectors address this need, particularly for medications that are losing patent protection and are likely to be subject to intense generic competition (Source: *Innovations in Pharmaceutical Technology* 2007). By 2012, generics are expected to replace approximately $70 billion in annual sales in the U.S. alone as more than 36 medicines go off-patent. Likewise, more than 67% of U.S. prescriptions during 2007 were for generic products. TMH believes that companies with products losing patent protection could use its patented ASI™ autoinjector device to extend sales of their medications.

Additionally, the growth of generic competition presents further opportunities for autoinjectors, as many of these entities may look to incorporate a novel delivery device to create more competitive generics that can command a higher price than they might without an accompanying self-injection system. For example, as of July 2008, Dr. Reddy's Laboratories Ltd., an Indian pharmaceutical company with a large generics business, intended to form a joint venture with a biotechnology company for the development of "biosimilars," essentially generic forms of biotechnology products. Regulatory pathways for these new follow-on biological products are still being established and refined, yet already the U.S. and European market for biosimilars is predicted to reach $21 billion by 2015 (Source: the *Business Standard*, India's business daily, 2008). TMH entered into a non-exclusive development, licensing, and supply agreement with Dr. Reddy's in July 2008 for the use of the Company's ASI™ autoinjector device to deliver one of Dr. Reddy's generic products. Greater details of this agreement are provided on pages 28-29.

TMH'S DRUG DELIVERY SYSTEMS

TMH owns two primary drug delivery technologies: (1) the needle-based AutoSafety Injector (ASI™) autoinjector platform; and (2) the reusable needle-free jet injectors. Under license agreements with TMH, pharmaceutical and biotechnology partners employ TMH's injection platforms as a means to deliver their own proprietary medications. A partner's medicine is inserted into one of the Company's delivery devices, which creates a new combined drug/device product. With funding and support from the licensee, TMH seeks regulatory approval for each new customized product and receives technology access fees or other payments depending on the structure of the license agreement. Over the past several years, drug/device combinations have achieved general acceptance and this trend toward convergence is expected to evolve into more realizable activities in the near future (Source: Deloitte Consulting 2008). To this effect, in a May 2008 report, Greystone Associates estimated that the market for combined medication/delivery device products has a 14% growth rate across all technology segments.

The Value of a Patient- and Physician-preferred Self-injection System

Many recently launched injectable products treat chronic, life-long conditions, such as RA or MS. Moreover, because these therapeutic proteins are rapidly broken down by enzymes and cellular activity in the bloodstream and then filtered out of the blood by the body's organs, patients must receive frequent (from daily to weekly) injections to maintain effective levels of the protein in the body. The costs of these long-term treatments can be high, for example, as much as $16,000 a year for a typical RA treatment or $3,473 a month for Schering-Plough's Intron® A (for hepatitis C) after insurer discounts (Source: *Seattle Times* 2008). Continuously visiting a physician's office for each therapy session is inconvenient and improbable for many patients. Thus, as the therapeutic protein market expands, TMH also expects companies to become increasingly aware of the competitive advantages that can be generated by supplying biologic medications within an easy to use self-injection product, such as the ASI™ autoinjector platform.

Since many injectable treatments can cost thousands of dollars a year or more and may require frequent use by the patient, TMH believes that a self-injection device has the potential to sway a lot of business. With a patient-preferred disposable autoinjector, TMH's partners can use the Company's delivery platform as a marketing tool to differentiate their injectable medications from their competitors' products. Moreover, given that the patient does not actually see the syringe or needle contained within such a device, it seems likely that users may view the autoinjector device as the therapeutic product. Therefore, replacing a prefilled device product that has become established and commercially successful could represent a lengthy, costly, and risky process for licensees, since it essentially requires the launch of a new product.

Technology Applications

At present, TMH's ASI™ autoinjectors are the Company's lead initiative as there are considerably more applications where a needle-based delivery system can be employed versus a needle-free system. Table 5 lists possible indications for each of these technologies, highlighting the wide range of potential uses of TMH's autoinjectors. Following Table 5, pages 21-26 detail the Company's ASI™ autoinjector platform and pages 26-27 summarize the needle-free jet injectors.

Table 5
The Medical House PLC
TECHNOLOGY APPLICATIONS

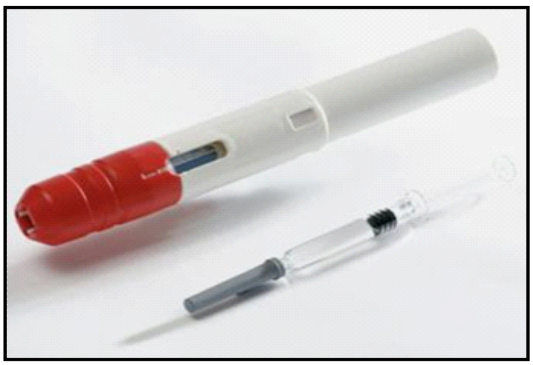
Disposable Autoinjectors	
Elective Therapies	
▪ Multiple Sclerosis	▪ Anemia
▪ Autoimmune Diseases (rheumatoid arthritis, psoriasis, Crohn's disease)	▪ Hepatitis
▪ Renal Disease	▪ Oncology
▪ Vaccination	▪ Anticoagulation
▪ Reproductive Health	
Emergency and Acute Therapies	
▪ Anaphylaxis (severe allergic reactions)	▪ Severe Migraine
▪ Chemical or Biologic Threats (nerve agent antidote, pandemic)	▪ Morphine (analgesia)
Needle-free Injectors	
▪ Human Growth Hormone (hGH)	▪ Insulin

Source: The Medical House PLC.

The AutoSafety Injector (ASI™) Autoinjector Platform

The Company's lead technology platform is the ASI™ autoinjector, as this device family is applicable to the widest range of medications and ailments. As illustrated in Figure 5, the ASI™ autoinjector apparatus is a single-use device that encases a needle integrated with a prefilled syringe. The syringe and its integrated needle are loaded into the ASI™ autoinjector system before the device is supplied to patients. The needle is hidden from view at all times within the autoinjector for the benefit of patients who are averse to needles. With the right gauge of needle, patients will likely not even feel the injection. Masking the needle also helps reduce the risk of accidental punctures as well as the transmission of infectious diseases that occur due to unintended needlestick injuries. Moreover, because the ASI™ autoinjector/medicine combination is supplied as one product, the Company believes that patients are likely to view the autoinjector as the therapy rather than focusing on the medication within it. This perspective enables TMH to position its ASI™ autoinjector family at the core of a licensee's long-term commercial strategy for a given drug compound.

Figure 5
The Medical House PLC
THE DISPOSABLE AUTOSAFETY INJECTOR (ASI™) AUTOINJECTOR PLATFORM



▪ Typical diameter	23 mm
▪ Typical length	120 mm - 160 mm
▪ Typical weight	50 g
▪ Needle type	Any depth or gauge*
▪ Drug formulations	Liquid (standard) or dry (powdered or lyophilized)*
▪ Power source	Spring
▪ Dose volume	Fixed (standard) or user-selectable*
▪ Injection depth	Fixed (standard) or user-selectable*

**Options that are available for a customized ASI™ autoinjector; however, even the standard settings, such as dimensions, may vary based on specific syringe geometry, drug formulation and volume, and licensee preference.*

Sources: The Medical House PLC and Crystal Research Associates, LLC.

As previously summarized in Table 5 (page 20), the TMH's technology can be used for a wide array of elective therapies, including those requiring frequent injections over a long period of time, such as in treatment of autoimmune diseases, as well as those applications using considerably fewer injections, such as for assisted reproductive therapy. The ASI™ autoinjector platform may also be employed for emergency treatments, such as with adrenaline to treat anaphylaxis or with morphine to help treat wounded military personnel. In addition, TMH could customize an autoinjector to quickly treat people in the event of biological warfare or a terrorist attack. In such a scenario, there is a clear benefit to having an easy to use device that first responders can provide to large groups of people for self-treatment.

The Company believes that its ASI™ autoinjector technology combines ease of use, versatility, cost-effectiveness, safety, and reliability into one convenient delivery platform, as described on the accompanying pages.

Ease of Use

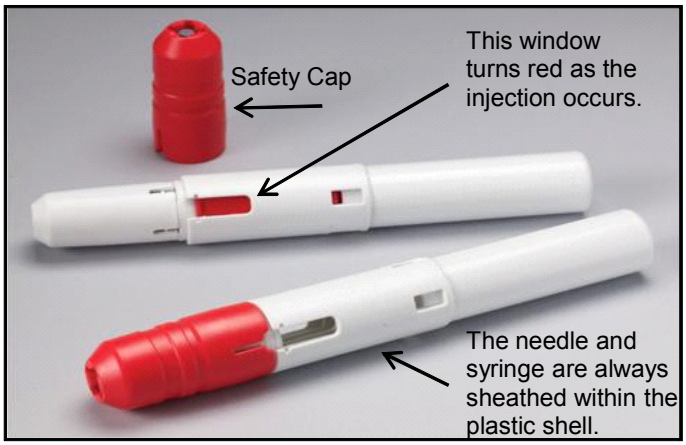
Studies have shown that the ASI™ autoinjector device is a preferred autoinjector by both patients and physicians, primarily due to its ease of use in the studies. Almost all patients surveyed indicated that they found the ASI™ autoinjector system to be a simple device to use. Results also suggested that clinicians could be willing to recommend that their patients self-inject prescribed drugs with this autoinjector.

Figure 6 (page 22) illustrates a version of the ASI™ autoinjector family that was developed for the intramuscular delivery of adrenaline, which requires a longer needle and thus a longer autoinjector. Each autoinjector is equipped with a safety cap that prevents the user from accidentally activating the device,

thus it can be safely carried and stored by patients. This capability is especially important for emergency applications, such as allergic reactions, where an individual carries the emergency medication (e.g., epinephrine) at all times for immediate access. As shown in Figure 6, the entire needle and syringe remain hidden within the autoinjector, even after the safety cap is removed. In studies involving ASI™ autoinjectors, participants reported not knowing whether or not they received the injection because they neither felt nor saw the needle, thus the ASI™ autoinjector family now incorporates both audible and visual notifications. The device makes a clicking noise and a viewing window changes color to notify the patient that the medication has been delivered.

Figure 6
The Medical House PLC
AN EARLY VERSION OF THE ASI™ AUTOINJECTOR

Safety Cap Prevents Inadvertent Device Activation

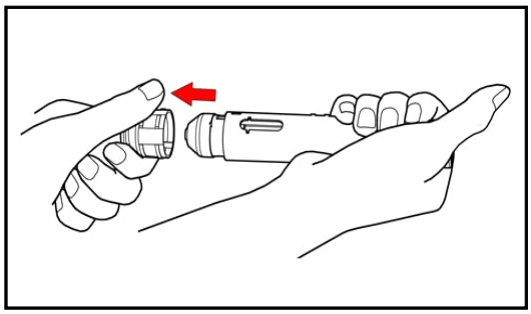


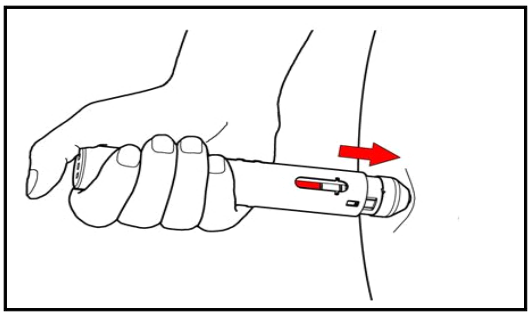
Sources: The Medical House PLC, Catalent Pharma Solutions, Inc., and Crystal Research Associates, LLC.

TMH believes that the primary differentiation between its ASI™ autoinjector and its competitors' devices is the simplicity of TMH's technology. As illustrated in Figure 7, there are only two user steps: (1) remove the safety cap, after which the device becomes "live"; and (2) push the unit against the skin at the selected injection site. Patients do not have to activate any triggers, buttons, or firing mechanisms, as is required by some competing devices. However, TMH could customize its autoinjector for button activation if a licensee preferred this method. The straightforward technique is anticipated to make this product particularly beneficial to patients suffering from dexterity, eyesight, strength, mobility, or other problems as a result of their illness. TMH has always sought to create an intuitive device due to the limiting nature of many of the diseases for which individuals require long-term injected therapies.

Figure 7
The Medical House PLC
A SIMPLE TWO-STEP PROCESS

Step 1: *Pull* the front cap from the ASI™ autoinjector. | **Step 2: *Push* the front of the device against the injection site.**





Sources: The Medical House PLC and Crystal Research Associates, LLC.

The Company believes that the operating methods of alternative injectors can be challenging for individuals who suffer from dexterity, motor, or coordination difficulties. Many competitive products also require the patient to manually remove the needle from the skin after injection. In contrast, after the person using the ASI™ autoinjector device pushes the injector against the skin, the process is entirely automated—from needle insertion and medication injection to needle withdrawal and full retraction back into the autoinjector. When the injection is completed, the entire unit is disposable.

Another ASI™ autoinjector feature is its ability to regulate dosing, as the injector is designed to supply a predetermined dose of medication from the syringe delivered over the time period that is desirable for a given injection. There is no specific clinical skill or knowledge required to use the ASI™ autoinjector platform, which makes this product suitable for at-home use by patients or their non-clinician caregivers, such as family members.

Versatility—Customized Autoinjectors

TMH offers its customers comprehensive development capabilities for either off-the-shelf product designs or more unique solutions tailored to their specific requirements, whether the licensee seeks to launch a new product, extend an existing product line, or market a generic. The ASI™ autoinjector family can be customized for functional, operational, ergonomic, or aesthetic features according to its intended application. For instance, the device can be configured for either subcutaneous (beneath the skin) or intramuscular injections or for rapid or slow injections of large or small volumes. By employing computer-aided design and computer-aided manufacturing (CADCAM) systems and rapid prototyping facilities, TMH can create functional device models within hours of a design modification. As a result, clients are able to participate in design decisions without incurring project delays. The Company estimates that developing and commercializing a customized autoinjector requires an 18-month timescale on average.

To meet licensees' unique needs, TMH has modified its ASI™ autoinjector platform to address drug delivery beyond just the administration of traditional non-viscous, liquid compounds. These device variants serve to further widen the portfolio of products that can be used with TMH's autoinjector technology platform. Examples of some of the versatile ASI™ autoinjector capabilities include injection of sustained-release (viscous) formulations and reconstitution and automated injection of dry biologic (e.g., powdered or lyophilized) formulations. The technology's viscous and reconstituted capabilities are overviewed below and on page 24, and descriptions of TMH's current partners and licensing agreements are provided in the Partnerships section on pages 28-30.

Sustained-release Viscous Formulations

Pharmaceutical companies often look for ways to extend the duration of action of injectable medicines, with the intent of reducing the frequency at which patients must inject themselves. For example, just injecting larger doses (called **bolus injections**) can extend the life of a treatment. Another method is to create sustained-release products that are slowly broken down by the body. In order to do this, an element typically needs to be added to the drug, which has the effect of increasing the size and viscosity of the molecules to be injected. For example, pegylation—the attachment of **polyethylene glycol (PEG)** molecules to a protein—is designed to lengthen the time a substance remains in the bloodstream without being metabolized and excreted by the body. However, this process increases the size of the therapeutic protein and can transform the medicine into a thicker, more viscous substance that is difficult to force through a needle. As pegylation and other similar processes become more widespread, companies commercializing autoinjectors must devise products that are capable of administering these larger volumes and more viscous medications. Moreover, entities developing viscous drugs may find that their patients must have an autoinjector device, as the injection of a viscous liquid could require too much strength for disabled or otherwise impaired individuals to manually administer on their own.

There is a demonstrated relationship between drug delivery, dosing frequency, and sales, as Pfizer Inc. (PFE-NYSE) was one of the first pharmaceutical companies to discover. Pfizer's development of Procardia XL® (nifedipine), a sustained-release version of one of its heart drugs, modified the administration from three times per day with the original version to once a day with the sustained-release version. By reducing the number of required doses, the company tripled its sales for that product. Because of its capability to administer sustained-release medications, TMH's ASI™ autoinjector platform may be suitable for use with many next-generation medications.

Increased Spring Force with a Novel Syringe Protection System (SPS)

TMH has determined that it can increase the spring force powering the ASI™ autoinjector device in order to overcome the higher resistance to flow that these viscous formulations possess, thereby enabling an effective administration of sustained-release medications. To protect the glass syringes from breaking under the higher spring force exerted for viscous applications, TMH designed a specific feature that is incorporated into its autoinjector. This SPS allows the device to operate without the glass syringe breaking. Whereas glass is weak and unpredictable under tension, it can be very strong in compression. TMH harnesses the inherent properties of glass to keep the syringe in compression during the injection. As such, the syringe has a greater resistance to high forces.

It is important to note that an ASI™ autoinjector unit designed for sustained-release medications still has a simple assembly and delivery process. TMH retained its commitment to not adding superfluous parts in order to keep the device from becoming costly or complicated. The Company has applied for patents on this invention and believes that it could add significant value to the ASI™ autoinjector family. In addition, TMH believes that there may be opportunities for other device companies to license the Company's SPS mechanism for use in their products. Maintaining syringe integrity is a vital aspect of creating a sustained-release autoinjector.

Reconstituted Dry Formulations

In addition, specific versions of the ASI™ autoinjector family have been developed to facilitate either fully automated or manual reconstitution of dry formulations prior to the initiation of the autoinjection process. TMH customized the device to automatically mix dry drug product with a diluent prior to injection. There are several benefits to demonstrating the ability to automatically reconstitute powdered or lyophilized compounds, most notably that manual reconstitution requires a degree of skill and dexterity that becomes unnecessary with an autoinjector that is capable of the task. As many medications, particularly biologics, are packaged in a dry form in order to extend shelf life, TMH believes that this technology may have considerable commercial potential. At present, a European government agency has collaborated with TMH in the creation of a disposable autoinjector that can administer dry packaged compounds in this manner. Such a device is primarily intended for use in emergency applications. Greater details of this business opportunity are presented in the Partnerships section on page 30.

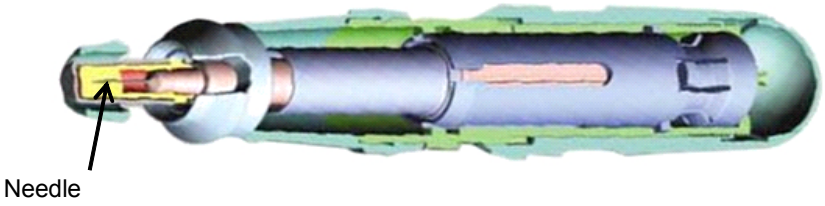
Cost-effectiveness

Injections that do not need to be administered by a physician or a nurse can be considerably less costly than those that require a visit to a clinic. For instance, several studies have been conducted that compare in-hospital treatment of patients with **deep vein thrombosis** to at-home, self-administered treatment for this same patient population. In these studies, pharmacoeconomic analyses indicated that home treatment presented a significant cost reduction of 69% to 92% less than the costs of traditional physician-administered therapies (Sources: *Pathophysiology of Haemostasis and Thrombosis* [2002] and *Angiology* [1999]). TMH believes that self-administered injections could reduce the typical cost of a shot by as much as 75%, which may have a considerable impact on overall treatment expenses.

Moreover, the ASI™ autoinjector family's user-friendly features and consistent delivery process are anticipated to improve compliance and treatment efficacy, which may eliminate many visits to the physician's office. In turn, this effect may significantly reduce costs for patients and insurers.

The simplicity of the ASI™ autoinjector design contributes to its cost efficiency via reduced manufacturing costs. The injector consists of only a few plastic components and two simple springs, which TMH believes to be fewer parts than are typically incorporated in competing products. The Company's technology is also suitable for use with many commonly available pre-fillable glass or plastic syringes. This minimalist design may be easier and more economical for partners to commercialize. To illustrate the type of plastic components that TMH uses, Figure 8 (page 25) depicts a cutaway to the inside of a typical ASI™ autoinjector device.

Figure 8
The Medical House PLC
CUTAWAY TO THE INSIDE OF A TYPICAL ASI™ AUTOINJECTOR DEVICE



Sources: The Medical House PLC and Crystal Research Associates, LLC.

Outsourced Manufacturing

TMH does not perform large-scale manufacturing of the ASI™ autoinjector devices itself. The Company believes that its expertise is in product development, customization, obtaining regulatory clearances, and managing industrialization projects and supply chains. As such, TMH asserts that its best strategy is to focus on designing innovative devices and work with established contract manufacturing partners skilled in production that can mass produce and assemble the plastic components. The Company works closely with its manufacturing partners throughout the process, keeping a focus on reliability, quality, and cost efficiency. As a result, TMH does not incur the high costs of building and equipping a production facility.

For production of ASI™ autoinjector devices under license agreements, TMH can also permit its licensees to select their production partner of choice, as many pharmaceutical companies already have a history with certain contract device manufacturers. TMH can then outsource, organize, and manage manufacturing and supply on behalf of its client.

Safety and Reliability—Regulatory Approvals

An ASI™ autoinjector device has relatively few components, which TMH believes enhances its reliability, as there are fewer mechanisms on the device that can malfunction. Particularly for the increased force associated with administering sustained-release (e.g., viscous) compounds, the ASI™ autoinjector family includes an SPS that prevents the enclosed glass syringe from cracking. This added component does not affect the injector's function but does improve its safety. Additionally, as the needle's insertion, withdrawal, and safe retraction after an injection is completely automated, the Company believes that its device is associated with a considerably reduced risk of accidental needlestick injuries. Prefilled syringes inherently regulate dosages, and thus diminish the likelihood of the patient injecting the wrong amount of medication.

Moreover, TMH's ASI™ autoinjector device family has received several regulatory designations in both Europe and the U.S. that further support the safety of this technology, as summarized in Table 6 and detailed thereafter on page 26.

Table 6
The Medical House PLC
REGULATORY APPROVALS

Europe
▪ CE Mark designation for several ASI™ autoinjector versions: subcutaneous, intramuscular, viscous, and non-viscous
U.S.
▪ FDA 510(k) clearance for an ASI™ autoinjector with viscous drugs (March 2008)
▪ FDA 510(k) clearance for an ASI™ autoinjector with non-viscous drugs (October 2008)

Source: The Medical House PLC.

The CE Mark

In Europe, four ASI™ autoinjector versions (subcutaneous, intramuscular, viscous, and non-viscous) are covered by the CE Mark, a European label certifying that the product has met certain health and safety requirements as established in European Directives.

510(k) Clearance

In the U.S. in March 2008, the FDA granted 510(k) medical device clearance (also called Premarket Notification) for a Compact ASI™ autoinjector (CASI) device with viscous formulations (510(k) number: K073476). This clearance, which TMH initially filed for in December 2007, represents the first U.S. approval for the Company's disposable autoinjector technology. With the 510(k) status, TMH can market the CASI device in the U.S. for self-administered, subcutaneous injections of fixed doses of FDA-approved drug products that are presented in standard 1-milliliter (ml) long prefilled syringes with staked needles. The Company must continue to meet certain other regulations as well, such as those governing product labeling and **good manufacturing practices (GMPs)**. Prior to the award of marketing clearance in the U.S., extensive performance, functional, and design verification tests were conducted. As noted in the 510(k) summary filed with the FDA for the CASI apparatus, results of these studies demonstrated that the device was safe and effective for its intended use.

In October 2008, TMH received a second 510(k) clearance—this time for use of the ASI™ autoinjector platform with non-viscous medicines (510(k) number: K082587). The Company believes that once one version of a device receives approval (as was granted in March 2008), subsequent submissions for variants are more likely to be successful.

Needle-free Jet Injectors

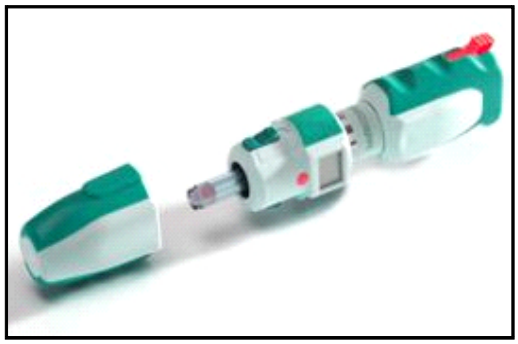
While the ASI™ autoinjector product family is its lead initiative, TMH believes that the development of a reusable needle-free jet injector still benefits its reputation and establishes further credibility for the Company. Many pharmaceutical companies still want to see what a device company is accomplishing in terms of needle-free delivery, as the prospect of ultimately administering injectable medications without any needle at all is enticing. Circumventing many patients' aversions to needles, which can cause individuals to forego their prescribed medications, may improve compliance to treatment regimens, thus enhancing a therapy's effect. In addition, eliminating the needle is believed to make jet injectors safer than alternative forms of needle-based drug delivery. However, due to the chemical formulations and required dose volumes of most of today's injectable medications, there are very few products for which needle-free delivery is appropriate. Insulin and human Growth Hormone (hGH) are two areas that TMH believes to be most suited to this form of administration.

To this extent, TMH originally supplied its reusable needle-free jet injectors directly to diabetics for self-injection of insulin under the brand name "SQ-PEN." However, the Company has since transitioned into a license-based business model where it no longer markets to the end user but rather focuses its resources on negotiating license agreements for the large-scale supply of injectors. Thus, TMH sold the commercial aspects of its insulin injector business to Diabetes Management International B.V. in August 2007 for £800,000. The Company retained ownership of this technology and rights of use for all other medicines aside from insulin, thus the jet injectors remain available for licensing agreements.

Similarly to the regulatory clearances issued for the ASI™ autoinjectors, the Company's reusable needle-free jet injectors have also received both Europe's CE Mark and the FDA's 510(k) clearance. Figure 9 (page 27) illustrates and summarizes the specifications of the Company's jet injectors. Similar to the ASI™ autoinjector platform, TMH's reusable jet injectors are spring powered.

The Company believes that its jet injectors offer patients, physicians, and drug manufacturers convenient, comfortable, reliable, versatile, and cost-effective delivery systems. Loading medication into these devices is a simple "click-in" process and TMH believes that it has designed nozzles that provide comfortable injections. The Company's jet injectors can be optimized for use with medications in their existing syringe, vial, or **cartridge** forms, which avoids potentially lengthy and costly repackaging projects. This feature may also enable streamlined regulatory processes.

Figure 9
The Medical House PLC
SPECIFICATIONS FOR TMH'S REUSABLE NEEDLE-FREE JET INJECTORS



▪ Delivery mechanism	Jet injector (replaceable nozzles—up to 2 weeks between replacements)
▪ Diameter	32 mm
▪ Length	130 mm
▪ Weight	126 g
▪ Power source	Spring
▪ Materials of construction	ABS* and metals
▪ Dose volume range	0.02 ml - 0.50 ml
▪ Dosing options	Variable (selected by user)
▪ Drug presentation	Fast-action loading mechanism suitable for vials, cartridges, and prefilled syringes

**ABS = Acrylonitrile-Butadiene-Styrene (Terpolymer), a strong plastic used in a variety of industrial applications.*

Sources: The Medical House PLC and Crystal Research Associates, LLC.

Human Growth Hormone (hGH) Partnership

A natural protein produced by the pituitary gland in the brain, hGH stimulates the production of **somatomedins** in the liver. Somatomedins then influence the metabolism of proteins, carbohydrates, and lipids as well as fuel growth of the body's bone and muscle. However, individuals who have problems in their **hypothalamus** (an area of the brain that regulates body temperature, hunger, and thirst) or in their pituitary gland, which is directly responsible for the natural release of hGH, can be afflicted with a deficiency of this growth hormone. The deficiency can also occur due to the body's inability to use its hGH. In children, growth hormone deficiency results in growth retardation, characterized by short stature, delayed secondary tooth eruption, and delayed puberty. In adults, it can cause an increase in fat tissues and a decrease in muscle mass, and may also negatively affect functioning of the heart (decreased cardiac output) or skeletal muscle (physical weakness). Roughly 1 in every 10,000 children is born with an hGH deficiency, and some countries report rates as high as 1 in 4,000. The Human Growth Foundation, Inc. estimates that 10,000 to 15,000 children and approximately 70,000 adults in the U.S. have growth failure due to hGH deficiency.

To treat many growth hormone deficiencies, hGH is injected daily into the subcutaneous fatty tissues beneath the skin, usually in the lower abdomen or thigh. Treatment of children typically involves daily injections of a constant dose of hGH that is adjusted every three to four months. It usually lasts until the child stops growing; however, severely deficient patients may need lifelong care. In most adults, physicians prescribe three injections of hGH a week, with a total dosage that is only 25% of a child's dose. There are hGH alternatives to injections that are available as an over-the-counter pill or in inhalation form; nevertheless, these therapies are not known to be as potent or as active in the body. Currently, the most productive way to deliver hGH therapy is through injection, since digestion in the stomach and intestines breaks down proteins and limits their efficacy before they can access the rest of the body. In addition to treating growth hormone deficiencies, hGH can be used to treat kidney disease, **Prader-Willi Syndrome**, **Turner's Syndrome**, and **Acquired Immune Deficiency Syndrome (AIDS)**-induced weight loss.

TMH believes that a needle-free option is an attractive proposition for children who must inject hGH daily for several years. Moreover, this capability could provide licensees with a valuable marketing tool to differentiate their hGH products by decreasing the anxiety that many young patients may have about performing daily self-injections. At present, TMH is partnered with Merck Serono for the delivery of hGH to children and adolescents via a needle-free jet injector. Merck Serono is Merck KGaA's small molecules and biopharmaceuticals division. In the U.S. and Canada, it operates as EMD Serono, Inc. Under this collaboration, TMH expects to launch a needle-free jet injector product for delivery of hGH in collaboration with Merck Serono. Greater details of this agreement are presented in the Partnerships section on page 30.

Partnerships

The accompanying pages overview some of the Company's current partners that have entered into formal contracts for combinations of development, licensing, and supply of TMH's delivery platforms. These entities include pharmaceutical and biotechnology entities, specifically Catalent Pharma Solutions, Inc. and Merck Serono International S.A. In addition to suppliers of proprietary biologics, TMH also markets its technologies to generic companies seeking novel delivery systems, such as Dr. Reddy's Laboratories Ltd., or to government agencies that have highly specific autoinjector needs.

TMH estimates that its existing agreements could create significant revenue over the next five to six years, with the potential to extend these licenses throughout the life of the related drug and device patents. If the ASI™ autoinjector and needle-free injector platforms are found to be successful delivery mechanisms for licensees' products, the Company believes that it is unlikely its partners would opt to change the delivery system for their products, even after the initial terms of the license agreements expire. A change in delivery system could be costly, time consuming, and risky for the licensees. As such, TMH has intentionally incorporated provisions into its agreements for extending collaborations beyond the initial specified term.

Undisclosed Global Pharmaceutical Company

In December 2006, TMH entered into a worldwide development, licensing, and supply agreement with a global pharmaceutical company. Under this agreement, the pharmaceutical entity is licensed to use the ASI™ autoinjector platform to deliver a particular medication that treats several diseases. The name of this partner is not yet disclosed, as the entity believes that TMH's technology is critical to its product launch and does not wish to provide its competition with advance knowledge of its commercialization plans. TMH retains the right to license its autoinjector to other pharmaceutical companies for combination with similar medicines to treat these same diseases.

Under this collaboration, the pharmaceutical company compensates TMH for all project management, development, and manufacturing costs. TMH also receives a license fee payment for each unit supplied, for which annual minimums are specified in the contract. TMH anticipates initiating commercial supply of this ASI™ autoinjector version to its partner by late 2009. Following launch, the initial term of the supply agreement is six years, with extensions available until 2023 (the end of the first patent for the ASI™ autoinjector family). The licensee has projected revenues to TMH to be up to £34 million in the first six years of commercial availability, of which £23 million relates purely to licensing payments. TMH has no further costs to incur in relation to the £23 million. Further, the partner is responsible for £3 million in pre-launch license fees, of which £2.5 million has already been paid. If the combined product receives all of its approvals, the minimum income for TMH under this agreement is £20.5 million (which includes £15 million for licensing payments). Moreover, this partner has a pipeline of similar products that TMH believes the ASI™ autoinjector technology could benefit as well.

As addressed on page 26, the FDA granted 510(k) clearance for the Compact ASI™ (CASI) autoinjector unit designed for this partnership in March 2008. In April 2008, TMH's pharmaceutical partner received regulatory approval in one of the principal territories covered by this agreement for a different formulation of the drug that is in development for use with the ASI™ autoinjector family. It is important to note that this regulatory approval does not specifically apply to the drug formulation being combined with the ASI™ autoinjector platform, and thus, the ASI™ autoinjector/drug candidate remains subject to regulatory clearances. At present, the companies are continuing with the pre-commercial preparations, which include establishing large-scale manufacturing systems and a supply chain.

Dr. Reddy's Laboratories Ltd.

In July 2008, TMH entered into a non-exclusive development, licensing, and supply agreement with Dr. Reddy's. Headquartered in India, Dr. Reddy's is a global, vertically integrated pharmaceutical company that produces active pharmaceutical ingredients (APIs) and provides custom pharmaceutical services, such as drug substance and drug product development and manufacturing. Dr. Reddy's is committed to drug discovery research in the areas of metabolic disorders and cardiovascular indications. The company

also has a large generics business that includes many branded generic formulations. Altogether, Dr. Reddy's presence spans more than 100 countries, with wholly owned subsidiaries in the U.S., UK, Russia, Germany, and Brazil; joint ventures in China, South Africa, and Australia; representative offices in 16 countries; and third-party distribution networks in 21 countries.

Under this agreement, TMH is customizing the ASI™ autoinjector family to be combined with one of Dr. Reddy's generic products. This particular generic that Dr. Reddy's intends to pair with TMH's autoinjector is not yet marketed and its identity is still confidential. The partnership entails an initial five-year supply term in the U.S., EU, and Canada, with an option for worldwide extension. The duration of the agreement is also extendable. TMH anticipates that this autoinjector product can be brought to market during 2009. In addition to the development costs associated with customization, the Company could receive revenues of approximately £5 million, including technology access fees, over the first five years of commercial supply.

One of the factors that contributed to TMH's decision to collaborate with Dr. Reddy's is that this company is not simply seeking to develop generic products at a cheaper price, it also aims to create improved versions of existing products. As such, TMH believes that Dr. Reddy's sought the device that could help it accomplish this goal, increase its margins, and achieve greater market share. TMH believes that its partnership with Dr. Reddy's can establish further credibility for the ASI™ autoinjector platform.

Catalent Pharma Solutions, Inc.

In October 2007, TMH and Catalent entered into a strategic marketing collaboration. TMH opted to partner with Catalent for sales, marketing, and new business development because, while TMH would have needed to hire, train, and oversee teams in the U.S., Europe, Asia, and other regions, Catalent already employs a worldwide sales and marketing force. At present, Catalent provides development, drug delivery, manufacturing, and packaging services for pharmaceutical, biotechnology, and consumer health companies in nearly 100 countries. Specifically, the company is also a major provider of services for prefilling glass syringes—a crucial element of TMH's technology. Due to this expertise and global presence, Catalent has access at an early stage to other companies that are creating injectable products centered around prefilled syringes, which may represent new business opportunities for the ASI™ autoinjector family.

Via this collaboration, Catalent now offers the ASI™ autoinjector as an in-house technology to its pharmaceutical clients for use with their injectable pipeline products. Together, TMH and Catalent also offer a "one-stop" capability that entails manufacturing the drug substance; filling the syringe; customizing, licensing, and manufacturing the ASI™ autoinjector units; assembling the final combined ASI™ autoinjector/medication product; obtaining regulatory approvals; and supplying the finished product. It is important to note that TMH is not constrained in being able to offer stand-alone ASI™ autoinjector licenses as well as through its collaboration with Catalent.

Formerly, Catalent operated as the Pharmaceutical Technologies and Services (PTS) division of Cardinal Health, Inc., an $87 billion global manufacturer and distributor of medical and surgical supplies and technologies for hospitals, medical centers, retail and mail-order pharmacies, clinics, physicians, and other healthcare providers. Catalent was officially created in April 2007 when the Blackstone Group L.P. (BX-NYSE), a financial advisory firm, acquired Cardinal Health's PTS segment. Under its collaboration with TMH, Catalent uses its sales and business development groups to promote the ASI™ autoinjector technology worldwide. This marketing collaboration partnership is for an initial period of two years (start date: November 2007).

Generic Product Development Based on the ASI™ Autoinjector

Additionally, TMH and Catalent are jointly developing certain generic ASI™ autoinjector/medicine products. This partnership leverages TMH's expertise with the ASI™ autoinjector technology and Catalent's experience formulating, developing, manufacturing, and obtaining regulatory approvals for the drug components. The companies intend to license and supply drug/device products resulting from this partnership to pharmaceutical marketing companies for commercialization under suitable licensing (e.g., profit share) arrangements. As these licenses are based on a finished product rather than just the ASI™ autoinjector for use with the licensee's medication, TMH believes that they may enable higher profit

sharing arrangements. A contract for the first generic ASI™ autoinjector/medication combination has been signed in Europe with Stallergenes SA, a European biopharmaceutical laboratory specializing in treatment of allergy-related respiratory conditions.

Under this joint agreement, TMH is customizing its ASI™ autoinjector for use with epinephrine supplied by Catalent. The combined product, called Adreflex®, is intended for the emergency treatment of both adult and pediatric anaphylactic shock, primarily due to venom or food allergies.

Merck Serono International S.A.

Switzerland-based Merck Serono is the small molecule and biopharmaceutical division of Merck KGaA. In the U.S. and Canada, the division operates as EMD Serono, Inc. In September 2004, TMH and Merck Serono entered into a development, licensing, and supply agreement for a reusable needle-free jet injector to deliver Merck Serono's hGH products. Although based on TMH's existing needle-free jet injector technology (described on pages 26-27), the device being created under this agreement incorporates many additional features that TMH believes to be novel in this type of system. This technology is now undergoing testing and validation. If successfully launched, TMH has stated that it anticipates receiving a minimum of £4 million in revenue during the product's first five years on the market, according to its agreement with Merck Serono.

A European Government Agency

In December 2005, TMH entered into a partnership with a European government agency for the development of a disposable autoinjector that could be used in emergency applications. For this purpose, the Company is customizing an ASI™ autoinjector device to automatically mix dry drug product with a diluent prior to injection, as addressed under Reconstituted Dry Formulations on page 24. The Company entered into a second development phase with this agency in March 2007, which entailed TMH manufacturing devices according to defined operational and functional requirements for a technical assessment. The European government agency has provided funding over the past two years for this project, with TMH retaining ownership of the intellectual property that is generated through this development program. The agency is expected to begin a competitive tendering process, where the successful entity is awarded a multi-year contract for the long-term development, manufacturing, and supply of a new autoinjector. If the device is successful in the competitive tendering process, then it may create further development revenues for TMH as well as subsequent revenues thereafter related to the supply of the product.

Competition

To the Company's knowledge, there are a modest number of companies actively marketing autoinjector technologies due to the barriers to entry that govern this space. However, TMH may also encounter competition from other medical device companies or large pharmaceutical and biotechnology companies that have device divisions as these entities may develop alternative injectable technologies, such as injection pens or needle-free techniques, or may offer customized development services that could compete with the ASI™ autoinjector platform and TMH's business model. The following section contains details of companies that are believed to be representative of competition the Company may face as it strives to commercialize or license its technologies. Table 7 provides a summary of these companies. It should be noted that of these potential competitors, a limited number of such companies (including TMH) have, to date, made public that they have entered into licensing agreements with pharmaceutical company partners for disposable autoinjector technologies. Thus, the list does not examine the potentially competing products in any great detail as often such detail is not made public knowledge.

Table 7
The Medical House PLC
POTENTIAL COMPETITION

Name	Symbol-Exchange	Headquarters	Last Trade (11/04/08)	52-wk Range	Avg. Vol. (3m)	Market Cap.
Antares Pharma Inc.	AIS-NYSE	Ewing, NJ	0.48	0.40 - 1.22	72,368	$32.6M
Becton, Dickinson and Company	BDX-NYSE	Franklin Lakes, NJ	70.27	63.13 - 93.24	1,693,320	$17.1B
Haselmeier GmbH	Closely held	Stuttgart, Germany	—	—	—	—
Meridian Medical Technologies, Inc. (Subsidiary of King Pharmaceuticals, Inc.)	KG-NYSE	Bristol, TN	9.13	6.98 - 12.60	3,502,950	$2.3B
Owen Mumford Ltd	Closely held	Oxford, United Kingdom	—	—	—	—
The Scandinavian Health Limited Group	Closely held	Taoyuan City, Taiwan	—	—	—	—
West Pharmaceutical Services, Inc.	WST-NYSE	Lionville, PA	37.00	35.20 - 52.00	300,895	$1.2B
Ypsomed Holding AG	YPSN-SWF	Burgdorf, Switzerland	CHF83.00	CHF64.80 - CHF101.00	—	CHF830.85M

Sources: Yahoo! Finance, Reuters, and Crystal Research Associates, LLC.

Antares Pharma Inc.

U.S.-based Antares Pharma, Inc. (AIS-NYSE) employs three technology platforms: (1) Advanced Transdermal Delivery (ATD)™ for transdermal gels; (2) Easy Tec™ fast-melt oral disintegrating tablets; and (3) injection devices, including reusable needle-free injectors and disposable mini-needle injectors. Its marketed products include the reusable Medi-Jector VISION®, a small needle-free injector for insulin and hGH delivery. Incorporating Medi-Jector technology, Ferring Pharmaceuticals BV markets ZomaJet® 2 Vision for hGH delivery in Europe and JCR Pharmaceutical Co., Ltd markets Twin-Jector® EZ II for hGH delivery in Japan. A disposable mini-needle injection system (Vibex™), which can be licensed for use with self-injected drugs, is sold for use in home health and acute care settings as well as for intermittent use with generic drugs. The company has relationships with corporate partners including Eli Lilly & Company (LLY-NYSE), BioSante Pharmaceuticals, Inc. (BPAX-NYSE), Teva Pharmaceutical Industries Ltd. (TEVA-NASDAQ), Ferring Pharmaceuticals, Inc., JCR Pharmaceuticals Co., Ltd, SciGen Ltd., and Solvay Pharmaceuticals, among others.

Becton, Dickinson and Company (BD)

Becton, Dickinson and Company (BDX-NYSE), headquartered in the U.S. with offices in at least 50 countries worldwide, is a medical technology company that is focused on improving drug delivery, enhancing the diagnosis of infectious diseases and cancers, and advancing drug discovery. BD develops, manufactures, and sells medical supplies, devices, laboratory instruments, antibodies, reagents, and diagnostic products to healthcare institutions, life science researchers, clinical laboratories, the pharmaceutical industry, and other groups. In 1906, the company's BD Medical division is believed to have built the first U.S. manufacturing facility for syringes and needles. Today, this division sells a variety

of injectable products (among other medical devices), including needles, syringes, and intravenous catheters; self-injected syringes and pen needles; pre-fillable drug/device combination products; and disposal containers for used sharps as well as some needleless systems. Target markets for these products include hospitals and clinics, physicians' offices, consumers and retail pharmacies, public health agencies, pharmaceutical companies, and healthcare workers.

Haselmeier GmbH

The closely held, German device developer, Haselmeier, supplies injection pens and autoinjectors to pharmaceutical companies, including Merck Serono, Novartis AG (NVS-NYSE), and Eli Lilly, for thrombosis prophylaxis, insulin therapy, and growth hormone deficiencies. Its products are designed for the self-administration of medicines by subcutaneous injection. Haselmeier's disposable, multi-dose autoinjector platform is called the Haselmeier-Penlet, a plastic device with a hidden needle. The company also markets two types of injection pens—automatic and manual—which are both reusable and offer the potential for variable dosing as well as custom design and production of OEM medical devices.

Meridian Medical Technologies, Inc.

Meridian, a subsidiary of King Pharmaceuticals, Inc. (KG-NYSE), is currently believed to be the only FDA-approved manufacturer of autoinjector nerve agent antidotes. The company supplies its products to emergency responders, the U.S. Armed Services, and allied nations. Altogether, Meridian has provided approximately 200 million emergency autoinjectors to more than 30 countries and the U.S. Department of Defense. Meridian is the original developer and manufacturer of the EpiPen® (epinephrine), which was exclusively licensed to Dey, L.P. in the U.S. and is marketed by King Pharma Canada Ltd. in Canada.

Owen Mumford Ltd.

UK-based and closely held Owen Mumford designs and manufactures medical devices and disposables used by healthcare providers and consumers worldwide. Its product line addresses capillary blood sampling, neuropathy screening, sexual healthcare, and drug delivery. In the area of injectable drug delivery, the company sells four categories of automatic injection devices and pen needles: (1) Autopen®; (2) Unifine® Pentips®; (3) Autoject® 2; and (4) UniGuard®. These products address therapeutic areas ranging from hGH and anaphylaxis to oncology and RA. Owen Mumford has over 50 years of experience in the medical device arena and is capable of design, development, and manufacture of automatic systems for self-injection, including single- and multi-dose reusable and disposable autoinjectors and pen systems. Its clients include Abbott, Amgen, Genentech, Inc. (DNA-NYSE), Johnson & Johnson, and Teva, among many others.

The Scandinavian Health Limited (SHL) Group

The Scandinavian Health Limited (SHL) Group maintains that it is one of the world's largest closely held developers of drug delivery devices, including injection pens, autoinjectors, and inhaler systems. Its SHL Medical division designs these devices, while other divisions, SHL Healthcare and SHL Technologies, produce rehabilitation equipment for the hospital and home healthcare market and perform medical and industrial manufacturing. SHL has offices, manufacturing facilities, and design centers in Sweden, the U.S., Taiwan, and China. SHL Medical owns and designs devices in-house including the Disposable Auto Injector (DAI™). SHL also offers customized drug delivery development services for pharmaceutical and biotechnology companies. Its pipeline includes compact disposable autoinjectors and injections pens as well as a variety of inhalers and reusable injectors with LCD displays.

West Pharmaceutical Services, Inc.

West Pharmaceutical (WST-NYSE) provides standard-setting systems and device components for parenterally administered medicines to pharmaceutical, biopharmaceutical, and medical device companies worldwide. Founded in 1923 and headquartered in Pennsylvania, West Pharmaceutical now has more than 50 locations throughout North America, South America, Europe, Mexico, Japan, Asia and the Pacific, and Australia. In 2007, West Pharmaceutical acquired the technology of Pharma-Pen, Inc., formerly Innoject, Inc. This technology has led to West Pharmaceutical's recent introduction of the Confi-Dose™ disposable autoinjector system. The Confi-Dose™ system eliminates preparation steps and

automates the injection of drugs, providing patients with a sterile, single-use disposable system that can be easily used at home. This autoinjector incorporates a prefilled syringe with a 1 ml long needle and a clear viewing window through which the user has full visibility of the medicinal content. Patients must press a button in order to activate the Confi-Dose™ autoinjector. After the injection, the needle is automatically and permanently retracted back into the device, where it remains shielded for safe disposal. Regularly scheduled self-injections are common for chronic diseases such as RA, multiple sclerosis, and anemia.

Ypsomed Holding AG

Swiss-based Ypsomed (YPSN-SWF) develops and manufactures injection systems for customized self-administration to treat diabetes, growth disorders, or infertility, among other conditions. The company sells and customizes needle-based injection pens (e.g., its Penfine® universal click™ pen needles) and autoinjectors that can be disposable, semi-disposable, or reusable. At present, the company is partnered with leading pharmaceutical and biotechnology entities, such as sanofi-aventis SA (SNY-NYSE), Eli Lilly, Pfizer, Genentech, and Merck Serono, among others.

Milestones

Recent Milestones

During 2007 and thus far in 2008, TMH has achieved the following milestones:

- Growth of its drug delivery division, as evidenced by a 43% increase in revenues for the six months ended June 30, 2008, versus the six months ended June 30, 2007;
- An operating profit of £342,000 for the six months ended June 30, 2008, up from an operating profit of £140,000 for the six months ended June 30, 2007;
- Extended a development, licensing, and supply agreement with a global pharmaceutical partner to an initial six years (extendable to 2023) with an associated increase in anticipated revenue to £34 million, and received £2.5 million in pre-launch license fees from this partner thus far;
- Received approval for a European patent for core elements of the autoinjector technology;
- Entered into a licensing agreement with Dr. Reddy's Laboratories for a customized ASI™ autoinjector;
- Signed a development, license, and supply agreement with Catalent for the Adreflex™ epinephrine autoinjector to be marketed by Stallergenes;
- Sold the needle-free insulin injection business in August 2007 for £800,000;
- Disposed of the loss-making orthopedic manufacturing division, which resulted in the elimination of £1.5 million of bank debt from TMH;
- Reduced borrowings by approximately £4 million from June 30, 2007, to June 30, 2008;
- Obtained Europe's CE Mark designation for a variant of the ASI™ autoinjector device; and
- Received two 510(k) clearances from the FDA to market variations of the ASI™ autoinjector family in the U.S.

Potential Milestones

In the coming 12 to 18 months, TMH anticipates being able to announce additional licensing and supply agreements for its technologies, which could include application of the ASI™ autoinjector technology to autoimmune therapies, such as RA. There is also the potential of the commercial launch of Merck Serono's hGH product using TMH's needle-free jet injectors. The Company further aims to extend its regulatory approvals and patent protections for the ASI™ autoinjector platform into more territories.

Key Points to Consider

- TMH specializes in the design, development, licensing, and supply of self-injection device platforms for the pharmaceutical and biotechnology industries. The Company is committed to the provision of safe, convenient, comfortable, and cost-efficient forms of drug delivery, believing that the right device can improve patient compliance and thus a therapy's effect, as well as increase demand for the pharmaceutical products incorporated within TMH's systems.

- TMH supplies two primary drug delivery platforms: (1) the disposable, needle-based AutoSafety Injector (ASI™) autoinjector system; and (2) reusable needle-free jet injectors.

- TMH's lead product line is its family of ASI™ autoinjector technologies, which can be used for a wide array of elective therapies as well as emergency treatments. This technology is entirely automated—from needle insertion and medication injection to needle withdrawal and full retraction back into the device. The needle is hidden from view at all times within the ASI™ autoinjector, and with the right gauge of needle, patients will likely not even feel the injection. The Company believes that its platform combines ease of use, versatility, cost-effectiveness, safety, and reliability into one convenient device.

- Four ASI™ autoinjector versions and the reusable needle-free jet injectors hold CE Mark approval in Europe. TMH also has 510(k) medical device clearances in the U.S. for the ASI™ autoinjector apparatus with viscous and non-viscous compounds and for the reusable needle-free jet injectors.

- The Company has license agreements for its ASI™ autoinjector platform with Dr. Reddy's Laboratories Ltd., Catalent Pharma Solutions, Inc. and Stallergenes SA, a European government agency, and a global pharmaceutical company. TMH is also partnered with Merck Serono International S.A., which seeks to launch a human Growth Hormone (hGH) product using the Company's reusable needle-free jet injectors.

- Many injectable treatments can cost thousands of dollars a year or more and must be administered frequently by the patient. TMH believes that the device itself can sway an individual's selection of a particular therapy and can influence compliance to the treatment regimen. The Company further believes that licensees of its patient-preferred autoinjector use the platform as a marketing tool to differentiate their injectable medications from their competitors' products.

- Once the ASI™ autoinjector is marketed in conjunction with a medicine, TMH believes that it is likely for patients to view the device as the therapy itself. This perspective may enable TMH to position its technology at the core of a licensee's long-term commercial strategy for a given compound and thus extend license agreements for the life of the medication. Replacing a successful delivery device, which may become an integral part of therapy, could be lengthy, costly, and risky for licensees.

- The implantable/injectable drug delivery market had global sales of $9.8 billion in 2006 and was forecast to be $12.6 billion by 2010, driven by patients' demand for improved injection systems, drug manufacturers' realization that novel devices can extend the life of products nearing patent expiration and provide a competitive edge, and growth of new biologic therapies requiring long-term injections.

- TMH believes that its technologies, associated intellectual property, pre-existing regulatory approvals, and experience in managing device customization and industrialization projects represent significant barriers to entry in an expanding worldwide market that has a modest number of participants. The core ASI™ autoinjector technology is patented in the UK and the EU (pending in the U.S.), with patent families also pending in the UK, EU, and globally under the Patent Cooperation Treaty (PCT).

- TMH supports the concept of an effective Board leading and controlling the Company, which includes approving corporate strategy and policy. Its leadership has expertise in a range of fields, such as intellectual property licensing, corporate recovery, finance, and transactions; sales and product management; and experience establishing companies in the medical sector.

- At June 30, 2008, TMH had cash and cash equivalents of (£284,000).

Historical Financial Results

Tables 8, 9 (page 37), and 10 (page 38) provide a summary of TMH's key historical financial statements—its Consolidated Interim Profit and Loss Statements, Balance Sheets, and Cash Flow Statements. In addition, Table 11 (page 39) summarizes the Company's ownership, including those holders with at least a 3% share.

Note: The accompanying financial statements are presented in the Company's functional currency, the British pound sterling (£). As of the date of these statements, June 30, 2008, the pound sterling/U.S. dollar exchange rate was £1 = ~US$1.99.

Table 8
The Medical House PLC
CONSOLIDATED INTERIM PROFIT AND LOSS STATEMENTS
for the six months ended June 30, 2008

	Unaudited Six months ended 30 Jun-08 £000	Unaudited Six months ended 30 Jun-07 £000	Audited *Six months ended 31 Dec-07 £000
Revenue	**1,422**	992	780
Cost of sales	**(42)**	(102)	(73)
Gross profit	**1,380**	890	707
Other income			363
Net income from operations	**1,380**	890	1,070
Administrative expenses	**(1,038)**	(750)	(1,234)
Operating profit/(loss)	**342**	140	(164)
Analysis of operating profit/(loss)			
Operating profit/(loss) before exceptional items	**375**	25	162
Intercompany debt waiver		127	
Other exceptional costs	**(33)**	(12)	(326)
	342	140	(164)
Financing expense	**(23)**	(49)	(30)
Profit/(loss) before income taxation	**319**	91	(194)
Income tax	**(103)**	161	537
Profit from continuing operations	**216**	252	343
Discontinued operation			
Loss from discontinued operation (net of income tax)	**(317)**	(592)	(3,825)
(Loss) for the period	**(101)**	(340)	(3,482)
Earnings per share			
Basic loss per ordinary share on total operations	**(0.17p)**	(0.57p)	(5.79p)
Diluted loss per ordinary share on total operations	**(0.17p)**	(0.57p)	(5.79p)
Basic profit/(loss) per ordinary share - continuing operations	**0.36p**	0.42p	0.57p
Diluted profit/(loss) per ordinary share - continuing operations	**0.36p**	0.42p	0.55p

* Change of year end from June to December adopted, therefore a six-month period

Source: The Medical House PLC.

Note: The accompanying financial statements are presented in the Company's functional currency, the British pound sterling (£). As of the date of these statements, June 30, 2008, the pound sterling/U.S. dollar exchange rate was £1 = ~US$1.99.

Table 9
The Medical House PLC
CONSOLIDATED INTERIM BALANCE SHEETS
for the six months ended June 30, 2008

	Unaudited 30-Jun-08	Audited 30-Jun-07	Audited 31-Dec-07
	£000	£000	£000
Assets			
Property, plant, and equipment	319	5,552	315
Intangible assets	2,066	2,041	1,907
Deferred tax assets	668	272	760
Total non-current assets	3,053	7,865	2,982
Inventories	80	1,436	87
Trade and other receivables	1,273	1,360	2,567
Prepayments	108	318	169
Corporation tax receivable	48		48
Asset held for resale	380		380
Total current assets	**1,889**	3,114	3,251
Total assets	**4,942**	**10,979**	**6,233**
Liabilities			
Finance leases	77	872	47
Deferred income	500	75	1,250
Total non-current liabilities	**577**	**947**	**1,297**
Bank overdraft	284	2,905	365
Finance leases	49	600	38
Trade and other payables	387	612	344
Deferred income	1,500	45	1,500
Accruals	341	483	776
Total current liabilities	**2,561**	4,645	3,023
Total liabilities	**3,138**	5,592	4,320
Equity			
Issued share capital	601	601	601
Share premium account	7,353	7,353	7,353
Other reserves	487	487	487
Retained earnings	(6,637)	(3,054)	(6,528)
Equity shareholders' funds	**1,804**	5,387	1,913
Total equity and liabilities	**4,942**	**10,979**	**6,233**

Source: The Medical House PLC.

Note: The accompanying financial statements are presented in the Company's functional currency, the British pound sterling (£). As of the date of these statements, June 30, 2008, the pound sterling/U.S. dollar exchange rate was £1 = ~US$1.99.

Table 10
The Medical House PLC
CONSOLIDATED INTERIM CASH FLOW STATEMENTS
for the six months ended June 30, 2008

	Unaudited Six months ended 30 Jun-08	Unaudited Six months ended 30 Jun-07	Audited Six months ended 31 Dec-07
	£000	£000	£000
Cash flows from operating activities			
Loss for the period	(101)	(340)	(3,482)
Adjustments for:			
Depreciation	35	304	238
Impairment			48
Amortization		12	3
Finance costs	23	136	126
(Gain)/loss on sale of property, plant, and equipment	6	4	(211)
Loss on disposal of discontinued operations	317		1,314
Deferred income arising from sale of SQ pen for Insulin			(116)
Deferred tax provision	92	(353)	(537)
Share-based payments	(8)	(4)	8
	364	(241)	(2,609)
Change in inventories	7	(89)	248
Change in trade and other receivables	444	(238)	(856)
Change in prepayments	61	(75)	29
Change in trade and other payables	(499)	(236)	1,245
Change in deferred income	(750)	22	2,746
	(737)	(616)	3,412
Interest paid	(23)	(136)	(126)
Net cash movement from operating activities	**(396)**	(993)	677
Cash flows from investing activities			
Proceeds from sale of property, plant, and equipment	51	23	794
Purchase of property, plant, and equipment	(74)	(91)	(25)
Overdraft and debt disposed of with subsidiary	680		1,511
Capitalized development expenditure	(159)	(163)	(124)
Cash movement in investing activities	**498**	(231)	2,156
Cash flows from financing activities			
Repayment of principal on hire purchase loans	(21)	(338)	(293)
Cash movement in financing activities	**(21)**	(338)	(293)
Increase/(Decrease) in cash in the period	**81**	(1,562)	2,540
Opening cash and cash equivalents	(365)	(1,343)	(2,905)
Closing cash and cash equivalents	**(284)**	(2,905)	(365)

Source: The Medical House PLC.

Table 11
The Medical House PLC
COMPANY OWNERSHIP (HOLDINGS OF 3% OR GREATER)

Holders	Percentage
Liontrust Investment Service Limited	15.04%
Cazenove Capital Management Limited (and its subsidiary companies)	9.40%
Gartmore Investment Limited	7.20%
Ian Townsend	33.60%
Issued share capital that is not in public hands	34.76%

Source: The Medical House PLC.

Risks

Some information in this Executive Informational Overview® (EIO®) relates to future events or future business and financial performance. Such statements can only be illustrative and the actual events or results may differ from those described. The content of this EIO® with respect to TMH has been compiled primarily from information available to the public and released by the Company through various filings to the London Stock Exchange (LSE) and other publications. TMH is solely responsible for the accuracy of that information. Information about other companies has been prepared from publicly available documents and has not been independently verified by TMH. For more information about the Company, please refer to the Company's website at www.themedicalhouse.com.

One should carefully consider the risks and information about TMH's business described below. One should not interpret the order in which these considerations are presented as an indication of their relative importance. The risks and uncertainties described below are not the only ones the Company faces. Additional risks and uncertainties not presently known or those it currently considers immaterial may also have an adverse effect on its business. If any of the matters discussed in the accompanying risk factors were to occur, TMH's business, financial condition, results of operations, cash flows, or prospects could be materially adversely affected.

Competition

Competition in the drug delivery market is intensifying. The Company may face competition from traditional needle syringes, newer pen-like and sheathed needle syringes, and needle-free injection systems as well as from alternative drug delivery methods, including oral, transdermal, and pulmonary delivery systems. A description of some of TMH's possible competitors in the autoinjector and needle-free jet injector segments is provided on pages 31-33 in the Competition section of this EIO®.

As injections are typically only used when other drug delivery methods are not feasible, the injection systems that TMH has developed may be made obsolete by the development or introduction of drugs or drug delivery methods that do not require injection. In addition, because the Company intends to enter into collaborative arrangements with pharmaceutical companies, its competitive position will depend upon the competitive position of the pharmaceutical company with which it collaborates for each drug application. TMH may find that certain of its competitors have substantially greater capital resources, more experienced research teams, larger facilities, and/or a broader range of products and technologies than the Company. As a result, competitors may succeed in developing competing technologies, obtaining government approvals, or acquiring significant pharmaceutical partners for devices before TMH. Competitors' products may gain market acceptance more rapidly than those products being developed by the Company or may be priced more favorably. Developments by competitors may render TMH's devices or potential devices noncompetitive or obsolete.

Government Regulation

TMH's products and technologies are subject to extensive government regulations in Europe, the U.S., and elsewhere. In these regions, the Company may be required to comply with a variety of mandates, including those governing the introduction of new medical devices, the observation of certain standards and practices with respect to the manufacturing and labeling of medical devices, the maintenance of certain records, and the reporting of device-related deaths, injuries, and certain malfunctions. Noncompliance can result in a variety of regulatory steps ranging from warning letters, product detentions, device alerts, or field corrections to mandatory recalls, seizures, injunctive actions, and civil or criminal actions or penalties.

Product Recall and Reimbursement

The development, manufacture, and sale of medical products involve product liability risks and can lead to product recall. The risk of product liability claims by a third party, risks in connection with the recall of products, negative developments in the reimbursement of costs of products through state-prescribed cost-saving measures in the area of healthcare or by health insurance schemes, and problems with

authorization and upholding authorization of drugs used together with the Company's products can result in detrimental effects, not only on business performance but also on TMH's financial situation and competitive position in the marketplace.

Patents and Technologies

In the medical devices market, disputes over patent rights occur fairly frequently and can involve costly and time-intensive negotiations and/or patent infringement suits. TMH's success depends, in part, on its ability to obtain and enforce patents for its devices, processes, and technologies and to preserve its trade secrets and other proprietary information. If the Company cannot do so, its competitors may exploit its innovations and deprive it of the ability to realize revenues and profits from its developments.

Currently, TMH's core ASI™ autoinjector technology is patented in the UK and Europe and is pending in the U.S. There are six patent families related to aspects of the Company's technologies still pending in the UK as well as in many other countries. Any patent applications the Company may have made or may make relating to inventions for its actual or potential products, processes, and technologies may not result in patents being issued or may result in patents that provide insufficient or incomplete coverage for its inventions. TMH's current patents may not be valid or enforceable and may not protect the Company against competitors that challenge its patents, obtain their own patents that may have an adverse effect on the Company's ability to conduct business, or are able to otherwise circumvent the Company's patents. Further, TMH may not have the necessary financial resources to enforce or defend its patents or patent applications.

Dependence on Licensing Agreements

TMH's business plan requires it to enter into license agreements with pharmaceutical and biotechnology companies covering the development, manufacture, use, and marketing of drug delivery technologies with specific drug therapies. The Company is currently party to a number of such agreements, all of which are currently in varying stages of development. TMH may not be able to meet future milestones established in its agreements (such milestones generally being structured around satisfactory completion of certain phases of clinical development, regulatory approvals, and product commercialization) and thus, would not receive the fees expected from such arrangements. Moreover, there can be no assurance that the Company will be successful in executing additional collaborative agreements or that existing or future agreements will result in increased sales of its drug delivery devices. In such event, the Company's business, results of operations, and financial condition could be adversely affected, and its revenues and gross profits may be insufficient to allow it to achieve and/or sustain profitability.

As a result of TMH's collaborative agreements, the Company is dependent upon certain efforts of its licensees. The amount and timing of resources that such licensees devote to these efforts are not within its control, and such licensees could make material decisions regarding these efforts that could adversely affect the Company's future financial condition and results of operations. In addition, factors that adversely impact the introduction and level of sales of any drug covered by such licensing arrangements, including competition within the pharmaceutical and medical device industries, the timing of regulatory or other approvals, and intellectual property litigation may also negatively affect sales of TMH's devices. TMH seeks to mitigate those effects wherever possible by agreeing to minimum levels of sales in the license agreements.

Foreign Exchange and Interest Rates

The Company's financial instruments comprise borrowings, cash and liquid resources, and various items, such as trade debtor and trade creditors, that arise directly from its operations. The main purpose of these financial instruments is to finance TMH's operations. The Board reviews and agrees on policies for managing each of the risks associated with interest rate, liquidity, and foreign currency. It is the Group's policy that no trading in financial instruments shall be undertaken.

TMH may be exposed to the effects of fluctuations in exchange rates. Currency risks apply to all monetary financial assets and financial liabilities denominated in a currency other than the functional currency, which for TMH is the pound sterling. Transaction risks apply to transactions executed in a currency other than the functional currency, given that the amounts paid or received in the local currency

are subject to exchange rate fluctuations. Transactions in foreign currencies are translated into TMH's functional currency using the rate of exchange ruling at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are translated using the rate of exchange ruling at the balance sheet date and the gains or losses on translation are included in the income statement.

Interest rate risks relating to interest rate changes could have a negative effect on the assets and income of the Company. Interest rate fluctuations lead to changes in interest income and expense in relation to interest-bearing assets and liabilities, thereby influencing the financial result. In addition, they can also have an impact on the fair value of certain financial assets and liabilities and on derivative financial instruments. Other price risks may include the share price risk and the general economic environment.

To manage and control its market risk within acceptable parameters, TMH minimizes exposure to foreign currency movements through contracting in pounds sterling wherever possible and minimizing its overdraft at all times. As of December 31, 2007, TMH did not have any of its debtors receivable in a foreign currency. It finances its operations through equity, bank borrowings, and hire purchase finance. Most borrowings are in sterling at a floating rate of interest.

Credit and Liquidity

Credit risk is the risk of financial loss to the Company if a customer fails to meet its contractual obligations, and arises principally from TMH's receivables from customers. The Company's exposure to credit risk is mainly influenced by the default risk inherent within the industry in which it operates. TMH trades mainly with large medical companies where this risk is perceived to be low. However, debts with individual companies are monitored closely. Prior to trading on credit with a new customer, an analysis of that company's most recent trading statement is undertaken so that a more thorough understanding of its financial position can be ascertained. Losses due to default by customers have occurred infrequently.

Liquidity risk is the risk that TMH will not be able to meet its financial obligations as they fall due. The Company's approach to managing liquidity is to ensure, as far as possible, that it will always have sufficient liquidity to meet its liabilities when due, under both normal and stressed conditions, without incurring unacceptable losses or risking damaging its reputation. TMH prepares annual budgets and re-forecasts regularly, which together assist in monitoring the anticipated future cash flows of the business and allows actions to be taken well in advance of any potential liquidity problem.

Trading on the LSE's Alternative Investment Market (AIM)

The issued Ordinary Shares in TMH are admitted to trading on the AIM. The AIM is a market designed primarily for emerging or smaller companies to which a higher investment risk tends to be attached than to larger or more established companies. A prospective investor should be aware of the risks of investing in such companies and should make the decision to invest only after careful consideration and, if appropriate, consultation with an independent financial adviser.

The share prices of public companies are often subject to significant fluctuations. The market price of TMH's shares may be volatile. The market price for shares in smaller companies is less liquid than for larger corporations. The Company's shares are intended to provide an opportunity for capital growth and therefore may not be suitable as a short-term investment. Consequently, the Company's shares may on any particular occasion be difficult to buy and sell. Investors may therefore not realize their original investment. In addition, investment in shares traded on the AIM carries a higher degree of risk than an investment in shares quoted on the LSE's Official List.

Recent Events

10/17/2008—The Medical House PLC announced the purchase of Ordinary Shares in TMH by directors of the Company, summarized as follows: (1) Mr. John K. Pool, 15,300 Ordinary Shares at 16 pence per share; (2) Mr. David Urquhart, 16,000 Ordinary Shares at 15.5 pence per share; (3) Mr. Bryan H. Bodek, 27,777 Ordinary Shares at 18 pence per share; and (4) Ms. Margaret Scott, 100,000 Ordinary Shares at 17.65 pence per share and 67,218 Ordinary Shares at 18 pence per share. Biographies of each of these directors are available on pages 11-12.

10/09/2008—Announced that TMH received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for a variant of its proprietary disposable AutoSafety Injector (ASI™) autoinjector being developed under agreement with Dr. Reddy's Laboratories Ltd. Details of this arrangement are presented on pages 28-29 of the Partnerships section.

10/07/2008—Announced that it signed a non-exclusive development, licensing, and supply agreement with Catalent Pharma, a global provider of advanced technologies and outsourcing services with which TMH signed a marketing collaboration agreement in 2007. Details of these arrangements are presented on page 29 of the Partnerships section.

09/15/2008—Released its interim financial results for the six-month period ended June 30, 2008, as well as updated shareholders on several of the Company's achievements during the period.

07/18/2008—Announced that it signed a non-exclusive development, licensing, and supply agreement with the global pharmaceutical company, Dr. Reddy's Laboratories.

07/18/2008—Updated the announcement made on April 21, 2008. The previous announcement resulted from a movement in the Company's share price coinciding with an initial inquiry as to whether the Board would contemplate an offer for TMH. The directors of TMH now believe that an offer for the issued share capital of the Company will likely not come from this source. As a result, the Company is no longer regarded by the Panel on Takeovers and Mergers as being in an "offer period" under the Takeover Code.

05/06/2008—Announced that following the sale of its sub-contract engineering subsidiary, Eurocut Ltd, to Semes Ltd (a company controlled by Eurocut's managing director, Mr. Stephen Shaw) in December 2007, the assets of that business were sold to Sandvik Medical Solutions Ltd. This resulted in TMH's expectation of receiving a cash sum of approximately £0.5 million, which could clear all bank debt of the Company, resulting in a position that is broadly cash neutral.

05/02/2008—Announced that a global pharmaceutical partner received regulatory approval in one of the principal territories to which the agreement relates for a drug (a different formulation of which is in development for use with TMH's technology). The new formulation and its combination with the TMH device remained subject to regulatory approvals. Details of this arrangement are presented on page 28 of the Partnerships section.

04/24/2008—Announced that its annual report and accounts for the year ended December 31, 2007, became available to shareholders on the Company's website at www.themedicalhouse.com.

04/21/2008—Initially confirmed that the Company received an approach that may or may not have led to an offer for TMH. See the above entry dated *07/18/2008* for more information.

04/16/2008—Announced preliminary results for the six months ended December 31, 2007.

03/11/2008—Announced that it received 510(k) clearance from FDA for its Compact ASI™ (CASI) autoinjector device.

12/27/2007—Announced that it agreed to sell the loss-making Eurocut subsidiary to Semes in an agreement that enabled TMH to concentrate all of its resources on growing its profitable drug delivery division. For the year ended June 30, 2007, Eurocut reported operating losses of £856,000; Eurocut's losses continued thereafter. At June 30, 2007, Eurocut had net assets of £1.6 million. Under the agreement, Mr. Shaw resigned as a director of TMH and as an employee of the Company, receiving £25,000 in respect of compensation for loss of office.

11/08/2007—Announced that it signed a strategic marketing agreement with Catalent Pharma.

11/07/2007—Announced that on November 6, 2007, the Company granted Options under an Unapproved Options Scheme to subscribe for 747,561 Ordinary Shares of 1 pence in the Company to Mr. Urquhart. The Options are exercisable at a price of 21.5 pence. They are not exercisable before the third anniversary of the date of issue and then only when agreed performance criteria have been satisfactorily achieved.

11/05/2007—Announced that it agreed to extend the term of the development, license, and supply agreement for its ASI™ autoinjector that was signed in December 2006 with a global pharmaceutical company.

10/18/2007—Announced preliminary results for the year ended June 30, 2007.

08/20/2007—Announced that it concluded the sale of its SQ-PEN needle-free insulin injector business to Diabetes Management International B.V. for an initial consideration of £750,000 in cash. TMH expected that an additional payment would be made in respect of all stocks of SQ-PEN materials held by the Company amounting to approximately £60,000.

08/17/2007—Announced that the information required by Rule 26 of the AIM Rules for Companies (February 2007) became available under www.themedicalhouse.com/financial/shareholder/rule26.asp or from the Shareholder Information section of the Company's website.

Glossary

510(k)—Section 510(k) of the U.S. Food, Drug, and Cosmetic Act requires device manufacturers to notify the FDA at least 90 days in advance of an intent to market a medical device. It allows the FDA to determine whether the device is equivalent to a device already categorized. Thus, "new" devices (not in commercial distribution before May 28, 1976) can be properly identified.

Acquired Immune Deficiency Syndrome (AIDS)—The late stage of the human immunodeficiency virus (HIV) characterized by a deterioration of the immune system and a susceptibility to a range of opportunistic infections and cancers.

Anaphylaxis—A severe, whole-body allergic reaction in response to an allergen. The most common causes include drug allergies, food allergies, and insect bites or stings. While rare, anaphylaxis is life-threatening and can occur at any time. Symptoms include breathing difficulty, loss of consciousness, and a drop in blood pressure.

Autoimmune Diseases—A group of diseases resulting from an overactive immune response against substances and tissues normally found in the body.

Autoinjector—A device capable of automatically inserting a needle and injecting a medicine. Some autoinjectors also automatically withdraw and hide the needle after an injection as well.

Bioequivalent—Acting on the body with the same strength and similar bioavailability in the same dosage as an existing drug. A product is considered to be bioequivalent if its rate and extent of absorption do not show a significant difference from the rate and extent of absorption of the reference drug.

Biologics—Products derived from a living organism that are used to diagnose or treat disease. Examples include therapeutic proteins, gene therapy, allergy shots, vaccines, and blood products.

Biologic License Application (BLA)—A request to the FDA for the authorization to market a biological product in interstate commerce.

Bolus Injections—The injection of a drug (or drugs) in a high quantity (called a bolus) at once.

Cartridge—A drug reservoir containing the drug to be administered.

CE Mark—Conformité Européenne. A mandatory European marking for certain product groups to indicate conformity with the essential health and safety requirements set out in European Directives. To permit the use of a CE Mark on a product, proof that the item meets the relevant requirements must be documented.

Crohn's Disease—A chronic inflammatory condition primarily involving the small and large intestine. Mild forms of the disease can cause small ulcers on the inner surface of the bowel, while severe forms yield deeper and larger ulcers that can lead to infection in the abdominal cavity and surrounding organs.

Deep Vein Thrombosis—A blood clot (thrombus) in a deep vein in the thigh or leg. The clot can break off as an embolus and make its way to the lung, where it can cause respiratory distress and respiratory failure.

Diluent—Any liquid or solid material used to dilute or carry an active ingredient.

Epinephrine—A form of adrenaline medication used to treat severe allergic reactions, such as anaphylactic shock or insect stings. It is a hormone produced by the medulla of the adrenal gland. Epinephrine causes quickening of the heart beat, strengthens the force of the heart's contraction, opens up the airways in the lungs, and has numerous other effects.

First-Line Treatment—The initial therapy for the condition being treated.

Good Manufacturing Practices (GMPs)—Regulations established by the FDA for all domestic and foreign manufacturers requiring the establishment of a quality system that includes stipulations related to the methods, controls, and facilities used for designing, manufacturing, packaging, labeling, storing, installing, and servicing products and medical devices intended for human use.

Hepatitis B—An inflammation of the liver caused by the hepatitis B virus that can be spread through needlesticks, body piercing and tattooing using un-sterilized instruments, dialysis, sexual and even less intimate close contact, and childbirth. Symptoms include fatigue, jaundice, nausea, vomiting, dark urine, and light stools. Treatment entails anti-viral drugs and/or hepatitis B immunoglobulin (HBIG). Chronic hepatitis B may be treated with interferon.

Hepatitis C—Previously known as non-A, non-B hepatitis, hepatitis C is an inflammation of the liver that causes fever, jaundice, abdominal pain, and weakness. Unlike other forms, hepatitis C is largely caused by blood transfusions, needles, and in rare cases, sexual contact.

Human Growth Hormone (hGH)—A hormone produced in the pituitary gland that assists in the stimulation of another hormone called somatomedin in the liver, which causes growth.

Hypodermic—Administered by injection beneath the epidermis via a hollow needle and syringe that has been adapted for this type of injection.

Hypothalamus—A central area, located on the bottom side of the brain, which controls involuntary functions such as body temperature, hunger, thirst, and the release of hormones, such as hGH.

Injection Pen—An injection device that looks like a fountain or ballpoint pen. The prescribed dose of medication is set by the user by adjusting a dosage knob and is injected from a cartridge through a cannula (pen needle) into the body. These devices incorporate medicine filled in multi-dose cartridges, and the needle is replaced after each injection.

Insulin—A hormone secreted by the pancreas that controls the level of glucose in the blood. As a result, insulin allows cells in the body to use glucose for energy. A variety of insulin-based therapies are available to aid diabetes patients in controlling their blood sugar levels. Most are available in an injectable formulation.

International Organization for Standardization (ISO)—The ISO develops, coordinates, and publishes national standards from more than 100 countries as a comprehensive guide to promote the international exchange of goods and services and to develop cooperation within intellectual, scientific, technological, and economic fields. Businesses that adopt these voluntary international standards can develop and market products and services meeting specifications that have wide international acceptance.

Intramuscular—Given by needle into the muscle versus given by a needle into the skin (intradermal), just below the skin (subcutaneous), or into a vein (intravenous).

ISO 13485:2003—Specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

ISO 9000—A certification demonstrating that an entity has a standard language for documenting quality processes, a system to manage evidence that these practices are instituted throughout an organization, and third-party auditing to review, certify, and maintain certification of organizations.

Marketing Authorization Application (MAA)—An application for authorization to place medical products on the market. This is a term specific for the European Union/European Economic Area (EU/EEA).

Multiple Sclerosis (MS)—A chronic, often disabling disease that attacks the central nervous system. Symptoms may be mild, such as numbness in the limbs, or severe, such as paralysis or loss of vision.

Needle-Free Jet Injectors—Refers to a technology that allows a medicinal product to be injected without a needle by imparting kinetic energy to the product, thereby expelling it through a fine nozzle, creating a jet stream that penetrates the skin.

Needlestick—An accidental puncture of the skin while handling needles or syringes that may result in exposure to blood or other bodily fluids. The main concern is exposure to the blood or bodily fluids of someone who may be carrying an infectious disease.

Notice of Allowance—A notification to the applicant that they are entitled to a patent under the law and a request for payment of a specified issue fee (and possibly a publication fee) within three months (non-extendable) from the mailing date of the Notice of Allowance.

Parenteral Drug Delivery—Taken into the body or administered in a manner other than through the digestive tract, as by intravenous or intramuscular injection.

Patent Cooperation Treaty (PCT)—Provides a mechanism by which an applicant can file a single application that, when certain requirements have been fulfilled, is equivalent to a regular national filing in each designated Contracting State.

Polyethylene Glycol (PEG)—A polymer made from ethylene oxide. It is not considered toxic, is slow to degrade, and is synthetic.

Prader-Willi Syndrome—A congenital syndrome of unknown cause characterized by short stature, mental retardation, excessive eating and obesity, and sexual infantilism.

Psoriasis—A reddish, scaly rash often located over the surfaces of the elbows, knees, scalp, and around or in the ears, navel, genitals, or buttocks. Psoriasis is an autoimmune disease mediated by T-cells.

Psoriatic Arthritis—A chronic inflammatory disease of the joints and connective tissue that causes pain, stiffness, and swelling in and around the joints.

Rheumatoid Arthritis (RA)—An autoimmune disease that causes chronic inflammation of the joints, the tissue around the joints, and additional organs throughout the body.

Sharps—Items such as hypodermic needles, syringes (with or without the attached needle), pasteur pipettes, scalpel blades, suture needles, and blood vials that may puncture the skin.

Somatomedins—Any of a group of peptides produced by the liver upon stimulation by somatotropin that act directly on cartilage cells to stimulate skeletal growth.

Subcutaneous—Under the skin. With a subcutaneous injection, a needle is inserted just under the skin. A medicine can then be delivered into the subcutaneous tissues. After the injection, the medication moves into small blood vessels and the bloodstream. The subcutaneous route is used with many protein products that, if given by mouth, would be broken down and digested in the gastrointestinal tract.

Turner's Syndrome—A chromosomal condition for females with common features that are caused by complete or partial absence of the second sex chromosome. It occurs when one of the two X chromosomes normally found in females is missing or contains certain structural defects. It occurs in approximately 1 in 2,000 live female births.

Viscous—A material that is thick, sticky, or glue-like and is thus resistant to flow.

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