

United States
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 20-F
as amended by
FORM 20-F/A1

(Mark One)

☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF
THE SECURITIES EXCHANGE ACT OF 1934

OR

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended: December 31, 1998

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____.

Commission file number: 1-13896

Elan Corporation, plc

(Exact name of Registrant as specified in its charter)

Ireland

(Jurisdiction of incorporation or organization)

Lincoln House, Lincoln Place, Dublin 2, Ireland

(Address of principal executive offices)

Securities registered or to be registered pursuant to
Section 12(b) of the Act:

<i>Title of each class</i>	<i>Name of each exchange on which registered</i>
American Depositary Shares ("ADSS"), representing Ordinary Shares, par value 5 Euro cents each ("Ordinary Shares")	New York Stock Exchange
Ordinary Shares	New York Stock Exchange*
American Depositary Warrant Shares, representing Warrants to purchase ADSS	New York Stock Exchange

* Listed, not for trading, but only in connection with the listing of American Depositary Shares, pursuant to the requirements of the Securities and Exchange Commission.

Securities registered or to be registered pursuant to Section 12(g) of the Act:

None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None

(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: **267,332,869 Ordinary Shares.**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days:

Yes: ☒ X

No: ☐

Indicate by check mark which financial statement item the registrant has elected to follow:

Item 17: ☐

Item 18: ☒ X

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General

Unless otherwise indicated, all amounts in this Annual Report on Form 20-F are expressed in United States dollars (“\$”).

All share and related information (such as per share information, options and warrants) has been adjusted to give effect, retroactively, to a two-for-one stock split effected in the form of a stock dividend paid on June 7, 1999 and a two-for-one stock split completed on August 22, 1996.

Trademarks and Service Marks

The following trademarks and service marks used herein are owned by or licensed to Elan:

Antegren® (atalizumab)	Neurobloc™ (Botulinum Toxin Type B)
Athena® Rx (pharmacy services)	Permax® (pergolide mesylate)
Diastat® (diazepam rectal gel)	Skelaxin® (metaxalone)
Medipad™ technology	Verelan® (verapamil hydrochloride)
Morphelan™ (morphine)	Zanaflex® (tizanidine hydrochloride)
NanoCrystal™ technology	Zelapar™ (selegiline)
NanoSystems®	Zonegran™ (zonisamide)
Naprelan® (naproxen sodium)	

The following trademarks and service marks used herein are owned by third parties:

Cardizem® CD (diltiazem, Hoechst Marion Roussel, Inc. (“HMR”))
Cardizem® SR (diltiazem, HMR)
LYONs™ (Liquid Yield Option Notes, Merrill Lynch & Co.)

PART I

Item 1. Description of Business.

General

Elan Corporation, plc, a public limited company organized under the laws of Ireland (collectively with its subsidiaries, “Elan” or the “Company”), is a leading worldwide specialty pharmaceutical company. Elan’s principal research and development, manufacturing and marketing facilities are located in Ireland, the United States (“US”) and Israel. Traditionally, Elan has focused on the development and commercialization of products for pharmaceutical industry clients utilizing its proprietary drug delivery systems. In recent years, Elan has continued to focus on drug delivery systems, but has embarked on a new strategy to expand its therapeutic focus through the development and commercialization of new pharmaceutical products for selected target markets, including the areas of neurology, pain management and acute care.

Elan’s objective is to be a fully integrated, worldwide specialty pharmaceutical company with a significant commercial presence in selected world markets and therapeutic areas. Elan plans to achieve this objective via two market-driven routes: (i) by developing pharmaceutical franchises in neurology, acute care and pain management and other target markets, and (ii) by being the premier drug delivery company in the pharmaceutical industry and the industry partner of choice for drug delivery services.

Elan currently conducts its operations through two primary business units: Elan Pharmaceuticals (“EP”) and Elan Pharmaceutical Technologies (“EPT”). EP is engaged in the discovery, development and marketing of therapeutic products for neurological disorders, acute care and pain management, and diagnostic services for neurological disorders. EP’s principal research and development activities focus on Alzheimer’s disease, pain management, epilepsy, multiple sclerosis (“MS”) and stroke. EPT is engaged in the development, licensing and marketing of drug delivery products and technologies based on Elan’s drug delivery systems.

Elan was incorporated as a private limited company in Ireland on December 18, 1969. On January 3, 1984, Elan became a public limited company. Elan’s principal executive offices are located at Lincoln House, Lincoln Place, Dublin 2, Ireland, telephone number 353-1-709-4000.

Company Acquisitions

NanoSystems LLC: On October 1, 1998 Elan completed the acquisition of all of the assets and liabilities of NanoSystems LLC (“NanoSystems”) for \$154.9 million, including the costs of acquisition. The purchase price consisted of \$138.5 million in cash and the issuance by Elan of warrants with an estimated fair value of \$16.4 million to acquire 1,500,000 Elan American Depositary Shares (“Elan ADSs”) at an exercise price of \$45 per Elan ADS. The warrants are exercisable until the eighth anniversary of the closing date of the transaction. NanoSystems is engaged in the formulation and manufacturing of enhanced delivery forms of poorly water-soluble drugs using its proprietary NanoCrystal technology. Pharmaceutical and biotechnology companies sometimes terminate drug development projects due to certain drugs being poorly water-soluble. The NanoCrystals technology improves a drug’s water-solubility by reducing its particle size. The productivity of pharmaceutical and biotechnology companies’ research and development efforts can be improved by application of the NanoCrystals’ technology as it can reduce the number of drug development projects terminated due to poor water-solubility. NanoSystems is a party to collaborative arrangements with a number of pharmaceutical and biotechnology companies, including Merck & Co., Inc., Warner-Lambert Company, Janssen Pharmaceutica, N.V. (“Janssen”), and Wyeth-Ayerst Laboratories (“Wyeth”), a division of American Home Products Corporation (“AHP”), to develop improved formulations of both marketed products and new chemical entities. Elan accounted for the acquisition of NanoSystems using purchase accounting. As a result of the transaction, Elan incurred a charge of \$88.5 million for the year ended December 31, 1998, representing the acquisition of in-process research and development, in accordance with Statement of Financial Accounting Standards No. 2 (“SFAS No. 2”) “Accounting for Research and Development Costs.”

The remaining portion of the purchase price was allocated to acquired technology, net tangible assets and workforce in the amount of \$55.5 million, \$10.4 million and \$0.5 million, respectively.

The purchase price of \$154.9 million for NanoSystems was allocated as follows:

	<u>\$000's</u>
Property, plant and equipment	11,738
Intangible assets	56,044
Current assets	1,036
Accounts payable	(2,419)
In-process research and development	88,500
Purchase price	<u>154,899</u>

Eleven development stage products were valued as in-process research and development at the date of the acquisition of NanoSystems. These products were NanoCrystal formulations of various pharmaceutical compounds. Technological feasibility of these products was not established at the acquisition date. These products were considered to have no alternative future use other than the therapeutic indications for which they were in development. Eight of these products were in development by licensees. Two products represented approximately \$28.0 million and \$36.0 million, respectively, of the in-process research and development charge. As both products were in development by licensees, NanoSystems' costs to completion of these products were expected to be minimal. The first product was in Phase III clinical trials with an estimated launch date during 1999. This product was estimated to be 80% complete, estimated peak revenues to NanoSystems were approximately \$18.0 million per annum and a discount rate of 24% was used. The second product was in Phase II clinical trials with an estimated launch date during 2001. This product was estimated to be 60% complete, estimated peak revenues to NanoSystems were approximately \$15.0 million per annum and a discount rate of 24% was used. The work remaining to complete the development products involved research, safety and efficacy studies and the submission of regulatory filings to seek marketing approvals. The principal risks related to the development products were the outcomes of such research, clinical studies and regulatory filings. As pharmaceutical products cannot be marketed without regulatory approvals, Elan will not receive any benefits unless it receives such regulatory approval.

Neurex Corporation: On August 14, 1998 Elan completed the acquisition of Neurex Corporation ("Neurex") for approximately \$810.0 million, including the costs of acquisition. Neurex has developed, and is developing, products for pain management and the acute care market, principally in the area of cardiorenal and neurological diseases. In connection with the acquisition, each outstanding share of Neurex common stock was exchanged for 1.02 Elan ADSs, resulting in the issuance of approximately 23.8 million Elan ADSs valued at \$736.6 million. Options granted by Neurex prior to the acquisition date were converted into options to acquire 3.0 million Elan ADSs. These options were valued in the determination of the purchase price of Neurex at \$67.1 million. Elan accounted for the acquisition of Neurex using purchase accounting. As a result of the transaction, Elan incurred a charge of \$787.1 million for the year ended December 31, 1998, representing the acquisition of in-process research and development, in accordance with SFAS No. 2.

The purchase price of \$810.0 million for Neurex was allocated as follows:

	<u>\$000's</u>
Property, plant and equipment	1,952
Intangible assets	14,505
Current assets	32,889
Accounts payable	(24,281)
Long-term debt	(2,158)
In-process research and development	787,100
Purchase price	<u>810,007</u>

Intangible assets include the value of Neurex's assembled workforce, developed technology and goodwill. These were valued at \$0.9 million, \$6.2 million and \$7.4 million, respectively. The acquired in-process research and development charge of \$787.1 million represents the value of Neurex's products in development at the date of acquisition. Technological feasibility of these products was not established at the acquisition date. These products were considered to have no alternative future use other than the therapeutic indications for which they were in development. The development products were estimated to be 67% complete on average, estimated peak sales were approximately \$1,072.0 million per annum, estimated costs to completion of these products were approximately \$70.0 million and discount rates of 24% were used. The average time to full completion of the remaining work for the products in development was estimated to be approximately 33 months. The work remaining to complete the products in development involved ongoing safety and efficacy studies and the submission of regulatory filings to seek marketing approvals. The principal risks related to the development products were the outcomes of such clinical studies and regulatory filings. As pharmaceutical products cannot be marketed without regulatory approvals, Elan will not receive any benefits unless it receives such regulatory approval.

GWC Health, Inc.: On May 29, 1998 Elan completed the acquisition of GWC Health, Inc. ("Carnrick") for approximately \$152.4 million, including the costs of acquisition. The purchase price consisted of \$134.4 million in cash and the issuance of an \$18.0 million promissory note. Carnrick markets and distributes a range of products, primarily for neurology and pain management applications, to general practitioners and pain specialists in the US and Puerto Rico. Elan accounted for the acquisition of Carnrick using purchase accounting. As a result of the transaction, Elan incurred a charge of \$19.9 million for the year ended December 31, 1998, representing the acquisition of in-process research and development in accordance with SFAS No. 2.

The purchase price of \$152.4 million for Carnrick was allocated as follows:

	<u>\$000's</u>
Property, plant and equipment	7,105
Intangible assets	101,650
Current assets	41,678
Accounts payable	(16,527)
Long-term debt	(1,416)
In-process research and development	19,930
Purchase price	<u>152,420</u>

Intangible assets include the value of Carnrick's assembled workforce, marketed products and goodwill. These were valued at \$0.6 million, \$59.7 million and \$40.7 million, respectively. The acquired in-process research and development charge of \$19.9 million represents the value of Carnrick's products in development at the date of acquisition. Technological feasibility of these products was not established at the date of acquisition. These products were considered to have no alternative future use other than the therapeutic indications for which they were in development. The development products were estimated to be approximately 63% complete on average, estimated peak sales were approximately \$57.0 million per annum, estimated costs to completion were approximately \$5.0 million and discount rates of 22 to 23% were used. The average time to full completion of the remaining work for the products in development was estimated to be approximately 21 months. The work remaining to complete the development products involved continuing formulation activity, ongoing safety and efficacy studies and the submission of regulatory filings to seek marketing approvals. The principal risks relating to the development products were the outcomes of such formulation activity, clinical studies and regulatory filings. As pharmaceutical products cannot be marketed without regulatory approvals, Elan will not receive any benefits unless it receives such regulatory approval.

Sano Corporation: On February 27, 1998, Elan completed the acquisition of Sano Corporation ("Sano") for approximately \$434.7 million, including the costs of acquisition. Sano primarily develops proprietary

transdermal drug delivery systems. In connection with the acquisition, each outstanding share of Sano common stock was exchanged for 1.20 Elan ADSs, resulting in the issuance of approximately 12.7 million Elan ADSs valued at \$377.0 million. Options granted by Sano prior to the acquisition date were converted into options to acquire 2.2 million Elan ADSs. These options were valued in the determination of the purchase price of Sano at \$53.0 million. Elan accounted for the acquisition of Sano using purchase accounting. As a result of the transaction, Elan incurred a charge of \$445.1 million in the year ended December 31, 1998, \$404.9 million of which represented the acquisition of in-process research and development and \$40.2 million of which represented the cost of integrating and rationalizing certain activities.

The purchase price of \$434.7 million for Sano was allocated as follows:

	<u>\$000's</u>
Property, plant and equipment	17,128
Intangible assets	9,873
Current assets	20,633
Accounts payable	(10,101)
Long-term debt	(7,801)
In-process research and development	404,918
Purchase price	<u>434,650</u>

Intangible assets include the value of Sano's assembled workforce, developed technology and goodwill. These were valued at \$0.6 million, \$1.5 million and \$7.1 million, respectively. The acquired in-process research and development charge of \$404.9 million represents the value of Sano's products in development at the acquisition date. Technological feasibility of these products was not established at the date of acquisition. These products were considered to have no alternative future use other than the therapeutic indications for which they were in development. The development products were estimated to be 65% complete, estimated peak sales were approximately \$618.0 million per annum, estimated costs to completion were approximately \$31.0 million and discount rates of 20% were used. The average time to full completion of the remaining work for the products in development was anticipated to be approximately 33 months. The work remaining to complete the development products involved continuing formulation activity, safety and efficacy studies and the submission of regulatory filings to seek marketing approvals. The principal risks to the development products were the outcomes of such formulation activity, clinical studies and regulatory filings. As pharmaceutical products cannot be marketed without regulatory approvals, Elan will not receive any benefits unless it receives such regulatory approval.

Product Acquisitions

Frovatriptan: In October 1998, the Company licensed from Vanguard Medica Group, plc ("Vanguard") exclusive North American sales and distribution rights for frovatriptan, which had completed Phase III studies in patients with migraine headaches. In addition, Elan paid \$10.0 million to Vanguard to acquire new ordinary shares and as part of the licensing collaboration. The terms of the license provide that Elan will make milestone payments of up to \$50.0 million to Vanguard and will pay royalties on future sales. To date, \$15.0 million of these milestone fees have been paid. In January 1999, a New Drug Application ("NDA") for frovatriptan was filed with the US Food and Drug Administration (the "FDA").

Naprelan and Verelan: In September 1998, Elan reacquired exclusive US and Canadian product distribution rights for Naprelan and Verelan from Wyeth for \$228.0 million, which is payable in installments. The terms of the acquisition require that Elan pay to Wyeth up to an additional \$30.0 million, depending on the amount and timing of launches of competitive generic products. Elan will continue to manufacture Naprelan and Verelan. Naprelan, a once-daily formulation of naproxen, is indicated for use in connection with mild to moderate pain, rheumatoid arthritis and a number of related inflammatory conditions. Elan markets Naprelan

directly in the US. Verelan, a once-daily formulation of verapamil, is used to manage hypertension. Elan has also developed an enhanced formulation of Verelan called Verelan PM, which provides certain improved therapeutic benefits.

On September 30, 1998, Elan entered into an agreement for the exclusive marketing and distribution rights to Verelan in the US with Schwarz Pharma, Inc. (“Schwarz”), the US affiliate of Schwarz Pharma A.G., a German pharmaceutical company with expertise in the cardiovascular market. This agreement set minimum sales targets to be achieved by Schwarz and also provided for Elan to supply product to Schwarz. Elan also licensed Verelan PM to Schwarz. In November 1998, the FDA approved an NDA for Verelan PM. Elan received a license fee of \$17.5 million upon execution of the agreement and a milestone payment of \$10.0 million upon FDA approval of the NDA for Verelan PM. These license and milestone fees were recognized as revenue in the year ended December 31, 1998.

In May 1999, generic products which compete with Verelan were launched and Elan expects that such products will reduce significantly revenue it receives from Verelan sales.

Mysoline: On February 28, 1998, Elan acquired from Wyeth exclusive product distribution and trademark rights for Mysoline in the US and Canada for \$46.0 million and a royalty on future sales. Elan markets Mysoline directly in the US.

Current Elan Products and Services: Marketing

The following table lists Elan’s principal marketed products, their indication and principal markets (see additional information below regarding the products and services marketed by Elan):

Product	Indication	Principal Markets
Cardizem CD/SR (diltiazem)	Calcium channel blockers indicated for the treatment of hypertension and/or angina.	Marketed in the US and Canada by HMR and by other licensees in other countries. Manufactured by Elan.
Naprelan (naproxen sodium)	Non-steroidal anti-inflammatory for the treatment of osteo-arthritis and rheumatoid arthritis.	US distribution and marketing rights acquired from AHP in 1998. Marketed by Elan in the US and in other countries under different brand names by licensees. Manufactured by Elan.
Permax (pergolide mesylate)	Dopamine agonist as adjunct therapy for the treatment of Parkinson’s disease.	US distribution and marketing rights acquired from Eli Lilly and Company in 1993. Marketed by Elan in the US.
Skelaxin (metaxalone)	Indicated for the relief of acute painful musculoskeletal conditions.	Marketed by Elan in the US.
Verelan (verapamil hydrochloride) and Verelan PM	Calcium channel blockers indicated for the treatment of hypertension.	Marketed and distributed by Schwarz in the US and by other licensees in other countries. Manufactured by Elan.
Zanaflex (tizanidine hydrochloride)	Oral treatment for the management of increased muscle tone associated with spasticity.	Elan licensed the exclusive distribution and marketing rights in the US, the United Kingdom, Canada and Ireland from Novartis Pharma AG. Marketed by Elan in the US, the United Kingdom and Ireland.

The products in the table above accounted for 62.5% and 58.6% of product sales in 1998 and 1997, respectively. The same products accounted for 37.8% and 42.3% of total revenues in 1998 and 1997, respectively. In 1998 Naprelan, Permax and Verelan accounted for 16.0%, 14.0% and 13.9% of product sales, respectively. In 1997 Permax accounted for 25.6% of product sales. No other product accounted for more than 10.0% of product sales in either 1998 or 1997. Elan’s remaining revenues are generated from a mix of other products and services.

Pharmaceutical Products and Services: Elan markets its pharmaceutical products and services in the US through its own sales and marketing group, including five separate national sales forces aggregating in

excess of 400 representatives. In addition to the above listed products, Elan markets other pharmaceutical products, including neurology and pain management products offered by Carnrick, diagnostic testing services offered by Athena Diagnostics, Inc. and pharmacy products and services offered by Athena Rx Home Pharmacy.

Outside of the US, Elan commercializes its pharmaceutical products through subsidiaries and joint ventures in the United Kingdom ("UK"), Ireland, Germany, Spain, the Philippines and Taiwan. In other markets, Elan commercializes its products through licensees and distributors. Elan has identified certain geographic markets for future expansion of its direct marketing efforts as its development candidates become available for marketing.

Drug Delivery: Elan uses its proprietary technologies and multidisciplinary expertise to develop, license and market drug delivery products, technologies and services to its pharmaceutical industry clients on a worldwide basis. Elan's portfolio of drug delivery technologies yields products that control release rate or enhance absorption and utilization of pharmaceutical compounds. Also included in Elan's technology portfolio are technologies that can increase the efficiency of its pharmaceutical industry clients' drug discovery efforts by allowing them to develop new compounds that may otherwise have been rejected as development candidates.

Elan primarily focuses on oral delivery technologies because oral products represent the largest commercial opportunity for drug delivery. Elan's technologies are applicable to conventional small molecule drugs and other technologies that improve delivery of macromolecule therapeutic agents, such as proteins and peptides. Elan, however, continues to seek significant drug delivery opportunities outside of oral delivery.

Elan's continued commercial success will depend on it possessing proprietary technologies that solve the pharmaceutical industry's drug delivery needs. Elan devotes significant resources to developing next generation technologies to overcome the complexities of delivering new and emerging therapies and drug candidates, including complex biotechnology products and poorly water-soluble drug candidates. In 1998, Elan acquired NanoSystems. NanoSystems' proprietary NanoCrystal technology is a leading technology for formulating and delivering poorly water-soluble drugs and is broadly applicable to all classes of such drugs and all conventional routes of administration, including oral, injectable, pulmonary and topical.

In 1996 Elan commenced a restructuring of its manufacturing operations in its Athlone, Ireland facility. As a result of the reorganization of manufacturing operations, certain products were withdrawn from certain non-US markets. These products included nifedipine, theophylline and verapamil.

Elan markets its drug delivery products, technologies and services in major pharmaceutical markets directly through subsidiaries, joint ventures and licensing arrangements with third parties. Elan's licensing and development arrangements vary from client to client. Elan performs product development work for clients. The initial work typically involves formulation, research and the testing necessary to incorporate the drug selected by the client into a drug delivery system. Elan typically manufactures product for *in vitro* and human clinical studies, develops pilot scale manufacturing and, ultimately, commercial manufacturing capacity. Regulatory filings may be prepared by Elan or by the client, as negotiated. Elan is reimbursed for its intellectual property by payments which may include license fees, research and development funding, milestone fees and, upon product launch, by manufacturing fees and royalties on product sales, as negotiated.

There are a wide variety of business relationship structures that are used in the life sciences industry. The business relationship may be comprised of a number of different elements such as a license to intellectual property, research and development services and manufacturing services. Elan negotiates its business relationships on an arms-length basis with unrelated parties on terms customary in the industry.

Research and Development

Elan's research and product development activities have been, and are expected to continue to be, either self-funded (developed on behalf of Elan), funded by licensees (developed by Elan on behalf of others), or both. Elan spent approximately \$143.5 million on research and development activities during the year ended December 31, 1998, \$75.2 million during the year ended December 31, 1997 and \$54.5 million during the nine months ended December 31, 1996. As of May 28, 1999, Elan had 769 employees engaged in research and development activities.

The following table lists the principal products currently under development by Elan, their indication and current status:

Product	Indication/description	Status
<i>Pharmaceutical products under research and development</i>		
Antegren (1)	Acute clinical exacerbations ("flares") in MS, and inflammatory bowel disease (including ulcerative colitis and Crohn's disease).	Phase II clinical studies completed for MS flare and ongoing for Crohn's diseases.
Frovatriptan	Acute treatment for migraine.	NDA filed with FDA.
Neurobloc (1)	Treatment for cervical dystonia.	Product license application/establishment license application filed with FDA.
Permax patch (1)	Transdermal formulation of pergolide as adjunctive treatment of Parkinson's disease.	Preclinical development.
Zelapar	Fast dissolving dosage form of selegiline, as adjunctive treatment for Parkinson's disease.	US, UK and Ireland distribution and marketing rights acquired from R.P. Scherer Corporation. Phase III clinical studies ongoing in the US. Marketed by Elan in the UK.
Ziconotide (1)	Neuronal calcium channel blocker for severe pain.	Completed Phase III studies for chronic malignant and chronic neuropathic pain for intrathecal administration. Safety studies ongoing.
Zonegran (1)	Adjunctive treatment of partial epileptic seizures.	FDA issued an approvable letter contingent on final labeling and provision of certain information. Response submitted in December 1998.

- (1) The clinical development of these products for the US market is currently being funded by Axogen Limited pursuant to a development and license agreement with Elan. Elan and Axogen Limited each have certain licensing, manufacturing and marketing rights to these products.

Product	Indication/description	Status
<i>Drug delivery system products under research and development</i>		
Buspirone transdermal delivery system	Treatment of anxiety.	Distribution and supply agreement with Bristol-Myers Squibb Company. Phase III clinical data inconclusive. Further review ongoing.
Fluvoxamine formulation	Extended-release formulation for the treatment of obsessive compulsive disorder.	License agreement with Solvay Pharmaceuticals, Inc. Phase III clinical studies ongoing.
Intravenous product	NanoCrystal formulation.	License agreement with Janssen.
Medipad	Subcutaneous delivery of drugs.	Various projects; feasibility and clinical studies ongoing.
Morphelan	Once-daily formulation of morphine for pain management.	License agreement with Ligand Pharmaceuticals Incorporated. Phase III clinical studies ongoing.
Nifedipine extended-release formulation	Treatment of hypertension.	Received tentative approval from the FDA pending resolution of legal and patent issues.
Rapamycin	Oral dosage form using NanoCrystal technology.	Development and license agreement with AHP.

In 1996 Elan commenced a restructuring of its research and development activities following the acquisition of Athena Neurosciences, Inc. (“Athena”). These activities included the elimination of certain research and development programs in both Elan and Athena. The programs were eliminated given the need to allocate limited resources to the best opportunities in the combined product pipeline.

Pharmaceutical products research and development: Elan’s principal research and development activities focus on Alzheimer’s disease, pain management, epilepsy, MS and stroke.

Elan believes that it has established a leadership position in pathology-based approaches to diagnose and treat Alzheimer’s disease, for which there is no known prevention or cure. In August 1998, Elan and Eli Lilly and Company (“Lilly”) ended the research collaboration they had initiated in 1988 to discover and develop drugs to treat Alzheimer’s disease. Elan has granted Lilly an exclusive, worldwide license under certain patents to make, have made, use and sell any compound owned by Elan and discovered during the exclusive collaboration, that reduces, via certain mechanisms, beta-amyloid peptide, the principal component of the amyloid plaque which is one of the hallmarks of Alzheimer’s disease. Elan retains certain commercial rights under the collaboration agreement.

Elan has also entered into a research arrangement with Neuralab Limited (“Neuralab”) to identify potential therapeutic compounds for Alzheimer’s disease. (See Item 1 — Research and Development Alliances).

The following description provides further information regarding each of the pharmaceutical product development candidates listed in the preceding table:

Antegren: Antegren is a humanized recombinant monoclonal antibody under development for the treatment of acute clinical exacerbations (“flares”) in MS and also for inflammatory bowel disease (including ulcerative colitis and Crohn’s disease). Antegren has the potential to prevent migration of lymphocytes and monocytes (specific types of leukocytes) into brain tissue, thereby reducing the ability of these cells to attack and initiate the destruction of myelin, the insulating sheath covering nerve fibers. A North American Phase II study of Antegren for flares has been completed pending data analysis. A pivotal study for patients with Crohn’s disease has recently been initiated in Europe. Elan has contracted with Lonza Biologics plc (“Lonza”) to undertake production of Antegren to provide material for clinical development and currently expects that Lonza will continue to supply its commercial requirements of this product.

Frovatriptan: Frovatriptan is a potent 5HT_{1B/1D} receptor agonist for the acute treatment of migraine, developed by Vanguard. Elan entered into a license and supply agreement for North American rights from Vanguard in October 1998. Vanguard filed an NDA with the FDA in January 1999 for frovatriptan.

Neurobloc: Botulinum toxin is a potent neurotoxin, best known as the cause of the potentially fatal form of bacterial food poisoning called botulism. Scientists have found that this toxin can be formulated into useful pharmaceutical agents. Neurobloc, Elan's formulation of botulinum toxin type B, is being developed for the treatment of cervical dystonia. Elan's formulation has been granted Orphan Drug designation by the FDA for the treatment of cervical dystonia. In December 1998, Elan filed the product license application/establishment license application for Neurobloc with the FDA.

Permax Patch: In March 1998, Elan entered into an agreement with an industry partner for the development of a transdermal formulation of pergolide. Elan currently markets an oral formulation under the brand name Permax in the US, a dopamine agonist indicated as adjunctive therapy for the treatment of Parkinson's disease. If the transdermal product is successfully developed, and subject to the rights of Axogen Limited ("Axogen") under an agreement between Elan and Axogen, Elan will have exclusive rights to market and distribute that product in the US. Elan's partner will supply the bulk drug product to Elan for the transdermal formulation and will retain all marketing and distribution rights outside the US. The product is in preclinical development.

Zelapar: In December 1996, Elan entered into, and subsequently amended, a license and supply agreement with R.P. Scherer Corporation ("Scherer") to develop and market exclusively in North America, the UK, Ireland and certain other countries a patented formulation of selegiline utilizing Scherer's proprietary Zydis technology. The product, known as Zelapar, is currently in Phase III clinical studies in the US and is currently marketed by Elan in the UK. Selegiline is a marketed product approved in the US and other countries as an adjunctive treatment for Parkinson's disease. Zelapar is a fast-dissolving dosage formulation designed for oral administration as adjunctive therapy for Parkinson's disease.

Ziconotide: In December 1998, Elan announced Phase III trial results for ziconotide in treating neuropathic pain, and Phase II trial results for the treatment of acute post-surgical pain. Ziconotide, a novel N-type neuronal calcium channel blocker, is being developed for the treatment of chronic intractable pain and acute post-surgical pain. Elan is conducting certain safety studies and expects to submit an NDA with the FDA for the treatment of chronic neuropathic and malignant pain in late 1999.

Zonegran: In March 1997, Elan entered into a license and supply agreement with Dainippon Pharmaceutical Co., Ltd. ("Dainippon") to market exclusively in North America, Zonegran (zonisamide), Dainippon's novel anti-epileptic product. In March 1998, Elan announced that the FDA had issued an approvable letter for Zonegran contingent on final labeling and the provision of certain additional safety information requested by FDA. Elan submitted a response to the FDA in December 1998.

Drug delivery systems research and development: Elan is applying its delivery systems and technologies to a number of pharmaceutical products, including those listed in the table above. As of May 31, 1999, Elan has over 40 drug delivery client-funded and internal projects under development. These projects are at various stages of development, ranging from initial characterization and feasibility studies to completion of regulatory filings.

Elan's approach to technology development focuses on identifying delivery problems relating to specific pharmaceutical products and developing the most effective delivery system or solution for each such problem. For this reason, Elan is constantly expanding its drug delivery expertise and technologies. Examples include Elan's 1998 acquisitions of NanoSystems and Sano. Elan now incorporates NanoCrystal technology into its technology offering both as a stand-alone technology platform and through incorporation of such technology into Elan's other technology platforms.

Elan has developed a number of different technologies that address a wide variety of drug delivery problems. Elan devotes significant resources to the refinement and improvement of its existing drug delivery systems which focus primarily on oral controlled- and sustained-release technologies, as well as to the development of the next generation of drug delivery technologies, with particular applicability to the delivery of new drug development candidates, including macromolecules and other complex biotechnology products.

Elan is conducting development work on a range of Medipad devices which are designed to deliver a variety of drugs using an internal gas generator that forces the drug through a probe into the subcutaneous tissue. Among the drug groups to which this technology should be applicable are complex macromolecules, antiemetic, antimigraine and anticancer compounds, narcotic analgesics and anticoagulants.

Elan is developing Morphelan, a once-daily oral formulation of morphine used in pain management therapy. This product is licensed to Ligand Pharmaceuticals Incorporated (“Ligand”) for the US and Canadian markets. Elan is also developing Medipad morphine which is designed to deliver constant levels of morphine to the patient. Medipad morphine is currently in Phase II clinical studies.

In addition to the Verelan PM marketed product, Elan is developing other chronotherapeutic products using its drug delivery technologies. The principle behind chronotherapeutic products is to deliver the drug in a controlled manner that corresponds with daily natural physiological rhythms of the body. That delivery is expected to optimize clinical efficacy and tolerability. Chronotherapeutic compounds for development include isosorbide-5-mononitrate and a beta blocker.

The acquisition of Sano provided Elan with passive transdermal drug delivery capability. Sano’s transdermal patches are small, flexible and user-friendly. The patches are particularly useful for applications requiring or benefiting from patch delivery of drug over several days. The transdermal portfolio includes a number of development projects at various stages of development.

Several products that incorporate the NanoCrystal technology platform are in various stages of clinical development. This technology improves the performance of poorly water-soluble drugs and it has been licensed to a number of pharmaceutical companies for their proprietary compounds. The most advanced oral product is in Phase III clinical studies while the most advanced intravenous product candidate is completing Phase II clinical trials. The first NanoCrystal pulmonary product is scheduled to enter clinical trials in late 1999.

Elan is also pursuing a number of projects which have relatively short development cycles. Each of these projects involves the filing of an Abbreviated New Drug Application (“ANDA”) with the FDA, whereby a bioequivalent match to an innovator product is developed.

Each of these development candidates are presently in various stages of preclinical and clinical development. There can be no assurance that any drug delivery formulation or pharmaceutical product under development will be successfully developed, any clinical studies undertaken will be completed successfully, or that any regulatory application prepared for marketing approval will be filed or, if filed, approved. For example, the Phase III studies with a transdermal formulation of buspirone (described in the table above) and another with a combination of nicotine and mecamylamine (“Nic/Mec”) for smoking cessation, each failed to demonstrate sufficient statistical significance of efficacy for an NDA filing. Certain data from these clinical studies are still being assessed. The development and commercialization process is time-consuming and costly, and Elan cannot be certain that any of its products, if and when developed and approved, will be successfully commercialized. Delays or unanticipated costs in any part of the process, Elan’s inability to obtain regulatory approval for its products or to maintain manufacturing facilities in compliance with all applicable regulatory requirements could have a material adverse affect on Elan.

Research and Development Alliances

Elan has entered into a number of research and development alliances. Alliances are customary in the pharmaceutical industry as part of licensing or product development activities.

Research and development arrangements: Elan has research and development arrangements with Neuralab and Axogen as set forth below:

Neuralab: In January 1998, Elan and Neuralab, a newly formed research and development company, consummated a private placement of 1,250,000 units, each unit consisting of one common share of Neuralab,

one initial warrant to purchase two Elan ADSs at an exercise price of \$65.01 for two Elan ADSs, and one additional warrant to purchase two Elan ADSs, the exercise price of which will be determined based on future trading prices of Elan ADSs and the exercisability of which is contingent upon future events. On January 15, 1999, the units separated into the underlying securities. The initial warrants are exercisable until January 14, 2003. The additional warrants are exercisable at a 20-day average of the last sales price per Elan ADS prior to the second separation date or the occurrence of certain events, primarily the acquisition or merger of Elan into another entity. The net proceeds of the private placement amounted to approximately \$47.0 million, substantially all of which is being used to fund payments to Elan under a development agreement between Elan and Neuralab.

Under the development and license agreement between Elan and Neuralab, Elan has agreed to use diligent efforts to conduct research and development for Neuralab to identify potential therapeutic compounds for each of the research projects relating to Alzheimer's disease (the "Neuralab Projects").

Payments to Elan under the development and license agreement for research and other costs of the Neuralab Projects (the "Development Costs") are determined on a funding rate per dedicated Full Time Equivalent ("FTE"). This rate is based on a "Scientific Year" which represents 1,880 employee hours per year of scientific work on the Neuralab Projects carried out by Elan employees at the level of research assistant (generally, having a baccalaureate degree, or its academic equivalent, in science) or above. The pricing structure based on the FTE rate is considered by Elan to be consistent with contractual relationships it has or had with other third parties. Neuralab makes monthly payments to Elan, based on invoices for all of the Development Costs incurred by or on behalf of Elan during the preceding month.

Neuralab owns all right, title and interest in the world, excluding certain Asian countries (the "Territory"), to know-how and patent rights discovered or developed by Elan during the term of and as a result of work funded by Neuralab on the Neuralab Projects. Patent rights include both pending applications and issued patents. Elan has, however, reserved rights to use this know-how and these patent rights in the Territory for the sole purpose of work on the Neuralab Projects and, following expiration of the development agreement to make, have made and use Alzheimer's disease therapeutic products for sale outside the Territory.

Elan granted to Neuralab a non-exclusive, royalty-free license in the Territory to make, have made, use and sell all know-how and patent rights existing on January 14, 1998 owned or licensed from third parties by Elan, which Elan has the right to sublicense and, subject to the terms and conditions of any relevant license, for the purpose of furthering the development of the Neuralab Projects. However, to the extent Elan has the right to receive revenue from persons other than Neuralab under non-exclusive licenses to these existing patent rights, Elan, not Neuralab, will receive that revenue. In addition, any additional know-how or patent rights relating to the Neuralab Projects with respect to which, during the term of the development agreement, Elan obtains licensing rights in the Territory, will be offered to Neuralab on the same terms and conditions. Elan's and Neuralab's respective research and funding commitments under the development agreement will terminate upon the payment to Elan of Neuralab's funds.

Under the services agreement between Elan and Neuralab, Elan provides management and administrative services to Neuralab for a quarterly fee of \$100,000. The services agreement terminates one year after the termination of the purchase option described below. Neuralab may terminate the services agreement at any time upon 60 days' notice to Elan.

Elan has a purchase option for Neuralab. This purchase option was established at the time of Neuralab's private placement in 1998 and represents the outcome of a negotiation between Elan and lead investors. Elan believes that the purchase option price represents fair value as it was determined by a negotiation between independent parties. The purchase option is an exclusive, irrevocable option to purchase all, but not less than all, of the issued and outstanding Neuralab common shares. The purchase option became exercisable on January 14, 1998 and will be exercisable at any time until the earlier of (i) December 31, 2001 or (ii) the 90th day after the date Neuralab provides Elan with quarterly financial statements of Neuralab showing cash or cash

equivalents of less than \$2.0 million; provided, however, that if, before such 90th day, Elan provides written confirmation to Neuralab that Elan will use commercially reasonable efforts, at no expense to Neuralab (beyond substantially all of the net proceeds of the Neuralab unit offering and any other revenues received and interest thereon, less working capital to be retained by Neuralab of \$0.5 million), to continue to develop the Neuralab Projects, the purchase option shall continue in effect through such date for so long as Elan continues to use commercially reasonable efforts, but in no case beyond December 31, 2001.

The purchase option exercise price per share is as follows:

	<u>Purchase Option Exercise Price</u>
Before February 1, 2000	\$61.01
On or after February 1, 2000 and on or before December 31, 2000	\$75.35
On or after January 1, 2001 and on or before December 31, 2001	\$93.05

The purchase option exercise price may be paid in cash, fully registered Elan ADSs or in any combination of the foregoing, at Elan's sole discretion. The Elan ADSs will be valued based upon the average of the closing prices for Elan ADSs on the New York Stock Exchange ("NYSE") for the twenty trading days immediately preceding the date of notice from Neuralab of cash or cash equivalents of less than \$2.0 million. Elan will retain the right, however, to use cash in lieu of Elan ADSs in the event the 20-day average trading price of Elan ADSs is less than the closing price of Elan ADSs on the trading day immediately prior to that notice. In the event the 12,000 special shares of Neuralab owned by Elan are transferred to a party other than Elan or its affiliates, the purchase option exercise price may be paid only in cash.

Further information regarding Neuralab is provided in Note 18 of the Consolidated Financial Statements.

Axogen: In November 1996, Elan concluded a development and license agreement and a services agreement with Axogen to develop therapeutic products for the treatment of neurological disorders. Also in November 1996, a public offering of 5,290,000 units was completed by Axogen. Each unit was comprised of one common share of Axogen and one warrant to purchase two Elan ADSs. The net proceeds to Axogen of the offering amounted to approximately \$89.0 million. On December 31, 1998 the units separated into the two underlying securities. The warrants are exercisable at \$37.54 for two Elan ADSs until December 31, 2001. The proceeds of the offering and the additional contribution are being used primarily to make payments, to Elan under the development contract.

Pursuant to the development and license agreement and subject to the Elan Option (as defined below), Elan granted to Axogen an option to acquire an exclusive license to sell and otherwise market and sublicense to market in the US certain products (the "Axogen Products"), on a product-by-product basis, and in the case of any Axogen Product for which Elan has manufacturing rights, a license to manufacture or obtain manufacturing for an Axogen Product (the "License Option"). Elan is the owner or existing licensee, as the case may be, of the Axogen Products. Product rights are often transferred by license in the pharmaceutical industry. In the event that Axogen exercises the License Option, Elan retains its respective ownership of, or license to, the Axogen Product. However, Axogen acquires certain economic interests by virtue of its licenses to the Axogen Product discussed below. The License Option will be exercisable by Axogen with respect to any Axogen Product within 90 days after the time that such Axogen Product is approved for marketing in the US by the FDA. If the License Option is exercised as to any Axogen Product, Axogen will acquire an exclusive license with respect to the rights described above for the License Period (as defined below) and a non-exclusive, royalty-free license thereafter. The License Option is not terminable by either Elan or Axogen. Certain of the Axogen Products are subject to supply arrangements with third parties other than Elan which will be assigned or licensed to Axogen to the extent necessary for Axogen to commercialize the licensed product in connection with the exercise of the License Option. Elan will have the right to terminate a license in the event that Axogen does not market such Axogen Products within nine months from the date of marketing approval by the FDA.

During the License Period, Axogen will make the following payments to Elan in the event of the exercise of the License Option with respect to each relevant Axogen Product:

(a) if the Axogen Product is sold by Axogen, base royalties in an amount equal to 60% of the net sales (such percentage of net sales being the “Net Profits”) of the relevant Axogen Product received by Axogen, multiplied by a fraction the numerator of which is the aggregate development costs and expenses incurred by Elan (including expenses incurred by Athena prior to the acquisition of Athena by Elan in July 1996) prior to October 31, 1996 in connection with the development of the relevant Axogen Product and the denominator of which is the sum of (x) the amount representing the aggregate development costs and expenses incurred by Elan (including expenses incurred by Athena) prior to October 31, 1996 in connection with the development of the relevant Axogen Product plus (y) the aggregate amount of Development Costs in connection with the development of the relevant Axogen Product incurred pursuant to the development and license agreement and any expenses incurred by Axogen in connection with the development of the relevant Axogen Product, other than pursuant to the Development Contract (such fraction, the “Fee Formula”); and

(b) an amount equal to any sublicensing fees or income received by Axogen pursuant to any licensing arrangement entered into by Axogen relating to the relevant Axogen Product and any “front-end” fees, prepaid royalties or similar one-time, infrequent, not in the ordinary course or special payments received by Axogen in respect of any such sublicensing arrangement (collectively, “Ancillary Fees”) multiplied by the Fee Formula.

During the License Period, Elan will make the following payments to Axogen in the event of the exercise of the License Option with respect to each relevant Axogen Product: (a) if the Axogen Product is sold by Elan or an Elan affiliate in any country of the world other than the US, 4% of the net sales in respect of sales of any relevant Axogen Product, as received by Elan or its affiliate and (b) 30% of Ancillary Fees received by Elan or an Elan affiliate in respect of any country of the world other than the US.

Elan will have the right to reject Axogen’s exercise of the License Option within 60 days of Axogen providing notice of its exercise thereof (the “Elan Option”) upon payment by Elan, at the option of Axogen, of either (a) a one-time cash fee of \$25.0 million or (b) base royalties of 10% of the net sales of the relevant Axogen Product during the License Period; provided, however, the Elan Option may only be exercised as to one Axogen Product. The determination of the one-time fee of \$25.0 million for Elan’s rejection of Axogen’s exercise of the license option was considered in 1996, in negotiations with the lead investor groups, to be a reasonable approximation of what fair value would potentially be at the date such option would be exercised.

Elan has agreed to use diligent efforts to conduct clinical development, final development, including US regulatory approval, and commercialization of the Axogen Products. Axogen is paying, and will pay, to Elan substantially all of the net proceeds of the Axogen offering, interest earned thereon and, if designated by Axogen, any licensing or marketing income earned by Axogen or cash payments received in connection with the Elan Option, less working capital to be retained by Axogen of \$1.0 million.

Development Costs consist of (i) direct research expenses (including direct research salaries, benefits and supplies), which are billed at a rate of cost plus 60% of costs; provided, however, that services provided by third parties will be billed at a rate of cost plus 15% of costs; (ii) indirect research costs (including general research management and support services) at a fixed rate of direct research salary expenses plus 10%; (iii) general and overhead expenses billed at a fixed rate of direct research salary expenses less 20%; and (iv) reimbursement of out-of-pocket costs incurred by Elan including the cost of research materials and external consulting services. The premium or discount applied to direct research salary expenses is intended to cover costs incurred by Elan which are not separately identified by its cost recording systems and include the depreciation of physical assets, amortization of intangible assets, direct and supervisory labor costs, insurance and a contribution to its general and administrative costs.

Under the services agreement, Elan will provide management and administrative services to Axogen for a quarterly fee of \$100,000. The services agreement terminates one year after the termination of the Purchase Option. Axogen may terminate the services agreement upon 60 days' notice to Elan.

Elan has an option, exercisable at Elan's sole discretion, to purchase, according to a pre-determined formula, all (but not less than all) of the outstanding common shares of Axogen. The purchase option became exercisable on November 19, 1996 and will be exercisable at any time until the earlier of (i) December 31, 2001 or (ii) the 90th day after the date Axogen provides Elan with quarterly financial statements of Axogen showing cash or cash equivalents of less than \$4.0 million. If the purchase option is exercised, the purchase price calculated on a per share basis will be as follows:

	Purchase Option Exercise Price
Before January 1, 2000	\$34.56
On or after January 1, 2000 and on or before December 31, 2000	\$45.04
On or after January 1, 2001 and on or before December 31, 2001	\$61.04

The purchase option exercise price may be paid in cash, in Elan ADSs or Ordinary Shares or in any combination thereof at Elan's sole discretion. The purchase option price was established at the time of Axogen's initial public offering and represents the outcome of a negotiation between Elan and the lead investors. Elan believes that the purchase option price represents fair value as it was determined by a negotiation between independent parties.

On December 18, 1998, Elan made a contribution of \$67.5 million to Axogen. This contribution was expensed by Elan for the year ended December 31, 1998. Further information regarding Axogen is provided in Note 18 of the Consolidated Financial Statements.

Strategic Collaborations: Elan's objective is to be the pharmaceutical industry partner of choice for the development of drug delivery products and technologies. Elan's strategy has been to significantly expand its drug delivery technology, product and client base. Its targeted client base includes established and emerging pharmaceutical and biotechnology companies.

Elan has entered into license agreements with certain emerging pharmaceutical and biotechnology companies to enable it to maximize the utilization of its technologies and product base. This activity has involved licensing technologies or products to these strategic licensees and contemporaneously making an investment in these companies, usually in the form of equity and convertible debt. Investments in strategic licensees, including their majority owners, are made at fair value. Elan cannot pursue all available opportunities itself, given the resource requirements of the number of products that Elan has in late-stage development. This strategic licensing program enables Elan to realize the value previously created through its research and development activities.

The strategic licensing program has significantly expanded Elan's business relationships with emerging pharmaceutical and biotechnology companies. For example, Elan has strategic collaborations covering new technology platforms for the delivery of vaccines, anti-sense compounds and genes. Elan believes these strategic collaborators are well positioned to leverage the technology or product licensed from Elan given the technical expertise and focus of the licensee in a particular field.

The research and development cycle in the pharmaceutical industry can take approximately 10 years from project commencement to product approval. The length of the development cycle means that product approvals arising from the strategic licensing program have not yet occurred. Elan's strategic licensing program currently has eight products in clinical development of which one is in Phase III, three are in Phase II and four are in Phase I. Expected completion dates are between 2001 and 2004. The most advanced product is a once-daily oral formulation of morphine that is in Phase III clinical trials. This product is licensed to Ligand. Six additional products are currently in pre-clinical development.

Elan's strategic collaborators are responsible for research and development on the licensed technologies or products. However, under many of the agreements, the strategic collaborator may request that Elan conduct research and development on its behalf. This work is charged to the strategic collaborator at pre-determined rates, which are set to recover Elan's costs for such work plus a mark-up of up to 45%. In the late stage development programs, Elan is supervising the clinical trials for one of the products under development. In the remaining late-stage programs, clinical development is being undertaken by the strategic collaborators. In the pre-clinical and Phase I programs, Elan is generally providing research and development services to the strategic collaborators.

Elan believes that its strategic licensing program's products and technologies are satisfactorily progressing through the research and development process. However, due to the risks and uncertainties inherent in the research and development process, no assurance can be given that any of the products under development in the strategic licensing program will receive marketing approval. In addition, due to these risks and uncertainties, it is not possible to estimate what impact one or more of these products may have on Elan's future results of operations.

Elan monitors the financial position of its strategic collaborators and the funding required for the programs through its participation on the boards of directors of the strategic licensees and memberships of any related development committees. To date, there have been no circumstances in which the strategic licensing programs have been impeded by a lack of funding. Elan believes that its strategic collaborators will have adequate funding to perform expected research and development activities under the programs through the remainder of 1999. The future funding requirement for the programs is expected to increase as more products enter or progress through clinical trials. The actual amount and timing of this additional funding, which will ultimately be required, is uncertain and will depend upon, among other factors, the speed of progress of the programs and the design and associated cost of the research and development activity for each program. There are risks and uncertainties inherent in the research and development process and this impacts on the speed, design and associated cost of research and development activities. However, Elan expects that additional funding will be required by the majority of its strategic collaborators during 2000.

Strategic collaborators can fund research and development activities in a variety of manners. They can utilize their existing cash resources, which may have arisen in part from Elan's initial investment, procure additional financing from public and private capital markets in the US and elsewhere or Elan may provide subsequent funding in conjunction with the strategic collaborators, subject to Elan's consent. Elan invested \$7.7 million in strategic collaborators during 1998, which was used to fund research and development.

Elan received license fees in the amount of \$114.5 million and \$55.0 million in 1998 and 1997, respectively, from such strategic collaborators. Elan received research revenues in the amount of \$6.2 million and \$5.1 million in 1998 and 1997, respectively, from these companies. Elan invested \$198.5 million and \$67.5 million in 1998 and 1997, respectively, in these strategic collaborators.

The following are the principal strategic collaborations established in 1998 and the principal additional investments in pre-existing collaborations during 1998, including the amounts invested by Elan, the product or technology licensed and the license fees received by Elan:

Company	Amount Invested	Product/Technology	License Fee Received
Multiple Peptide Systems, Inc.(1) MPS Newco Ltd.	\$17.0 million \$3.0 million	Licensed technology relating to delivery of protein and peptide therapeutics	\$15.0 million
Ligand(2)	\$65.0 million	Licensed US and Canadian Morphelan rights	\$15.0 million
Iomai Corporation(3) Xairo Corporation	\$8.5 million \$2.0 million	Licensed technology relating to transdermal delivery of vaccines	\$10.0 million
Endorex Corporation(4) Endorex Newco Ltd.	\$8.4 million \$2.1 million	Licensed Medipad technology for delivery of certain compounds	\$10.0 million
Electropharmacology, Inc.(5)	\$8.1 million	Licensed iontophoretic technology for local delivery of drugs	\$7.5 million
Sheffield Pharmaceuticals, Inc.(6)	\$18.5 million	Licensed technology relating to pulmonary delivery of drugs	\$12.5 million
Delsys Pharmaceutical Corporation(7) Tackson Ltd.	\$12.0 million \$6.0 million	Licensed certain oral drug delivery technology	\$15.0 million
RTP Pharma, Inc.(8) Cyclosporine Therapeutics Ltd.	\$19.6 million \$1.3 million	Licensed technology relating to delivery of certain compounds	\$12.5 million
Acorda Therapeutics, Inc.(9) MS Research & Development Corporation	\$12.0 million \$3.0 million	Licensed rights to fampridine for treatment of multiple sclerosis	\$15.0 million
Emisphere Technologies, Inc.(10) Ebbisham Limited	\$4.1 million \$5.0 million	Joint venture with Emisphere Technologies, Inc. to develop oral formulations of heparin	N/A

- (1) Multiple Peptide Systems, Inc. specializes in the custom synthesis of peptides and the development of compounds using combinatorial libraries.
- (2) Ligand discovers, develops and markets new drugs in several areas including cancer, skin diseases, hormone-related diseases, osteoporosis, metabolic disorders and cardiovascular and inflammatory diseases.
- (3) Iomai Corporation is developing a number of proprietary delivery technologies for the transdermal delivery of vaccines.
- (4) Endorex Corporation is a drug delivery and cancer products company.
- (5) Electropharmacology, Inc. is a biotechnology company which is developing drug delivery and drug design technologies.
- (6) Sheffield Pharmaceuticals, Inc., is developing a number of pulmonary delivery technologies over a range of therapeutic areas.
- (7) Delsys Pharmaceutical Corporation is developing a novel manufacturing technology, and has established collaborations with several companies, including Warner-Lambert Company, SmithKline Beecham, plc, and Glaxo Wellcome, plc.
- (8) RTP Pharma, Inc. develops novel formulations of drugs that are insoluble or poorly water-soluble.
- (9) Acorda Therapeutics, Inc. specializes in the development of drugs for the treatment of central nervous system diseases. The terms of the original agreement provided for Elan to appoint a director to the board of MS Research and Development Corporation and members to a joint management committee. These terms were revised and such appointments were not made. The impact of this revision is that Elan accounts for MS Research and Development Corporation using the cost method.
- (10) Emisphere Technologies, Inc. is developing drug delivery systems for the oral delivery of macromolecules and other compounds. Elan previously invested \$4.5 million in Ebbisham Limited and \$9.2 million in Emisphere Technologies, Inc.

The following are the principal strategic collaborations established in 1997, including the amount invested by Elan, the product or technology licensed and the license fees received by Elan.

Company	Amount Invested	Product/Technology	License Fee Received
Endorex Corporation(1) Innovax Corporation	\$10.0 million \$2.0 million	Licensed technology relating to oral and mucosal delivery of vaccines	\$10.0 million
Bioject Medical Technologies, Inc.(2) Marathon Medical Technologies, Inc.	\$15.0 million \$3.0 million	Licensed technology relating to an ambulatory glucose monitoring system	\$15.0 million
RTP Pharma Inc.(3)	\$12.5 million	Licensed technology relating to cyclosporine	\$7.5 million
Cytogen Corporation(4) Targon Corporation	\$10.0 million	Licensed rights to a once-daily morphine product.	\$7.5 million
IOMED, Inc.(5)	\$15.0 million	Licensed iontophoretic technology for systemic delivery of drugs	\$15.0 million

- (1) Endorex Corporation is a drug delivery and cancer products company.
- (2) Bioject Medical Technologies, Inc. develops, manufactures and markets jet injection systems for needle-free injections.
- (3) RTP Pharma, Inc. develops novel formulations of drugs that are insoluble or poorly water-soluble.
- (4) Cytogen Corporation develops and commercializes diagnostic and therapeutic products for cancer and urological diseases. Elan acquired Targon Corporation in 1998.
- (5) IOMED, Inc. develops and manufactures iontophoretic drug delivery systems.

Ligand Pharmaceuticals Incorporated: In September 1998, Elan and Ligand entered into a strategic collaboration. Ligand discovers, develops and markets new drugs in the areas of cancer, skin diseases, hormone-related diseases, osteoporosis, metabolic disorders and cardiovascular and inflammatory diseases. Elan agreed to:

- purchase \$20.0 million of Ligand common stock;
- purchase up to \$110.0 million in issue price of Ligand's zero coupon convertible senior notes due 2008, which are convertible into Ligand common stock; and
- enter into a license agreement providing for a license to Ligand in the US and Canada of Elan's proprietary product Morphelan for the oncology and HIV markets. Morphelan, a once-daily solid oral dosage form of morphine, is currently in Phase III clinical trials.

In 1998, the Company completed its purchase of Ligand's common stock and purchased \$30.0 million in issue price of Ligand's zero coupon convertible senior notes due 2008. The license agreement provides that, under certain circumstances, Ligand may co-promote Morphelan in Europe and Elan may co-promote Morphelan in the US. In connection with the license agreement, Ligand paid to Elan a non-refundable license fee of \$15.0 million, which Elan recognized as revenue in 1998, in the form of additional shares of Ligand common stock of \$5.0 million and additional zero coupon convertible senior notes due 2008 of \$10.0 million. In addition, Ligand will make future milestone payments to Elan upon filing of an NDA with the FDA and upon FDA approval of Morphelan for marketing in the US.

Elan has a remaining commitment to purchase additional zero coupon convertible senior notes due 2008 of Ligand with an aggregate issue price of up to \$70.0 million on or before December 31, 1999.

Manufacturing

Elan's facility in Athlone, Ireland is the primary location for the manufacture of oral controlled-release dosage technology and microparticulate oral drug delivery technology. Elan's facility in Gainesville, Georgia also provides oral controlled-release dosage technology manufacturing capability and is registered with the US Drug Enforcement Administration for the manufacture, packaging and distribution of Schedule II controlled drugs. Elan's facility in Mezzovico, Switzerland is the primary location for the development and manufacture of Elan's effervescent and fast melt oral dosage technology. Elan's facility in Miramar, Florida is the primary location for the manufacture of transdermal dosage technology.

Elan generally retains manufacturing rights to the drug delivery products it develops. Elan manufactures for certain client companies some or all of their product requirements, including Cardizem CD and Cardizem SR for HMR, Verelan and Verelan PM for Schwarz and a range of products for licensees, distributors and joint venture partners throughout the world. Elan currently utilizes outside manufacturers for certain of its EP products, and in the near-term, Elan expects to continue to rely on outside manufacturers to produce such products. The Company believes that there is currently substantial capacity worldwide for the production of its current and proposed products and that it will be able to establish manufacturing arrangements on acceptable terms. Elan's long-term plan is to establish certain internal manufacturing-related capabilities for its EP products, including the ability to formulate, fill, label, package and distribute such products in order to meet its clinical trial and commercial manufacturing needs.

All facilities and manufacturing techniques used for the manufacture of products and devices for clinical use or for sale in the US must be operated in conformity with current Good Manufacturing Practices ("cGMP") regulations, the FDA regulations governing the production of pharmaceutical products. In 1998 and early 1999, the FDA conducted pre-approval inspections and noted no adverse inspection observations for certain products to be manufactured in each of Elan's strategic facilities (Athlone, Ireland; Gainesville, Georgia; and Miramar, Florida), evidencing cGMP compliance at these facilities. Elan's facilities are also subject to periodic regulatory inspections to ensure ongoing compliance with cGMP regulations. Elan believes that it is in substantial compliance with cGMP regulations. Any future determination by the FDA that Elan is not in substantial compliance with such regulations could have a material adverse effect on Elan.

There can be no assurance that Elan will be able to continue to obtain adequate supplies of products in a timely manner, at acceptable quality levels and at acceptable prices. In addition, there can be no assurance that Elan will continue to be able to enter into arrangements with manufacturers whose facilities and procedures comply with cGMP regulations and other regulatory requirements, that Elan's manufacturers will continue to comply with such regulations and requirements or that such manufacturers will be able to satisfactorily supply Elan with its product needs. Elan's dependence on third parties for the manufacture of its marketed products may adversely affect Elan's business, financial condition and results of operations, and Elan's ability to develop and deliver new products on a timely and competitive basis.

Government Regulation

The design, development, testing, manufacturing and marketing of pharmaceutical products and devices are regulated by governmental authorities, including the FDA and comparable regulatory authorities in other countries. For example, the Federal Food, Drug and Cosmetic Act (the "FDCA"), the Controlled Substances Act and other US Federal statutes and regulations impose requirements on the testing, safety, effectiveness, manufacturing, labeling, storage, record-keeping, advertising, marketing and approval of Elan's products in the US. Non-compliance with applicable requirements can result in fines and other judicially imposed sanctions, including the initiation of product seizures, import restrictions, injunctive actions and criminal prosecutions based on products or manufacturing practices that violate statutory requirements. In addition, administrative remedies can involve requests to recall violative products, the refusal of government to enter into supply contracts and/or refusal to approve pending license applications (e.g., NDAs, ANDAs, biologic product license, Product License Applications ("PLA")) and Establishment License Applications ("ELA") for biological

products or other pre-market approval applications (“PMAs”) and “510(k)s” for medical devices) until manufacturing or other alleged deficiencies are brought into compliance. The FDA also has the authority to withdraw approval of licenses in accordance with statutory due process procedures.

The activities required before a pharmaceutical agent may be marketed in the US begin with preclinical testing. Preclinical tests include laboratory evaluation of product chemistry and animal studies to assess the potential safety and efficacy of the product candidate. The results of these studies must be submitted to the FDA as part of an investigational new drug (“IND”) application, which must be reviewed and approved by the FDA before proposed human clinical testing can begin. Typically, clinical testing generally involves a three-phase process. In Phase I, clinical studies are conducted with a small number of subjects to test the early safety profile and the pattern of drug distribution and metabolism. In Phase II, clinical studies are conducted with groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In Phase III, larger scale, often multicenter, well-controlled clinical studies are conducted in patients with a target disease in order to provide enough data for the statistical proof of efficacy and safety required by the FDA. The successful outcome of these studies cannot be assured, as evidenced by the inconclusive Phase III results obtained with the transdermal formulations of buspirone and Nic/Mec. The results of the preclinical and clinical testing, along with the information regarding the manufacturing of the product (See Item 1- Manufacturing) and proposed product labeling, are then submitted to the FDA through a license application for approval to commence commercial sales. In responding to such applications, the FDA may grant marketing approval, approve the product for a narrower indication, impose labeling restrictions, request additional information, require post-approval (Phase IV) studies, or deny the application if it determines that the application does not satisfy its regulatory approval criteria. There can be no assurance that approvals for any of Elan’s products will be granted on a timely basis, if at all.

In certain cases, an ANDA may be filed in lieu of filing an NDA. An ANDA relies on bioequivalency tests which compare the applicant’s drug with an already approved reference drug, rather than on clinical studies. An ANDA might be available to Elan for a new formulation of a drug, such as its nifedipine extended-release tablets, for which bioequivalent sustained-release forms have already been approved by the FDA. As the majority of Elan’s drug development has been carried out on drugs which do not have such forms approved by the FDA, Elan expects that most of its new drug formulations will require NDA filings. There can be no marketing in the US of any drug or biologic for which a license application is required until such application has been approved by the FDA. Until an application is actually approved, there can be no assurance that the information requested and submitted will be considered adequate by the FDA to justify approval. Additionally, any significant change in the approved product or in how it is manufactured, including changes in formulation or the site of manufacturing, require prior FDA approval in the form of an approved supplement. The packaging and labeling of all Elan-developed products are also subject to FDA approval and ongoing regulation. It is impossible to anticipate the amount of time that will be required to obtain approval from the FDA to market any product.

An FDA approval of an NDA for a new chemical entity or new dosage form/delivery system which was based, at least in part, upon the required submission of new clinical (human) data (such as Zanaflex and Diastat) is entitled to non-patent regulatory exclusivity against another person obtaining effective approval of an ANDA pending the expiration of the applicable exclusivity period (generally five years for a new chemical entity and three years for other approvals based upon submission of new clinical data). This regulatory exclusivity does not operate to preclude the effective approval of a full NDA during the exclusivity period or apply to most biological products.

Whether or not FDA approval has been obtained, approval of a pharmaceutical product by comparable regulatory authorities must be obtained in any foreign country prior to the marketing of the product in that country. The approval procedure varies from country to country and can involve additional testing, and the time required may differ from that required for FDA approval. Although there are some procedures for unified filings for certain European countries, in general, each country has its own procedures and requirements, many

of which are time consuming and expensive. Thus, there can be substantial delays in obtaining required approvals from both the FDA and foreign regulatory authorities after the relevant applications are filed. After such approvals are obtained, further delays may be encountered before the products become commercially available and the products are potentially subject to a withdrawal proceeding if new evidence raises significant questions of safety or effectiveness. If, subsequent to approval, new information becomes available concerning the safety of any of Elan's approved products, this could result in the need to revise the labeling for the affected product or in the withdrawal of the approval of that product.

From time to time, the FDA and other federal, state and foreign governmental agencies may adopt guidelines or regulations that affect the manufacturing and marketing of products by Elan, including special regulations that may apply to any products utilizing biotechnology compounds. It is not possible to predict the impact that any such regulations, if adopted, might have on Elan or its operations.

The approval process for products is generally lengthy, expensive and subject to unanticipated delays. Currently, Elan is actively pursuing marketing approval for a number of its products from regulatory authorities, including the FDA. Continued growth in Elan's revenues and income will depend, in part, on the successful introduction and marketing of some or all of such products. There can be no assurance as to when or whether such approvals from regulatory authorities will be received.

Certain *in vitro* diagnostic products and certain delivery systems (for example, Medipad) are regulated or potentially regulated under the FDCA as medical devices. As medical devices, these products would be subject to premarketing and postmarketing requirements applicable to devices, including those governing (i) clinical testing, (ii) prior FDA approval in the form of (a) an FDA determination through the 510(k) process of substantial equivalence to a marketed device or (b) an approved PMA, (iii) postmarketing record and reporting obligations and (iv) cGMP regulations. The failure to adhere to these requirements can result in a refusal of permission to market, a withdrawal of permission to market and the imposition of sanctions, including seizure, recall notification, injunction, and civil and criminal penalties. Additionally, as a condition to marketing or continued marketing, the FDA may impose certain postmarket surveillance and/or tracking requirements which may significantly increase the regulatory costs associated with a product. There can be no assurance that a given medical device will obtain the necessary approvals or that any approval will be obtained within a specified time framework. Under the FDCA, it is also possible for a given product to be regulated both as a drug and a medical device or as a biologic and medical device.

Patents and Patent Applications

Elan's competitive position and results of operations will depend, in part, on its ability to obtain patents in various jurisdictions on its current and future technologies and products, to defend its patents and protect its trade secrets and to operate without infringing on the proprietary rights of others. In addition, under a number of license agreements for its drug delivery products to which Elan is a party, the failure to obtain patents on the products which are the subject of such license agreements will reduce the royalty rate to which Elan is entitled. Finally, Elan's tax position is based, in large part, upon Irish tax law which disregards income arising from qualifying patents from corporation tax in certain circumstances.

Elan has filed numerous product patent applications in several countries. Patents have been issued, or applied for, covering most of Elan's advanced products and technologies including those that are under development with third parties. There can be no assurance, however, that Elan's existing patent applications will mature into patents or, if issued, that they will be enforceable. Although a patent has a statutory presumption of validity in the US, the issuance of a patent is not conclusive as to such validity or as to the enforceable scope of the claims of the patent. There can be no assurance that (i) any additional patents will be issued in any or all appropriate jurisdictions in the future, (ii) Elan's patents will not be successfully challenged, (iii) Elan's technologies or products will not infringe upon the patents of third parties or (iv) the scope and validity of Elan's patents will prevent third parties from developing similar technologies or products.

Naprelan accounted for 8% of Elan's total revenues for the year ended December 31, 1998. It has patent protection until 2014 (delivery system). In October 1998, Elan filed suit against Andrx for patent infringement of Elan's patent covering its Naprelan formulation. The lawsuit is in the discovery stages of litigation. Andrx has also filed counterclaims alleging non-infringement, patent invalidity and misuse. Should Andrx prevail in the proceeding, Elan expects that its revenues from Naprelan will decline.

It is also possible that third parties will obtain patents or other proprietary rights that might be necessary or useful to Elan. In cases where third parties are first to invent a particular product or technology, it is possible that those parties will obtain patents that will be sufficiently broad so as to prevent Elan from using such technology or from marketing such products. If such third parties assert that our products or technologies allegedly infringe their intellectual property rights, we may be required to obtain licenses from such third parties and there can be no assurances that Elan would be able to obtain such licenses on commercially reasonable terms, if at all, or that any licensed patents or intellectual property will be valid or enforceable. In addition, the scope of intellectual property protection is subject to scrutiny and change by courts and other governmental bodies. Litigation and other proceedings concerning patents and proprietary technologies can be protracted, expensive and distracting to management. Any litigation, including any interference proceeding to determine priority of inventions and oppositions to patents, may be costly and time-consuming and could have a material adverse effect on Elan's business, financial condition and results of operations. In addition, if Elan relies on unpatented proprietary technology, there can be no assurance that others will not independently develop or obtain similar products or technologies.

Competition and Markets

The pharmaceutical industry is characterized by intense competition and rapid technological change. In recent years a large number of pharmaceutical companies have become increasingly interested in the development and commercialization of products incorporating advanced or novel drug delivery systems and in the research, development and marketing of therapeutic products in Elan's chosen markets of neurology, pain management and acute care. Elan's products could be rendered obsolete or made uneconomical by (i) the development of new pharmaceuticals to treat the diseases or conditions treated by Elan's products and (ii) technological advances affecting the cost of production or marketing or pricing actions by one or more of Elan's competitors. There can be no assurance that such competition will not have a material adverse impact on Elan's business, financial condition and results of operations. Elan believes that competition among branded prescription pharmaceuticals, including those incorporating drug delivery systems, and generics will be based on, among other things, the degree of patent protection, product efficacy, safety, reliability, availability, convenience and price.

Naprelan and Permax may encounter competition from generic products in the near- to medium-term. Generic competitor products to Verelan were launched in May 1999. A generic competitor product to Cardizem CD was recently launched. Generic competition generally results in significant declines in a product's revenue, market share and profitability. There can be no assurance that generic competition will not have a material adverse impact on Elan's business, financial conditions and results of operations.

Elan's current and future products face competition from both traditional forms of drug delivery systems, as well as more advanced drug delivery systems developed by others. In addition, in certain cases, Elan's products face direct competition from products manufactured and marketed by major multinational pharmaceutical companies, some of which may potentially include certain of Elan's current clients. A number of patents having claims which may be competitive with products in development or marketed, or processes used by Elan, have been issued to other companies or institutions. In addition, competitors have filed patent applications, may have been issued patents or may obtain additional patents and proprietary rights relating to products or processes competitive with one or more of the products or technologies being developed by Elan. Many of these other pharmaceutical concerns have far greater financial resources, technical staffs and manufacturing and marketing capabilities than Elan.

Elan's ability to earn sufficient returns on its products may depend, in part, on the availability of reimbursement from third party payors, such as government health administration authorities, private health insurers and other organizations such as health maintenance organizations ("HMOs"). Third party payors are increasingly challenging the price and cost-effectiveness of medical products and services. There can be no assurance that adequate third party reimbursement will be available to enable Elan to achieve or maintain price levels sufficient to realize an appropriate return on its investment in product development.

In addition, global efforts to contain health care costs, particularly among managed care organizations, continue to exert downward pressure on product pricing. Furthermore, a number of regulatory and legislative proposals aimed at changing the health care industry in the US and other countries have been proposed. There can be no assurance that private sector reform or government health care reform measures, if adopted, will not have a material adverse effect on Elan's business, financial condition and results of operations.

Certain of Elan's revenues are derived from sales of EPT products which generally have been marketed through agreements with third parties, by way of license agreements or otherwise. There can be no assurance that such third party arrangements can continue to be successfully negotiated or that any such arrangements will be on commercially reasonable terms. Even if acceptable and timely arrangements are available, there can be no assurance that products developed by Elan will be accepted in the marketplace or that, if initially accepted, sales of such products will not thereafter decline. Additionally, since Elan's clients or marketing partners for its drug delivery systems in many cases make material marketing and other commercialization decisions, a significant number of the variables that may affect Elan's revenues and net income are not exclusively within its control.

Employees

On May 28, 1999, Elan had 2,678 employees, of whom 769 were engaged in research and development activities, 724 were engaged in manufacturing activities, 688 were engaged in sales and marketing activities and the remainder worked in general and administrative areas.

Item 2. Description of Properties.

The following table lists the location, use, size and ownership interest for Elan's principal properties:

Location	Use	Size	Ownership
Dublin, Ireland	Corporate administration	19,100 Sq. Ft.	Leased
Athlone, Ireland	Research and development, manufacturing, sales and administration	255,500 Sq. Ft.	Owned
South San Francisco, California, USA	Research and development, sales and administration	222,500 Sq. Ft.	Leased
Worcester, Massachusetts, USA	Diagnostic testing, sales and administration	20,000 Sq. Ft.	Leased
Smithfield, Rhode Island, USA	Manufacturing, sales and administration	29,000 Sq. Ft.	Leased
Yavne, Israel	Research and development	22,600 Sq. Ft.	Leased
Letchworth, Hertfordshire, UK	Sales and administration	18,000 Sq. Ft.	Leased
Gainesville, Georgia, USA	Manufacturing and administration	55,000 Sq. Ft. and 150 acres (40% zoned for commercial use)	Owned
Miramar, Florida, USA	Research and development, manufacturing and administration	120,000 Sq. Ft.	Leased
Mezzovico, Switzerland	Manufacturing, sales and administration	36,500 Sq. Ft.	Owned
Cedar Knolls, New Jersey, USA	Sales and administration	127,500 Sq. Ft.	Owned
King of Prussia, Pennsylvania, USA	Research and development	49,000 Sq. Ft.	Leased

Elan believes that its facilities and equipment, together with planned additions, are sufficient to meet current requirements and future growth in its activities.

Item 3. Legal Proceedings.

In October 1998, Elan filed suit against Andrx for patent infringement of Elan's patent covering its Naprelan formulation. The lawsuit is in the discovery states of litigation. Andrx has filed counterclaims alleging non-infringement, patent invalidity and misuse.

AHP's and Elan's patent infringement lawsuit against Mylan Pharmaceuticals, Inc. ("Mylan"), and Mylan's counterclaims against AHP and Elan, were each dismissed without prejudice by the United States District Court for the Western District of Pennsylvania in September 1998, pursuant to a stipulated order of dismissal. In January 1999, AHP's and Elan's claims against Biovail Corporation International ("Biovail") were dismissed by the United States District Court for the District of Puerto Rico. AHP, Elan and Biovail filed a joint motion to dismiss Biovail's counterclaims, with each party to pay its own costs. Elan does not anticipate any further litigation with respect to this matter.

In May 1998, the motion filed by Novartis Pharmaceuticals Canada Inc. and Alza Corporation against Sano Corporation was discontinued by the Federal Court of Canada upon motion by all parties. Under the discontinuance, each party bore its own costs.

In December 1998, the Superior Court of California, County of San Mateo, sustained Neurex's demurrer to the shareholder class action suit against Neurex, with prejudice.

There are no other pending legal proceedings to which Elan is a party, or to which any of its property is subject.

Item 4. Control of Registrant.

- (a) Elan, to its knowledge, is not directly or indirectly owned or controlled by another corporation or by any government.
- (b) The following table sets forth certain information regarding the beneficial ownership of Elan's Ordinary Shares at May 31, 1999 by all directors and officers of Elan as a group (either directly or by virtue of ownership of Elan ADSs).

<u>Name of Owner or Identity of Group</u>	<u>No. of Shares</u>	<u>Percent of Class(1)</u>
All directors and officers as a group (18 persons) (2)	3,681,980	1.4%

- (1) Based on 266,530,322 Elan Ordinary Shares outstanding on May 31, 1999 and 1,776,012 Elan Ordinary Shares (including Elan ADSs) issuable upon the exercise of currently exercisable options held by directors and officers as a group as of May 31, 1999.
- (2) Includes 1,776,012 Elan Ordinary Shares (including Elan ADSs) issuable upon exercise of currently exercisable options held by directors and officers of Elan as a group as of May 31, 1999.

Elan did not, to its knowledge, have any person owning 10% or more of its Ordinary Shares (either directly or by virtue of ownership of Elan ADSs) at May 31, 1999.

The information above does not reflect the 1,000 Executive Shares and 21,375 'B' Executive Shares presently issued. Elan does not know of any arrangements, the operation of which, might result in a change of control of Elan.

Item 5. Nature of Trading Market.

Elan ADSs are traded on the NYSE, the principal trading market for Elan's securities, under the symbol "ELN". The following table sets forth the high and low per share sale prices on the NYSE Composite Tape as reported on published financial sources for the Elan ADSs for the periods indicated.

	<u>High</u>	<u>Low</u>
Calendar 1999:		
Quarter ended June 30, 1999 (through June 25, 1999)	38 ¹³ / ₃₂	24 ¹³ / ₁₆
Quarter ended March 31, 1999	43 ⁵ / ₈	33 ⁹ / ₃₂
Calendar 1998:		
Quarter ended December 31, 1998	35 ⁷ / ₈	29 ⁵ / ₈
Quarter ended September 30, 1998	37 ³¹ / ₃₂	28 ¹ / ₄
Quarter ended June 30, 1998	33 ²⁵ / ₃₂	29 ¹ / ₁₆
Quarter ended March 31, 1998	34 ¹ / ₂	24 ¹ / ₁₆
Calendar 1997:		
Quarter ended December 31, 1997	28 ⁷ / ₁₆	22 ³ / ₁₆
Quarter ended September 30, 1997	25 ¹⁹ / ₃₂	21 ³ / ₈
Quarter ended June 30, 1997	22 ¹¹ / ₁₆	15
Quarter ended March 31, 1997	19 ³ / ₈	16 ³ / ₈

Elan's Ordinary Shares are also traded in Dublin on the Official List of the Irish Stock Exchange and in London on the Official List of the London Stock Exchange. The volume of trading in Elan's Ordinary Shares on such markets is, however, very limited.

A total of 266,530,322 Ordinary Shares of Elan were issued and outstanding at May 31, 1999, of which twelve Ordinary Shares were held by holders of record in the US (excluding shares held in the form of American Depositary Receipts ("ADRs")). 261,346,466 Ordinary Shares were represented by Elan ADSs (each Elan ADS representing one Ordinary Share), evidenced by ADRs issued by The Bank of New York, as depositary, pursuant to a deposit agreement. At May 31, 1999, the number of holders of record of Ordinary Shares was 249, which includes one holder of record in the US, and the number of registered holders of ADRs was 3,073. Because certain of these Ordinary Shares and ADRs were held by brokers or other nominees, the number of holders of record or registered holders in the US and Ireland is not representative of the number of beneficial holders or of the residence of beneficial holders.

American depositary warrant shares ("ADWSs"), representing warrants to purchase Elan ADSs ("Warrants"), trade on the NYSE under the symbol "ELNWSA". The ADWSs are represented by American Depositary Warrant Receipts issued by The Bank of New York, as depositary, under a deposit agreement. Each Warrant is exercisable for two Elan ADSs at an exercise price of \$37.54. The following table sets forth the high and low sales prices per ADWS on the NYSE Composite Tape as reported in published financial sources for the periods indicated.

	<u>High</u>	<u>Low</u>
Calendar 1999:		
Quarter ended June 30, 1999 (through June 25, 1999)	46	27
Quarter ended March 31, 1999	56	38 ³ / ₄

A total of 5,288,080 ADWSs were issued and outstanding as of June 25, 1999 and were held by 31 holders of record as of that date. Because some ADWSs were held by brokers and other nominees, the number of holders of record or registered holders is not representative of the number of beneficial holders.

Item 6. Exchange Controls and Other Limitations Affecting Security Holders.

Irish exchange control regulations ceased to apply from and after December 31, 1992. Except as indicated below, there are no restrictions on non-residents of Ireland dealing in domestic securities, which includes shares

or depositary receipts of Irish companies such as Elan. Except as indicated below, dividends and redemption proceeds also continue to be freely transferable to non-resident holders of such securities. The Financial Transfers Act, 1992, gives power to the Minister for Finance of Ireland to make provision for the restriction of financial transfers between Ireland and other countries. Financial transfers are broadly defined and include all transfers which would be movements of capital or payments within the meaning of the treaties governing the member states of the European Union. The acquisition or disposal of American Depositary Receipts representing shares issued by an Irish incorporated company and associated payments falls within this definition. In addition, dividends or payments on redemption or purchase of shares and payments on a liquidation of an Irish incorporated company would fall within this definition.

Any transfer of, or payment in respect of, an American Depositary Share involving the government of any country which is currently the subject of United Nations sanctions, any person or body controlled by any of the foregoing, or by any person acting on behalf of the foregoing, may be subject to restrictions pursuant to such sanctions as implemented into Irish law.

Currently, there are orders in force by the Minister of Finance of Ireland under the Financial Transfers Act, 1992, including restrictions applicable to Angola, Yugoslavia, Serbia, Libya and Iraq.

In addition to the prohibitions on financial transfers referred to above, there are also a number of Ministerial Orders prohibiting the supply of certain products and services to a number of states. At present, these restrictions apply to Angola and Yugoslavia.

Elan does not anticipate that orders under the Financial Transfers Act, 1992, or United Nations sanctions implemented into Irish law will have a material effect on its business.

Item 7. *Taxation.*

The following is a general description of certain Irish tax consequences to US Holders (as defined below) of the purchase, ownership and disposition of Elan ADSs or Ordinary Shares. As used herein, references to the Elan Ordinary Shares include Elan ADSs representing such Elan Ordinary Shares, unless the tax treatment of the Elan ADSs and Ordinary Shares has been specifically differentiated. This description is for general information purposes only and does not purport to be a comprehensive description of all the Irish tax considerations that may be relevant in a US Holder's decision to purchase, hold or dispose of Elan Ordinary Shares. It is based on the various Irish Taxation Acts, all as in effect on the date hereof and all of which are subject to change (possibly on a retroactive basis). The Irish tax treatment of a US Holder of Elan Ordinary Shares may vary depending upon such Holder's particular situation and holders or prospective purchasers of Ordinary Shares are advised to consult their own tax advisors as to the Irish or other tax consequences of the purchase, ownership and disposition of Ordinary Shares.

For purposes of this tax description, a "US Holder" is a holder of Ordinary Shares that is: (i) a citizen or resident of the US; (ii) a corporation or partnership created or organized in or under the laws of the US or of any political subdivision thereof; (iii) an estate the income of which is subject to US federal income taxation regardless of its source; or (iv) a trust if a US court is able to exercise primary supervision over the administration of such trust and one or more US persons have the authority to control all substantial decisions of such trust.

Taxation of Corporate Income. Elan is a public limited company incorporated, and resident for tax purposes, in Ireland. Under current Irish legislation, a company is regarded as resident for tax purposes in Ireland if it is centrally managed and controlled in Ireland, or, in certain circumstances, if it is incorporated in Ireland. The Taxes Consolidation Act, 1997, provides that a company which is resident in Ireland and which is not resident elsewhere shall be entitled to have any income from a qualifying patent disregarded for taxation purposes. The legislation does not provide a termination date for this relief. A qualifying patent means a patent in relation to which the research, planning, processing, experimenting, testing, devising, designing, developing

or similar activities leading to the invention which is the subject of the patent, were carried out in Ireland. Income from a qualifying patent means any royalty or other sum paid in respect of the use of the invention to which the qualifying patent relates, including any sum paid for the grant of a license to exercise rights under such patent, where that royalty or other sum is paid, for the purpose of activities which would be regarded under Irish law as the manufacture of goods, or by a person who is not connected with Elan. Accordingly, Elan's income from such qualifying patents is disregarded for taxation purposes in Ireland. Any Irish manufacturing income of Elan and its subsidiaries is taxable at the rate of 10% in Ireland until December 31, 2010. Income arising from qualifying activities in Elan's Shannon certified subsidiary is taxable at the rate of 10% in Ireland until December 31, 2005. From January 1, 2006, such income will be taxable at 12.5%. Any income of Elan which does not qualify for the patent exemption or the 10% rate of tax will be taxable at the Irish corporation tax rate of 28% (which rate is reducing annually to a rate of 12.5% from January 1, 2003) in respect of trading income. Non-trading income will be taxable at 25% from January 1, 2000.

Taxation of Capital Gains and Dividends. A person who is neither resident nor ordinarily resident in Ireland and who does not carry on a trade in Ireland through a branch or agency will not be subject to Irish capital gains tax on the disposal of Elan ADSs or Ordinary Shares. Unless exempted, all dividends paid by Elan will be subject to Irish withholding tax at a rate of 24%. An individual shareholder resident in a country with which Ireland has a double tax treaty, which includes the US, or in a member state of the European Union, other than Ireland (together a "Relevant Territory"), will be exempt from withholding tax provided he or she makes the requisite declaration. A transitional provision permits dividends to be paid free of withholding tax to investors whose address in the share register is in a Relevant Territory until April 6, 2000. Corporate shareholders ultimately controlled by residents of a Relevant Territory, or the principal class of shares of which, or of a 75% parent, is traded on a stock exchange in a Relevant Territory will be exempt from withholding tax provided the appropriate declaration is made. Holders of Elan ADSs will be exempt from withholding tax if they are beneficially entitled to the dividend and their address on the register of depositary shares maintained by the depositary is in the US, provided that the depositary has been authorized by the Irish Revenue Commissioners as a qualifying intermediary. Where such withholding is made it will satisfy the liability to Irish tax of the shareholder except in certain circumstances where an individual shareholder may have an additional liability. A charge to Irish social security taxes and other levies can arise for individuals. However, under the Social Welfare Agreement between Ireland and the US an individual who is liable for US social security contributions can normally claim exemption from these taxes and levies.

Irish Capital Acquisitions Tax. A gift or inheritance of Elan ADSs or Ordinary Shares will be within the charge to Irish capital acquisitions tax. Capital acquisitions tax is charged on a sliding scale of rates ranging between 15% and 40% above a tax free threshold. This tax free threshold is determined by the amount of the current benefit and of previous benefits taken since December 2, 1988 within the charge to capital acquisitions tax and the relationship between the donor and the successor or donee. Gifts and inheritances between spouses are not subject to capital acquisitions tax. There is also a probate tax which is charged at 2% on the value of the estate of deceased persons which exceed a specified threshold. To the extent that they pass under a will or on intestacy, Elan's ADSs or Ordinary Shares would be within the charge to this tax.

The Estate Tax Convention between Ireland and the US generally provides for Irish capital acquisitions tax paid on inheritances in Ireland to be credited against tax payable in the US and for tax paid in the US to be credited against tax payable in Ireland, based on priority rules set forth in the Estate Tax Convention, in a case where Elan ADSs or Ordinary Shares are subject to both Irish capital acquisitions tax with respect to inheritance and US Federal estate tax. The Estate Tax Convention does not apply to Irish capital acquisitions tax paid on gifts.

Irish Stamp Duty. Under current Irish law, no stamp duty, currently at the rate and on the amount referred to below, will be payable by US holders on the issue of Elan ADSs, Ordinary Shares or American depositary warrant shares. Under current Irish law, no stamp duty will be payable on the acquisition of American depositary warrant shares or Elan ADSs by persons purchasing such American depositary warrant

The person accountable for payment of stamp duty is the transferee or, in the case of a transfer by way of gift or for a consideration less than the market value, all parties to the transfer. Stamp duty is normally payable within 30 days after the date of execution of the transfer. Late or inadequate payment of stamp duty will result in liability to pay interest penalties and fines.

The selected financial data set forth below as of and for the years ended December 31, 1998 and 1997, the nine months ended December 31, 1996 and the years ended March 31, 1996 and March 31, 1995 have been derived from Elan's audited Consolidated Financial Statements, including the reconciliation between US and Irish generally accepted accounting principles contained therein, contained in Elan's annual reports to shareholders and should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the audited Consolidated Financial Statements of Elan included elsewhere in this Annual Report on Form 20-F. Such audited Consolidated Financial Statements of Elan have been audited by KPMG. Chartered Accountants.

- (1) After other charges of \$659,865,000 relating to the acquisition of in-process research and development, costs of a fundamental restructuring and a provision for loss on sale of a business.
- (2) After other charges of \$1,423,718,000 relating to the acquisition of in-process research and development, rationalization and integration costs, a loss on a sale of a business and a contribution to Axogen.
- (3) Earnings per share is based on the weighted average number of outstanding Ordinary Shares and the effect of potential dilutive securities including options, warrants and convertible securities.

Dividends

Elan has not paid cash dividends on its Ordinary Shares in the past. The declaration of any cash dividends will be at the recommendation of Elan's Board of Directors. The recommendations of Elan's Board of Directors will depend upon the earnings, capital requirements and financial condition of Elan and other relevant factors. Although Elan does not anticipate that it will pay any cash dividends on its Ordinary Shares in the foreseeable future, Elan expects that its Board of Directors will review Elan's dividend policy on a regular basis. Dividends may be paid on Elan's Executive shares and 'B' Executive Shares at a time when no dividends are being paid on the Ordinary Shares. For additional information relating to the Executive Shares and 'B' Executive Shares, see Note 16 of the Consolidated Financial Statements of Elan included elsewhere in this Annual Report on Form 20-F.

Item 9. *Management's Discussion and Analysis of Financial Condition and Results of Operations.*

The development of Elan's business during fiscal 1998 has been characterized by significant growth and change as the company transitions to being a fully integrated worldwide specialty pharmaceutical company. Elan made four significant corporate acquisitions during 1998 and in-licensed a number of marketed products and products in late-stage development. Revenues increased during 1998 as a result of product and company acquisitions, growth in license fees and revenues from international sales and marketing activities. The Company's sales and marketing activities and research and development activities increased, reflecting more products being marketed and a growing product development pipeline.

Elan's revenues are derived from (i) product sales of drug and diagnostic products and services; (ii) license fees; (iii) royalties; and (iv) research revenues for performing research and development activities on behalf of pharmaceutical industry clients. Product sales of drug products arise from products developed and manufactured by Elan on behalf of its clients, and from products developed by Elan for its own account or products licensed from third parties and sold by Elan. License fees include fees relating to the licensing to third parties of Elan's technologies or product rights and the attainment by Elan of product development milestones under existing license agreements. Royalties generally arise on sales of Elan developed drug products by third parties. Non-refundable license fees and royalties are recognized as revenue when earned. During the three periods covered by this Annual Report on Form 20-F, there were no refundable royalties or license fees received by Elan. Historic year to year comparisons may not be meaningful because license fees, milestone payments, company and product acquisitions and launches of new products have had a disproportionate impact on revenues.

Historically, the contributions to total revenues generated from each of the four sources described above have varied considerably from period to period. In addition, each of these sources results in significantly different gross margins (for example, licensing and royalty revenues generally result in significantly higher gross margins than product sales and research revenues) and the gross margins of each of the different products manufactured or licensed by Elan may vary significantly. The costs of developing products and technologies to be licensed generally occur over an extended period of time prior to license revenues being generated from such products or technologies. Furthermore, during the initial period following the launch of a new product, gross margins relating to the sale of such newly launched product may be adversely affected by the start-up costs related to its launch. Therefore, the comparability of gross margins from period to period will be affected by the source of revenues earned, the mix of products sold and the introduction of new products during such periods.

To date, Elan has denominated most of its contracts in US dollars and its reporting currency, effective April 1, 1996, is the US dollar. Elan manages its non-US dollar foreign exchange risk primarily through forward currency contracts. See Item 9A, "Quantitative and Qualitative Disclosures About Market Risk".

Company Acquisitions

During 1998, Elan completed four significant acquisitions to enhance its drug delivery and pharmaceutical business.

On October 1, 1998 Elan acquired all the assets and liabilities of NanoSystems, a unit of Eastman Kodak Company. NanoSystems is a drug delivery company focused on the enhanced delivery of poorly water-soluble drugs. The total consideration, including costs of acquisition, consisted of \$138.5 million in cash and the issuance of warrants to purchase 1,500,000 Elan ADSs at an exercise price of \$45 per Elan ADS, with an estimated fair value of \$16.4 million. The acquisition was accounted for using purchase accounting. NanoSystems had been loss making prior to its acquisition and has been integrated into EPT, Elan's drug delivery division. As a result of the acquisition Elan incurred a charge of \$88.5 million for the year ended December 31, 1998, representing the acquisition of in-process research and development, in accordance with SFAS No. 2.

On August 14, 1998 Elan acquired Neurex, a late-stage biopharmaceutical company developing products for pain management and the acute care market, principally in the area of cardiorenal and neurological disease. The total consideration for the acquisition, including costs of acquisition, was \$810.0 million and resulted in Elan issuing approximately 23.8 million Elan ADSs. Neurex had been loss making prior to its acquisition and has been integrated into EP, Elan's pharmaceuticals division. The acquisition was accounted for using purchase accounting. As a result of the acquisition Elan incurred a charge of \$787.1 million for the year ended December 31, 1998, representing the acquisition of in-process research and development, in accordance with SFAS No. 2.

On May 29, 1998 Elan acquired Carnrick, a company that markets and distributes a range of products, primarily for neurology and pain management applications, to general practitioners and pain specialists. The total consideration, including costs of acquisition, consisted of \$134.4 million in cash and in the issuance of an \$18.0 million promissory note. The acquisition was accounted for using purchase accounting. Carnrick has been integrated into EP, Elan's pharmaceuticals division. As a result of the acquisition Elan incurred a charge of \$19.9 million in the year ended December 31, 1998, representing the acquisition of in-process research and development, in accordance with SFAS No. 2.

On February 27, 1998 Elan completed the acquisition of Sano, a developer of proprietary drug delivery systems with an emphasis on transdermal products. The total consideration for the acquisition, including costs of acquisition, was \$434.7 million and resulted in the issuance of approximately 12.7 million Elan ADSs. The acquisition was accounted for using purchase accounting. Sano has been integrated into EPT, Elan's drug delivery division. As a result of the acquisition Elan incurred a charge of \$445.1 million in the year ended December 31, 1998, \$404.9 million of which represented the acquisition of in-process research and development, in accordance with SFAS No. 2, and \$40.2 million of which represented the cost of integrating and rationalizing certain activities. The principal products in development by Sano at the date of acquisition, transdermal products containing Nic/Mec and buspirone, failed to demonstrate sufficient statistical efficiency in Phase III clinical studies to support NDA filings. Certain data from these clinical studies are still being assessed.

Product Acquisitions

In October 1998, the Company licensed from Vanguard exclusive North American sales and distribution rights for frovatriptan, which had completed Phase III studies in patients with migraine headaches. In addition, Elan paid \$10.0 million to Vanguard to acquire new ordinary shares and as part of the licensing collaboration. The terms of the license provide that Elan will make milestone payments of up to \$50.0 million to Vanguard and will pay royalties on future sales. To date, \$15.0 million of these milestone payments have been made. In January 1999 an NDA for frovatriptan was filed with the FDA. The purchase consideration was capitalized as an intangible and is being amortized over the period expected to benefit from this product.

In September 1998, Elan reacquired exclusive US and Canadian product distribution rights for Naprelan and Verelan from Wyeth for \$228.0 million, which is payable in installments. The terms of the acquisition require that Elan pay to Wyeth up to an additional \$30.0 million, depending on the amount and timing of launches of competitive generic products. The purchase consideration was capitalized as an intangible and is

being amortized over the period expected to benefit from these products. Elan will continue to manufacture Naprelan and Verelan. Naprelan, a once-daily formulation of naproxen, is indicated for use in connection with mild to moderate pain, rheumatoid arthritis and a number of related inflammatory conditions. Elan markets Naprelan directly in the US. Verelan, a once-daily formulation of verapamil, is used to manage hypertension. Elan has also developed an enhanced formulation of Verelan called Verelan PM, which provides certain improved therapeutic benefits.

On September 30, 1998, Elan entered into an agreement for the exclusive marketing and distribution rights to Verelan in the US with Schwarz. This agreement set minimum sales targets to be achieved by Schwarz and also provided for Elan to supply product to Schwarz. Elan also licensed Verelan PM to Schwarz. In November 1998, the FDA approved an NDA for Verelan PM. Elan received a license fee of \$17.5 million upon execution of the agreement and a milestone payment of \$10.0 million upon FDA approval of the NDA for Verelan PM. These license and milestone fees were recognized as revenue in the year ended December 31, 1998.

In May 1999, generic products that compete with Verelan were launched and Elan expects that such products will significantly reduce revenue it receives from Verelan sales.

On February 28, 1998, Elan acquired from Wyeth exclusive product distribution and trademark rights for Mysoline in the US and Canada for \$46.0 million and a royalty on future sales. Elan markets Mysoline directly in the US. The purchase consideration was capitalized as an intangible and is being amortized over the period expected to benefit from this product.

Segmental Analysis

Elan completed a number of significant corporate acquisitions in the year ended December 31, 1998. As a result of these acquisitions and the general growth in its business, a more formalized divisional and reporting structure was put in place during 1998 as compared to that existing previously. These structures will continue to evolve and are expected to become more formalized during the year ended December 31, 1999 and thereafter.

Elan's business is currently conducted through two primary segments, consisting of a pharmaceuticals business, EP, and a drug delivery business, EPT. EP discovers, develops and markets therapeutic products for neurological disorders, acute care and pain management, and diagnostic services for neurological disorders. EP's principal research and development activities focus on Alzheimer's disease, pain management, epilepsy, MS and stroke. EPT develops, manufactures, markets and licenses drug delivery products and technologies based on Elan's drug delivery systems. Elan devotes significant resources to the refinement and improvement of its existing drug delivery systems, as well as to the development of next generation technologies, with particular applicability to the delivery of new drug development candidates, including macromolecules and other complex biotechnology products.

EP's revenues grew by 114% to \$348.5 million in 1998 from \$162.8 million in 1997. Operating profit increased to \$77.2 million in 1998 from \$30.1 million in 1997. The increase in revenues primarily reflects product and company acquisitions and increased research revenues. EPT's revenues grew by 48% to \$327.1 million in 1998 from \$220.3 million in 1997. Operating profit increased to \$178.3 million in 1998 from \$107.6 million in 1997. The increase in revenues primarily reflects higher product sales on acquired products and revenues from milestones and new license agreements. Other charges of \$1,423.7 million included in the Consolidated Financial Statements have not been allocated to the reportable segments. See Note 17 of the Consolidated Financial Statements for a more detailed analysis of Elan's reportable segments.

Results of operations for the year ended December 31, 1998 compared with the year ended December 31, 1997

	Year ended December 31, 1998 \$000s (Audited)	Year ended December 31, 1997 \$000s (Audited)
Revenues:		
Product sales	342,078	215,486
License fees	207,473	64,049
Royalties	31,660	46,857
Research revenues	95,523	57,789
Total revenues	676,734	384,181
Costs and expenses:		
Cost of goods sold	137,935	106,182
Selling, general and administrative	155,869	71,764
Research and development	143,536	75,160
Other charges:		
Acquisition of in-process research and development	1,311,149	—
Rationalization and integration	41,747	—
Loss on sale of business	3,322	—
Contribution to Axogen Limited	67,500	—
Total operating expenses	1,861,058	253,106
Operating (loss) income	(1,184,324)	131,075
Interest and other income	46,457	53,291
Interest expense	(23,578)	(5,843)
Share of losses from investments accounted for under the equity method	(5,256)	(7,458)
Minority interests	(38)	260
(Loss) income before provision for income taxes	(1,166,739)	171,325
Provision for income taxes	(3,874)	(1,186)
Net (loss) income	(1,170,613)	170,139

Total revenues for the year ended December 31, 1998 increased by 76% to \$676.7 million from \$384.2 million for the year ended December 31, 1997. Product sales for 1998 increased by 59% to \$342.1 million from \$215.5 million for 1997, reflecting the acquisition of Carnrick, growth in Elan's international operations, increased sales of Naprelan and Verelan following the re-acquisition of the marketing rights in September 1998 and the acquisition of the marketing rights to Mysoline in the US. Product revenues from Naprelan and Verelan increased by \$33.7 million and \$28.9 million, respectively, for 1998 as compared to 1997. Carnrick contributed \$50.0 million to product sales in 1998.

Cardizem CD/SR, Naprelan, Permax, Skelaxin, Verelan and Zanaflex accounted for 62.5% and 58.6% of product sales in 1998 and 1997, respectively. The same products accounted for 37.8% and 42.3% of total revenues in 1998 and 1997, respectively. In 1998 Naprelan, Permax and Verelan accounted for 16.0%, 14.0% and 13.9% of product sales, respectively. In 1997 Permax accounted for 25.6% of product sales. No other product accounted for more than 10.0% of product sales in either 1998 or 1997. Elan's remaining revenues are generated from a mix of other products and services.

The growth in license fees to \$207.5 million for 1998 from \$64.0 million for 1997 primarily reflects new license agreements entered into during 1998 and the achievement of milestones on existing development agreements. Elan received license fees in the amount of \$114.5 million and \$57.5 million in 1998 and 1997, respectively, from strategic collaborators. Elan invested \$198.5 million and \$67.5 million in these companies in

1998 and 1997, respectively (See Item 1 — Research and Development Alliances, Strategic Collaborations). Royalties decreased by 32% to \$31.7 million for 1998 from \$46.9 million for 1997, reflecting the switch from royalty revenue to product sales following Elan's September 1998 re-acquisition of the marketing rights to Naprelan and Verelan, and the maturity of a number of Elan products, including Cardizem CD. Royalties from Naprelan and Verelan decreased by \$11.5 million in 1998 compared to 1997. Research revenues for 1998 increased by 65% to \$95.5 million from \$57.8 million for 1997, primarily reflecting increased revenues from Axogen and Neuralab, including a higher level of payments for external work done on behalf of Axogen on late-stage product candidates in Phase III clinical studies. Research revenues from Axogen and Neuralab increased to \$77.8 million for 1998 from \$39.3 million for 1997. Elan made a contribution of \$67.5 million to Axogen in December 1998. Neuralab was established in 1998. Elan received research revenues in the amount of \$6.2 million for 1998 and \$2.5 million for 1997 from strategic collaborators (See Item 1 — Research and Development Alliances, Strategic Collaborations).

The contribution of \$67.5 million to Axogen was expensed by Elan for the year ended December 31, 1998. It is separate from the research and development costs incurred in respect of research and development activities undertaken for Axogen and Neuralab, of \$57.4 million, that are discussed below.

The decision to make this contribution was taken in 1998 as Axogen would otherwise have expended its cash resources prior to the development programs reaching a stage of sufficient advancement whereby Elan could decide to exercise the purchase option or otherwise. The funds arising from this contribution to Axogen are being used for the research and development activities that Elan undertakes for Axogen (see Note 18 of the Consolidated Financial Statements for additional information on the purchase option and the development and license contract). This contribution was made in December 1998 and had no impact on revenues received by Elan from Axogen in 1998. It will result in revenues to Elan in 1999.

Axogen accounted for approximately 14% and 10% of Elan's total revenues for 1998 and 1997, respectively. Elan had no other customer accounting for more than 10% of revenues in 1998.

Cost of goods sold increased by 30% to \$137.9 million for 1998 from \$106.2 million for 1997. The increase primarily reflects the inclusion in 1998 of the product cost of sales arising from the acquisitions of Carnrick and Elan's former UK and Irish marketing joint ventures, and the acquisition of the marketing rights to Mysoline. Cost of sales includes those costs associated with the cost of products sold and the costs associated with generating royalties. Gross margin, based on total revenues, increased to 80% for 1998 from 72% for 1997, reflecting the inclusion in product sales of a higher percentage of higher margin product sales and increased license fees. Gross margin based on product sales increased to 60% for 1998 from 51% for 1997, reflecting the growth in higher margin sales of directly marketed products primarily as a result of the acquisition of Carnrick, growth in Elan's international operations, the re-acquisition of Naprelan and Verelan and the licensing of Mysoline.

Selling, general and administrative expenses for 1998 increased by 117% to \$155.9 million from \$71.8 million in 1997, primarily reflecting the acquisition of Carnrick, the expansion of international operations, the scale-up of sales and marketing activities in the US and the impact of products acquired during the period. The increases in selling, general and administration expenses arising from the acquisition of Carnrick, the expansion of international operations and the expansion of existing US sales and marketing activities were \$15.6 million, \$14.7 million and \$19.5 million, respectively, for 1998 compared to 1997.

Research and development expenses increased by 91% to \$143.5 million for 1998, from \$75.2 million for 1997, reflecting the effect of company acquisitions in 1998 and the number of products in late-stage development. Research and development costs incurred in respect of Axogen and Neuralab were \$57.4 million and \$24.9 million in 1998 and 1997, respectively. The margin on research and development activities undertaken on behalf of Axogen and Neuralab was 26.2% in 1998.

Primarily as a result of the acquisitions of Neurex, Sano, NanoSystems and Carnrick in 1998, Elan incurred charges of \$1,311.1 million, representing the acquisition of in-process research and development pursuant to SFAS No. 2 (see Note 2 of the Consolidated Financial Statements for additional information relating to these acquisitions).

Following the February 1998 acquisition of Sano, a developer of transdermal drug delivery products, Elan integrated Sano into its drug delivery activities and rationalized both Sano and Elan's existing drug delivery business. Costs incurred during 1998 include asset write-downs of \$21.8 million and other costs of \$3.2 million arising from the acquisition of Sano and the transfer of transdermal activities from Elan's Athlone, Ireland facility to Sano's Miramar, Florida facility. Costs to close certain drug delivery departments amounted to \$2.8 million in 1998. Costs of \$6.0 million were incurred to rationalize and terminate certain Sano and Elan pre-existing drug delivery research and development projects. Costs of \$6.5 million were incurred by Sano to terminate certain license and supply agreements in 1998. Costs of \$1.6 million were also incurred to rationalize and integrate Elan's US diagnostic businesses.

A charge of \$3.3 million was incurred during 1998 resulting from a loss on disposal of an investment and loan note.

A charge of \$67.5 million was incurred during 1998 resulting from a contribution of \$67.5 million to Axogen (see Note 18 of the Consolidated Financial Statements for additional information relating to Axogen).

Interest and other income for 1998 decreased by 13% to \$46.5 million from \$53.3 million for 1997, reflecting a decline in realized portfolio gains and foreign exchange gains in 1998, off-set by interest earned on higher average cash and liquid resources during the year. Interest expense for 1998 increased by 307% to \$23.6 million from \$5.8 million for 1997, primarily reflecting the inclusion for the full year of interest payable on \$325.0 million 4.75% Exchangeable Notes due 2004 issued in November 1997, interest payable on the \$128.0 million promissory note issued by Elan in connection with an acquisition of products and higher foreign exchange losses primarily arising on Irish pound activities.

Share of losses from investments accounted for under the equity method declined to a loss of \$5.3 million in 1998 from a loss of \$7.5 million for 1997. The loss for 1998 primarily reflects Elan's share of losses in its joint venture with Emisphere Technologies, Inc. ("Emisphere") as a result of a heparin development product entering later stage clinical development.

Tax charges for 1998 increased by 225% to \$3.9 million from \$1.2 million for 1997. This charge reflected tax at standard rates in the jurisdictions in which Elan operates, Irish patent-derived income which is exempt from tax, tax at a 10% rate on Irish manufacturing operations, foreign withholding tax and the availability of loss carryforwards. Elan's Irish income was largely exempt from taxation pursuant to Irish legislation which exempts from Irish taxation income which is derived from qualifying patents. A qualifying patent means a patent in relation to which the research, planning, processing, experimenting, testing, devising, designing, developing or similar activities leading to the invention which is the subject of the patent, were carried out in Ireland. Income from a qualifying patent means any royalty or other sum paid in respect of the use of the invention to which the qualifying patent relates, including any sum paid for the grant of a license to exercise rights under such patent, where that royalty or other sum is paid, for the purpose of activities which would be regarded under Irish law as the manufacture of goods, or by a person who is not connected with Elan. Accordingly, Elan's income from such qualifying patents is disregarded for taxation purposes in Ireland. Any Irish manufacturing income of Elan and its subsidiaries is taxable at the rate of 10% in Ireland until December 31, 2010. Income arising from qualifying activities in Elan's Shannon certified subsidiary is taxable at the rate of 10% in Ireland until December 31, 2005. From January 1, 2006, such income will be taxable at 12.5%. Any income of Elan which does not qualify for the patent exemption or the 10% rate of tax will be taxable at the Irish corporation tax rate of 32% (28% with effect from January 1, 1999).

Elan has restated its consolidated financial statements for a change in the method used to account for two investments made in 1997. These investments were originally accounted for under the cost method in Elan's consolidated financial statements. The restatement reflects a change in the accounting method used to the equity method. The effect of the restatement is to reduce 1997 net income by \$5.0 million to \$170.1 million. There is no impact on Elan's 1998 net income. Amounts in this Annual Report on Form 20-F reflect the restatement. See Note 29 of the Consolidated Financial Statements included in this Annual Report on Form 20-F.

Results of operations for the year ended December 31, 1997 compared with the year ended December 31, 1996

	Year ended December 31, 1997 \$000s (Audited)	Year ended December 31, 1996 \$000s (Unaudited)
Revenues:		
Product sales	215,486	158,873
License fees	64,049	46,660
Royalties	46,857	48,750
Research revenues	57,789	56,137
Total revenues	<u>384,181</u>	<u>310,420</u>
Costs and expenses:		
Cost of goods sold	106,182	84,930
Selling, general and administrative	71,764	49,930
Research and development	75,160	75,156
Other charges:		
Acquisition of in-process research and development	—	571,839
Cost of fundamental restructuring	—	70,000
Provision for loss on sale of business	—	18,026
Total operating expenses	<u>253,106</u>	<u>869,881</u>
Operating income (loss)	131,075	(559,461)
Interest and other income	53,291	33,846
Interest expense	(5,843)	(9,140)
Share of losses from investments accounted for under the equity method	(7,458)	(8,511)
Minority interests	260	160
Income (loss) before provision for income taxes	171,325	(543,106)
Provision for income taxes	(1,186)	(845)
Net income (loss)	<u>170,139</u>	<u>(543,951)</u>

(For the purpose of this comparison, the year ended December 31, 1997 has been compared to the year ended December 31, 1996. The audited financial statements cover the periods for the year ended December 31, 1997 and the nine months ended December 31, 1996.)

Total revenues for the twelve months ended December 31, 1997 increased by 24% to \$384.2 million from \$310.4 million for the twelve months ended December 31, 1996. Product sales for the twelve months ended December 31, 1997 increased by 36% to \$215.5 million from \$158.9 million for the twelve months ended December 31, 1996, reflecting the inclusion of Athena for the full twelve months of 1997 as compared with six months in 1996 (July 1, 1996, its date of acquisition, to December 31, 1996) continued growth in sales of Permax, the introduction of new products in the US during 1997, certain low margin one-off sales during 1997 and increased non-US sales of drug delivery products. The increase in sales of Permax, due to its inclusion for

a full twelve months during 1997 as compared with six months for 1996 and its continued growth in sales, was \$30.5 million. The increase in product sales was offset, in part, by lower Naprelan sales during 1997, as 1996 had included initial launch quantities for Naprelan, and lower Verelan sales in 1997. License fees increased by \$17.4 million in the twelve months ended December 31, 1997 compared to the twelve months ended December 31, 1996, mainly reflecting new license agreements. No significant license agreements were canceled during the year. Royalties decreased by \$1.9 million for the twelve months ended December 31, 1997 compared to the twelve months ended December 31, 1996, primarily reflecting the maturity of products such as Cardizem CD and SR and Verelan. Research revenues for the twelve months ended December 31, 1997 increased by 3% to \$57.8 million from \$56.1 million for the twelve months ended December 31, 1996, primarily reflecting increased revenues from Axogen and the inclusion of Athena for the full twelve months of 1997, offset, in part, by the cessation of revenue from Advanced Therapeutic Systems Limited (“ATS”), which Elan acquired in 1996. Research revenues from Axogen, which commenced operations in November 1996, increased to \$39.3 million for the twelve months ended December 31, 1997 from \$3.5 million for the twelve months ended December 31, 1996, reflecting a higher level of payments for external work done on behalf of Axogen and as Axogen was operational for twelve months for the year ended December 31, 1997 compared to two months for the twelve months ended December 31, 1996. Research revenue from ATS amounted to \$39.5 million for the twelve months to December 31, 1996. ATS raised \$73.5 million from investors in August 1993 and Elan made a contribution of \$35.0 million to ATS at that time.

AHP and HMR accounted for approximately 18% of Elan’s total revenues for the year ended December 31, 1997. Revenues from AHP arose primarily on Verelan and Naprelan. Revenues from HMR arose on Cardizem CD and SR. Elan was dependent on AHP as licensee for Verelan and Naprelan, and is dependent on HMR as licensee for Cardizem CD and SR, to generate revenues on these products. As the marketing of Verelan and Naprelan was controlled by AHP, and the marketing of Cardizem CD and SR is controlled by HMR, Elan had limited ability to impact the revenues and income generated by these products. Elan generated 33% and 49% of revenues from these two companies in the nine month period and year ended December 31, 1996 and March 31, 1996, respectively. Elan expects that the significance of these relationships will continue to diminish as revenues from other sources increase and as a result of the repurchase of Naprelan and Verelan from AHP in September 1998. Axogen accounted for approximately 10% of Elan’s total revenues for the year ended December 31, 1997. ATS accounted for 22% and 18% of total revenues in the nine month period and year ended December 31, 1996 and March 31, 1996, respectively.

Cost of goods sold increased by 25% to \$106.2 million for the twelve months ended December 31, 1997 from \$84.9 million for the twelve months ended December 31, 1996. The increase reflects the growth in existing product sales and the inclusion of Athena for the full twelve months of 1997. Cost of sales includes those costs associated with the cost of products sold and the costs associated with generating royalties. Gross margin, based on total revenues, was 72% and 73% for the years ended December 31, 1997 and 1996 respectively. Gross margin based on product sales increased to 51% for the twelve months ended December 31, 1997 from 47% for the twelve months ended December 31, 1996, primarily reflecting a combination of the inclusion of higher margin Athena revenues for the full twelve months of 1997, compared to six months for 1996, together with improved margins on newer drug delivery products.

Selling, general and administrative expenses for the twelve months ended December 31, 1997 increased by 44% to \$71.8 million from \$49.9 million for the twelve months ended December 31, 1996, primarily reflecting the inclusion of Athena in Elan’s results for the full twelve months of 1997 compared to six months for 1996. Prior to the acquisition of Athena, Elan had not directly marketed pharmaceutical products in the US. Subsequent to the acquisition, Elan began marketing pharmaceutical products directly in the US, which requires a sales force and related marketing and distribution costs. In addition, after the acquisition, Elan increased Athena’s sales and marketing infrastructure in the US and the UK for the introduction of new products. The new products included Zanaflex and Diastat, both of which were launched during 1997. Athena’s selling, general and administrative costs were \$45.4 million for the twelve months ended December 31, 1997 compared to \$16.0 million in the six month post-acquisition period included in Elan’s results for the twelve months ended December 31, 1996.

Research and development expenses were \$75.2 million for the twelve months ended December 31, 1997 and 1996, reflecting the inclusion of Athena for the full twelve months of 1997 compared to six months for 1996, offset by the rationalization and restructuring of Elan's research activities following the acquisition of Athena in 1996. Research and development costs incurred in respect of Axogen and ATS were \$24.9 million and \$29.8 million in the year ended December 31, 1997 and the nine months ended December 31, 1996, respectively. The margins on research and development activities undertaken on behalf of Axogen and ATS were 36.6% and 28.2% in the twelve months ended December 31, 1997 and the nine months ended December 31, 1996 respectively.

In April 1996, Warner Chilcott, plc ("Warner Chilcott"), an investment that was accounted for under the equity method, in which Elan had a 25% equity interest, acquired a division of the Warner-Lambert Company. The acquisition resulted in a charge representing the acquisition of in-process research and development pursuant to SFAS No. 2, of which Elan's share amounted to \$4.8 million.

The acquisition of Athena in July 1996 gave rise to a charge of \$412.6 million, representing the acquisition of in-process research and development pursuant to SFAS No. 2. The purchase price of \$537.2 million for Athena was allocated as follows:

	<u>\$000s</u>
Property, plant and equipment	5,259
Intangible assets	110,877
Current assets	46,457
Accounts Payable	(15,115)
Long-term debt	(22,880)
In-process research and development	412,591
Purchase price	<u>537,189</u>

Intangible assets include the value of Athena's assembled workforce, developed technology and marketed products. These were valued at \$2.2 million, \$34.7 million and \$74.0 million, respectively. The acquired in-process research and development charge of \$412.6 million represented the value of Athena's projects in research and development at the acquisition date. Athena's principal research and development projects were focused on Alzheimer's disease, multiple sclerosis and neuromuscular disorders. Technological feasibility of these projects was not established at the acquisition date and it was considered that these projects had no alternative future use other than the therapeutic indications for which they were in research and development. The projects were estimated to be approximately 40% complete on average and the estimated costs to completion were approximately \$240.0 million. The average time to full completion of the remaining work for the projects in research and development was estimated to be approximately 57 months at the date of acquisition. The work remaining to complete the research and development projects involved research, preclinical studies, safety and efficacy studies and the submission of regulatory filings to seek marketing approvals. The principal risks related to the research and development projects are the outcomes of such research, preclinical studies, safety and efficacy studies and regulatory filings. As pharmaceutical products cannot be marketed without such regulatory approvals, Elan will not receive any benefits unless it receives such regulatory approval.

Alzheimer's disease research projects represented approximately \$250.0 million of the in-process research and development charge. The work remaining to complete the projects involved research, preclinical studies, safety and efficacy studies, and the submission of regulatory filings to seek marketing approvals. The principal risks related to the development products are the outcomes of such research, preclinical studies, safety and efficacy studies and regulatory filings. As pharmaceutical products cannot be marketed without regulatory approvals, Elan will not receive any benefits unless it receives such regulatory approval. The Alzheimer's projects' estimated peak sales were approximately \$820.0 million per annum, estimated costs to completion were approximately \$110.0 million and a discount rate of 24% was used. It was estimated that the projects would take between eight and ten years to complete.

The acquired research and development projects have progressed since the acquisition of Athena. Diastat received FDA approval in 1997. Cumulative Diastat revenues since launch to December 31, 1998, were \$7.9 million compared to \$17.0 million per the in-process research and development valuation. However, projected peak sales for Diastat remain at the same level as in the in-process research and development valuation report. Neurobloc completed clinical trials and an application for marketing approval was filed with the FDA in December 1998. Clinical development of Antegren and research into Alzheimer's disease therapeutics is progressing, although slightly slower than initially expected. This delay did not have a material impact on Elan's financial condition, results of operations or liquidity in 1998 or 1997. Antegren is expected to commence pivotal clinical trials in 1999. IND applications are expected to be filed for two Alzheimer's disease therapeutics in 1999. The estimated aggregate research and development expenditure, at the date of acquisition, for Neurobloc, Antegren and Alzheimers' research for 1998 and 1997 were \$35.4 million and \$32.5 million, respectively, compared to actual amounts spent in 1998 and 1997 of \$43.7 million and \$31.3 million, respectively.

The acquisition of ATS in October 1996 gave rise to a charge of \$154.5 million, representing the acquisition of in-process research and development pursuant to SFAS No. 2. The acquisition of ATS was accounted for using purchase accounting. The principal research and development activities of ATS related to products with delivery or absorption issues, including protein and peptide drugs, highly insoluble drugs and drugs with large molecular structures. These products included proton pump inhibitors, potassium channel blocker drugs and drugs for early stage treatment of pain and cancer. At the date of acquisition, the ATS programs were in development and none had been approved by the FDA for marketing. Technological feasibility of these products was not established at the date of acquisition and it was considered that these products had no alternative future use other than the therapeutic indications for which they were in development. The work remaining to complete the development products involved research, safety and efficacy studies and the submission of regulatory filings to seek marketing approvals. The principal risks related to the development products were the outcomes of such research, clinical studies and regulatory filings. As pharmaceutical products cannot be marketed without such regulatory approvals, Elan would not receive any benefits unless it receives such regulatory approval. The estimated costs to completion of the products were approximately \$100.0 million. Elan subsequently out-licensed a number of these projects. The licensees are responsible for research and development costs on such projects. Approval of these products are expected beginning in 2000, with the initial approval of products for the treatment of pain. This is approximately one to two years later than expected at the time of acquisition. This delay did not have a material impact on Elan's financial condition, results of operations or liquidity in 1998 or 1997.

In 1996, following a strategic review of operations, the Company commenced a fundamental restructuring of its business resulting in a restructuring charge of \$70.0 million. The restructuring charge included \$33.0 million for the restructuring and rationalization of manufacturing operations, \$23.5 million for the integration and rationalization of research and development activities, \$4.5 million for integration and rationalization of corporate functions, and asset write-offs of \$9.0 million. The restructuring was necessitated by the acquisition of Athena on July 1, 1996 and due to a concurrent need to make changes in existing manufacturing operations.

The acquisition of Athena resulted in an increase in the number of projects in research and development and a significant increase in research and development resource requirements. The costs incurred in rationalization and integration of research and development activities included the cost for elimination of certain research and development projects and the costs incurred on certain third party collaborations. The costs incurred in the rationalization and integration of corporate functions represented run-off public company costs including costs to cover the defense of a shareholder suit, director and officer insurance for the retiring directors, various professional fees and costs related to the completion of pre-acquisition activities. The assets written off related primarily to equipment no longer needed due to the elimination of certain product lines and regulatory compliance activities.

Manufacturing operations had expanded rapidly due to actual and projected growth in production volumes. This rapid growth resulted in manufacturing issues particularly as production volume forecasts were decreased

after the installation of capacity. Restructuring of manufacturing operations included incremental efforts arising from cGMP activities and cost management and savings activities. During 1996 and 1997, Elan revised cGMP procedures in its Athlone facility. Elan improved manufacturing efficiency by improving quality and by reducing costs. Cost savings included a reduced level of reprocessing activity, improved quality, a change in a supplier of raw materials and a reduction in the number of employees.

The restructuring provision was utilized as follows:

	Year Ended December 31, 1997 \$000s
Balance on provision, January 1, 1997	31,733
Research and development rationalization and integration	15,333
Manufacturing operations	15,564
Other	836
Total provision utilization	31,733
Balance on provision, December 31, 1997	—

The main elements of the restructuring plan were substantially completed by September 1997. Significant achievements included the elimination or rationalization of research and development programs, the restructuring of research and development activities and an increase in manufacturing efficiency. Elan believes that future operating profitability will increase compared to profitability if the restructuring had not been undertaken, primarily through a lower level of costs. Similarly, future liquidity and capital resources should increase compared to liquidity and capital resources if the restructuring had not been undertaken.

In December 1996, Elan committed to dispose of its medical nutrition business to an unrelated public company, Nutrition Medical, Inc. In January 1997, Elan signed the definitive legal sale agreement. The decision to dispose of the business was taken following the acquisition of Athena in July 1996 and the resulting strategic review of operations. This strategic review resulted in a decision to focus Elan's strategic direction on its core drug delivery and pharmaceutical activities. Management decided that the medical nutrition business did not fit with Elan's future strategic direction. The total consideration for the asset sale was valued by Elan at \$4.3 million and consisted of 855,000 shares of common stock in Nutrition Medical, Inc. and a seven year \$3.0 million loan note bearing interest at 3%. The common stock was valued at the quoted market price on December 31, 1996 and the loan note was discounted giving a net present value of \$1.1 million. The net book value of the assets disposed of amounted to \$22.3 million including goodwill of \$16.2 million, other intangible assets of \$3.7 million, fixed assets of \$1.0 million, inventories at \$0.8 million and other items at \$0.6 million. At December 31, 1996 a provision for loss on disposal of this business amounting to \$18.0 million was charged to the income statement based on the expected loss on disposal. This provision was fully utilized in 1997.

Interest and other income for the twelve months ended December 31, 1997 increased by 58% to \$53.3 million from \$33.8 million for the twelve months ended December 31, 1996, reflecting interest earned on higher average cash and liquid resources in the current period, realized portfolio gains and foreign exchange gains. Interest expense for the twelve months ended December 31, 1997 decreased by 36% to \$5.8 million from \$9.1 million for the comparable period in 1996, primarily reflecting the reduction in the Liquid Yield Option Notes due 2012 ("the 2012 LYONs") outstanding as a result of exchanges during the current period and their full redemption effective November 1997, offset in part by interest expense on the issuance by Athena of \$325.0 million in aggregate principal amount of 4.75% Exchangeable Notes due 2004 in November 1997.

Share of losses from investments accounted for under the equity method declined to a loss of \$7.5 million for the twelve months ended December 31, 1997 from a loss of \$8.5 million for the comparable period in 1996, primarily reflecting profitability from Elan's share of its ventures in the UK and Spain in the current year, offset by losses in Elan's joint venture with Emisphere and Elan's share of losses from Warner Chilcott.

Tax charges for the twelve months ended December 31, 1997 increased by 40% to \$1.2 million from \$0.8 million for the twelve months ended December 31, 1996. The increase was mainly attributable to withholding taxes on certain royalty payments. The effective tax rate of approximately 1% in the year ended December 31, 1997 reflected tax at standard rates in the jurisdictions in which Elan operates, Irish patent-derived income which is exempt from tax, tax at a 10% rate on Irish manufacturing operations, foreign withholding tax and the availability of loss carryforwards. Elan's Irish income was largely exempt from taxation pursuant to Irish legislation which exempts from Irish taxation income which is derived from qualifying patents. A qualifying patent means a patent in relation to which the research, planning, processing, experimenting, testing, devising, designing, developing or similar activities leading to the invention which is the subject of the patent were carried out in Ireland. Income from a qualifying patent means any royalty or other sum paid in respect of the use of the invention to which the qualifying patent relates, including any sum paid for the grant of a license to exercise rights under such patent, where that royalty or other sum is paid for the purpose of activities which would be regarded under Irish law as the manufacture of goods, or by a person who is not connected with Elan. Currently, there is no termination date in effect for such exemption. Elan's income from Irish manufacturing operations was taxed at a rate of 10% in Ireland for the periods covered in this report. Such rate of taxation will be available to Elan until December 31, 2010.

Elan has restated its consolidated financial statements for a change in the method used to account for two investments made in 1997. These investments were originally accounted for under the cost method in Elan's consolidated financial statements. The restatement reflects a change from the accounting method used to the equity method. The effect of the restatement is to reduce 1997 net income by \$5.0 million to \$170.1 million. There is no impact on 1996 net income. Amounts in this Annual Report on Form 20-F reflect this restatement. See Note 29 of the Consolidated Financial Statements included in this Annual Report on Form 20-F.

Balance Sheet Review

The increase in intangible assets to \$734.9 million at December 31, 1998 from \$188.7 million at December 31, 1997 primarily reflects the effect of company and product acquisitions discussed elsewhere in this Annual Report on Form 20-F, including those of Carnrick, Nanosystems, Neurex, Sano, Mysoline, Naprelan and Verelan. The increase in property, plant and equipment to \$196.7 million at December 31, 1998 from \$118.4 million at December 31, 1997 primarily reflects the effect of company acquisitions and growth in Elan's infrastructure in the US. The increase in investments and available for sale securities to \$339.3 million at December 31, 1998 from \$274.3 million at December 31, 1997 primarily reflects new investments in emerging pharmaceutical and biotechnology companies including Delsys Pharmaceutical Corporation, Electropharmacology, Inc., Endorex Corporation, Ethical Holdings, plc, Iomai Corporation, Ligand, Multiple Peptide Systems, Inc., RTP Pharma Inc. and Sheffield Pharmaceuticals Inc., partly offset by a decrease in the fair value of available for sale securities.

Liquidity and Capital Resources

The Company's working capital increased to \$1,080.1 million at December 31, 1998 from \$675.7 million at December 31, 1997, primarily reflecting an increase in cash and cash equivalents following the issuance of Liquid Yield Option Notes by Elan Finance Corporation Limited ("Elan Finance") (see below) and the general level of growth in the Company's business reflected in increased investment in current assets. As Elan's direct marketing and selling businesses develop, its investment in working capital for inventories and receivables will increase. The combined investment in receivables, inventories and prepayments increased to \$318.9 million at December 31, 1998 from \$138.5 million at December 31, 1997, reflecting increased levels of business activity.

At December 31, 1998, the Company had the following amounts outstanding under borrowing facilities which are unsecured and exchangeable into Elan ADSs and due for repayment between 2004 and 2018:

- 3.25% Zero Coupon Subordinated Exchangeable Notes due 2018. In December 1998, Elan Finance, a wholly owned subsidiary of Elan, issued, at a substantial discount, Liquid Yield Option Notes due

2018 (“2018 LYONs”), in the principal amount of \$1,643.5 million at maturity. The gross proceeds to the Company amounted to \$862.5 million issued at a price of \$524.78 per \$1,000 principal amount at maturity. The expenses associated with this transaction amounted to \$22.3 million. Cash interest is not payable on the 2018 LYONs until maturity. The 2018 LYONs are irrevocably and unconditionally guaranteed by Elan and the guarantee is subordinated to all existing and future senior indebtedness of Elan. The 2018 LYONs are exchangeable at the option of the holder thereof at any time prior to maturity, unless previously redeemed or otherwise purchased, into 13.75 Elan ADSs per each \$1,000 principal amount at maturity, representing an initial exchange price of \$38.165. The securities will be redeemable for cash by Elan at any time on or after December 14, 2003, and by the holders of the 2018 LYONs on specified dates beginning December 14, 2003. The liability outstanding as at December 31, 1998, net of financing costs, was \$841.5 million.

- 4.75% Exchangeable Notes due 2004. In November 1997, Athena, a wholly-owned subsidiary of Elan, issued 4.75% Exchangeable Notes due 2004 (the “Notes”), in the principal amount of \$325.0 million. The expenses associated with this transaction amounted to \$8.6 million. Interest on the Notes is payable in cash semi-annually. The Notes will mature on November 15, 2004. The Notes are irrevocably and unconditionally guaranteed by Elan and the guarantee is subordinated to all existing and future senior indebtedness of Elan. Each Note is exchangeable at the option of the holder thereof at any time prior to maturity unless previously redeemed or otherwise purchased, for Elan ADSs, at an exchange rate of 28.1516 Elan ADSs per \$1,000 principal amount of Notes. The Notes may be purchased at the option of Athena commencing on November 15, 2000.

During 1998, Elan entered into a promissory note with an initial amount of \$128.0 million, bearing interest at 7% and repayable in eight equal installments of \$16.0 million between October 1, 1998 and July 1, 2000, arising from an arrangement to acquire products. At December 31, 1998, the balance outstanding, including accrued interest, amounted to \$114.0 million.

At December 31, 1998, Elan had a short-term loan of \$35.0 million included in bank loans and short-term debt. The loan consisted of a reverse repurchase agreement with an external fund manager against US treasury bills as collateral. The loan was repaid in early January 1999.

In November 1997, Elan International Finance, Limited (“EIF”), a wholly-owned subsidiary of Elan, redeemed all outstanding 2012 LYONs issued in October 1992. During the year up to redemption, a total of 14.2 million Elan ADSs were issued on exchange of the 2012 LYONs in the principal amount of \$326.2 million at maturity and the remaining 2012 LYONs in the principal amount of \$51,000 were redeemed for cash on November 30, 1997.

Cash and cash equivalents at December 31, 1998 amounted to \$819.9 million compared to \$316.7 million at December 31, 1997. Cash flow from operating activities amounted to \$62.5 million for 1998 compared to \$108.2 million for 1997. Cash expended to acquire tangible and intangible fixed assets amounted to \$254.6 million for 1998 compared to \$59.2 million for 1997 primarily reflecting product acquisitions during 1998 and the development of the Company’s marketing and research infrastructures. Cash expended to acquire investments of \$174.6 million for 1998 compared to \$115.5 million for 1997 primarily reflects investments in emerging pharmaceutical and biotechnology companies. Cash paid for acquisitions in 1998 of \$264.7 million primarily reflects cash paid for the Carnrick and NanoSystems acquisitions. During 1998, Elan had cash inflow from financing activities of \$1,025.5 million primarily reflecting net proceeds of \$840.2 million on the issue of the 2012 LYONs and proceeds from the issue of share capital on the exercise of stock options and warrants of \$166.3 million primarily reflecting the expiry of warrants in August 1998 issued in connection with the funding of ATS.

At December 31, 1998, Elan had a number of commitments and contingencies as outlined in Elan’s Consolidated Financial Statements. Elan has committed, under certain circumstances, to purchase up to \$70.0 million of zero coupon convertible senior notes due 2008 from Ligand.

Elan anticipates that its capital expenditure on property, plant and equipment for 1999 will be similar to the 1998 level of \$65.5 million.

During 1998, Elan incurred research and development expenditure of \$143.5 million developing its product candidates. Elan anticipates that its overall spending on research and development for 1999 may equal or exceed the 1998 level.

Axogen, Neuralab and ATS have each positively affected Elan's results of operations and liquidity by paying for research and development activities. The more rapid than expected utilization of funds by Axogen and ATS reflects the greater than expected level of research and development activity undertaken by these entities. To the extent that Elan would have undertaken the same level of research and development activities in the absence of the third party funding by Axogen, Neuralab and ATS, all the revenues received from Axogen, Neuralab and ATS have positively affected Elan's results of operations and liquidity. Elan does not consider that the exhaustion of funds from these companies will have a material effect on Elan's future profitability or liquidity. Elan expects that revenues from these companies will be replaced by other third party revenues. However, there can be no assurance that Elan will be able to replace such funding by other third party revenues.

Treasury activities, which do not operate as a profit center, are managed centrally in accordance with Elan's treasury policy as approved by the Board of Directors. The company uses derivative financial instruments primarily to reduce exposures to market fluctuations in foreign exchange rates. Elan does not enter into derivative financial instruments for trading or speculative purposes.

Elan believes that its current manufacturing, research, product development and corporate facilities are adequate for its current and projected needs. Elan will use its capital to make such capital expenditures as are necessary from time to time, to make such investments in the purchase or licensing of products, companies and technologies and to make investments in marketing and other alliances with third parties to support Elan's long-term strategic objectives.

Post Balance Sheet Events: On February 3, 1999, Elan entered into a \$325.0 million senior unsecured revolving credit facility with a group of financial institutions, as lenders, and Merrill Lynch International, as lead arranger. The credit facility provides for revolving borrowings by the company and certain of its subsidiaries from time to time. Borrowings under the credit facility bear interest at LIBOR, the London Interbank Offered Rate, plus a borrowing margin of between 0.4% and 2.0% depending on Elan's credit rating at the time of any such borrowing or, in certain circumstances, on the date of repayment of the borrowing. The credit facility will expire on February 3, 2002, unless terminated sooner upon an event of default. The expiration date of the credit facility may be extended by mutual agreement of Elan and the lenders under the credit facility. Borrowings under the credit facility are guaranteed by Elan and certain of its subsidiaries. The credit facility contains customary covenants that restrict the Company and its subsidiaries from taking certain actions and that require the Company to achieve and maintain certain financial ratios.

Elan expects to complete the sale of a portfolio of equity and debt instruments to a special purpose entity ("SPE") during August 1999. The sales proceeds are expected to be \$285.0 million. There is expected to be no gain or loss arising on this sale. On June 29, 1999, the SPE issued \$350.0 million aggregate principal amount of senior guaranteed notes due June 2002 in a private placement to a group of financial institutions. The senior notes are guaranteed on a subordinated basis by Elan. The purpose of the SPE is for Elan to raise cash through the sale of an investment portfolio. The SPE is governed by an independent board of directors. Decision making power over the SPE rests with its board of directors. Elan carries out administrative functions on behalf of the SPE's board of directors. The SPE is a bankruptcy-remote wholly owned subsidiary of Elan.

Year 2000

The advent of the Year 2000 may negatively impact Elan's business systems and processes if Elan is unable to adequately address Year 2000 date transition problems.

In 1997, Elan commenced a Year 2000 project, led by our Year 2000 Project Office, to address the identification, evaluation and implementation of changes to computer systems and applications and to equipment with embedded chips necessary to achieving a Year 2000 date conversion compliance. The goal of the Year 2000 project is to ensure that our systems and applications will recognize and process the Year 2000 and beyond.

Using both internal and external resources, an inventory of all critical systems and processes has been prepared, the impact of Year 2000 non-compliance has been assessed and plans have been developed to remediate or replace non-compliant systems and processes and to assess the readiness of key third parties. The inventory and assessment phases are complete and remediation or replacement of material Year 2000 non-compliant systems and processes is underway. Currently, all critical conversion efforts are expected to be completed prior to September 1, 1999. This expectation has been derived utilizing numerous assumptions of future events, including the availability of certain resources, third party modification plans and other factors. Elan cannot provide any assurance, however, that timely completion will be achieved and actual results could differ materially from those anticipated.

In addition to the risks associated with our internal systems, the Company has relationships with, and is to varying degrees dependent upon, third parties that provide us with information, goods and services. Programs have been installed to contact key third parties, assess their level of Year 2000 compliance, including the extent to which Elan is vulnerable to any third party's failure to achieve Year 2000 compliance for their own systems, and address any non-compliance issues.

Although our Year 2000 Project is designed to significantly reduce Elan's exposure to Year 2000 compliance problems, Elan cannot provide any assurance that the Company or key third parties from whom information, goods or services are received will adequately address these problems. If Elan or key third parties fail to address material Year 2000 problems, the result could be a failure of or interruption to normal business operations. Any failure or interruption could cause the company to lose revenue or incur significant costs.

A formal methodology for contingency planning has been established and external consultants have been appointed to work with all business units to develop contingency and business continuation plans in the event of the failure of business systems and processes due to Year 2000. Final contingency plans are expected to be completed by September 30, 1999.

Management believes that the incremental future costs of addressing these issues will not materially effect Elan's consolidated financial position, liquidity or results of operations.

Euro

On May 3, 1998, the European Council of Economic and Finance Ministers announced the irrevocable fixing of currency exchange rates for the 11 members of the European Union eligible and willing to accede to Economic and Monetary Union, and the creation of a new European currency (the "Euro"). From January 1, 1999, the exchange rate between the Irish pound and the Euro is irrevocably fixed at 0.7876 Irish pounds per Euro. Elan believes that the introduction of the Euro will not have a material impact on its consolidated financial position, liquidity or results of operations.

Prospective Information

In 1998, Elan derived revenues from sales of products protected by patent (e.g. Cardizem CD, Verelan and Permax) or through regulatory exclusivity (e.g. Zanaflex and Naprelan). Certain products face exposure from generic competition during the next several years. Generic forms of Verelan were launched in May 1999 and a generic form of Cardizem CD was recently launched. Naprelan and Permax may face generic competition in the near- to medium-term. The sudden loss of or significant reduction in demand for these products could adversely affect Elan. There can be no assurance that Elan's products will continue to be accepted in the marketplace or that Elan will be successful in developing and marketing new products.

Future results are likely to be affected by many factors not limited to but including (i) Elan's ability to successfully develop and market or license products and technologies in its development pipeline, (ii) Elan's ability to continue to successfully market current products and technologies in an industry characterized by intense competition, including generic competition, and increasing pricing pressure, (iii) Elan's ability to successfully integrate and manage acquired businesses and products, (iv) Elan's ability to comply with government regulation, including FDA regulations, as they apply to companies in the pharmaceutical industry, and (v) Elan's ability to attract and retain high caliber employees in all areas of its business. Elan cannot provide any assurance that these factors will not have a material adverse impact on Elan's business, consolidated financial position, liquidity or results of operations.

Inflation

Inflation had no material impact on Elan's operations during 1998.

Forward-looking Statements

This Annual Report on Form 20-F contains certain forward-looking statements (as defined in Section 21E of the United States Securities Exchange Act of 1934, as amended, and Section 27A of the United States Securities Act of 1933, as amended) with respect to the financial condition, results of operations and business of Elan and certain of the plans and objectives of management of Elan with respect thereto. Such statements include, but are not limited to, statements concerning economic, competitive, governmental, technological and other factors discussed or implied under "Item 1. Description of Business", "Item 9. Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Item 9A. Quantitative and Qualitative Disclosures About Market Risk."

The foregoing Year 2000 discussion and the information contained herein is provided as a 'Year 2000 Readiness Disclosure' as defined in the Year 2000 Information Readiness Disclosure Act of 1998 and contains 'forward-looking statements' within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements, including, without limitation, anticipated costs and the dates by which Elan expects to complete certain actions, are based upon management's best current estimates, which are derived utilizing numerous assumptions about future events, including the continued availability of certain resources, representations received from third parties and other factors. However, there can be no assurance that these estimates will be achieved, and actual results could differ materially from those anticipated. Specific factors that might cause such material differences include, but are not limited to, the ability to identify and remediate all relevant systems, results of Year 2000 testing, adequate resolution of Year 2000 issues by government agencies, businesses and other third parties who provide information, products or services to Elan, unanticipated costs and the adequacy of and ability to implement contingency plans and similar uncertainties. The 'forward-looking statements' made in the foregoing Year 2000 discussion speak only as of the date on which such statements are made, and Elan undertakes no obligation to update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect occurrences of unanticipated events.

By their nature, forward-looking statements involve risk and uncertainty, and the factors described in the context of such forward-looking statements, and other factors referred to in this Annual Report on Form 20-F, could cause actual results and developments to differ materially from those expressed in or implied by such forward-looking statements.

Item 9A. *Quantitative and Qualitative Disclosures About Market Risk*

The Company is exposed to financial market risks, including changes in interest rates, foreign currency exchange rates and marketable equity security prices. The primary risks relate to marketable investment securities, primarily consisting of high grade debt securities and available for sale equity securities, and foreign exchange rate risks. The Company does not use derivative financial instruments for speculative or trading purposes.

The primary objective of investments in debt securities, consisting of commercial debt instruments and US government treasury bills, is to protect principal while at the same time maximizing returns within the parameters set forth in the Company's treasury policy. The Company's debt securities are largely managed by external independent fund managers. The Company's treasury policy is to invest in high grade instruments with low credit risk. To mitigate certain of these risks, the Company utilizes derivative financial instruments. Elan's portfolio of debt securities at December 31, 1998 consisted of trading debt securities of \$2.6 million and held to maturity securities of \$36.3 million as outlined in Note 3 of the Consolidated Financial Statements. As the Company has the positive ability and intent to hold fixed income held to maturity securities until maturity, they are not subject to market risk from fluctuations in interest rates. Trading debt securities of \$2.6 million had a duration of 1.41 years. A duration of 1.41 years means that for a 1% rise in interest rates the value of the trading debt securities would fall by 1.41% in value. Thus a 1% rise in interest rates would not materially affect the value of Elan's trading debt securities.

The Company is exposed to equity price risks primarily on its available for sale securities which consist of a number of equity investments in quoted companies. At December 31, 1998, available for sale securities and trading equity securities were carried at a fair value of \$159.0 million and had a cost of approximately \$203.9 million. These investments are primarily in emerging pharmaceutical and biotechnology companies. A 10% adverse change in equity prices would result in an approximate \$15.9 million decrease in the fair value of the Company's available for sale equity securities.

A substantial majority of the Company's revenue, expense and capital purchasing activities are transacted in US dollars. However, the Company does enter into transactions in other currencies, primarily Irish pounds and Japanese yen. To protect against reductions in value and the volatility of future cash flows caused by changes in foreign exchange rates, the Company has established revenue and expense hedging programs and closely monitors any balance sheet exposures. Currency forward contracts and currency options are utilized in these hedging programs. The Company's hedging programs reduce, but do not entirely eliminate, the impact of foreign currency exchange rate movements. At December 31, 1998, Elan had entered into a number of forward foreign exchange contracts and foreign currency options at various rates of exchange in the normal course of business, to sell US dollars for Irish pounds and Japanese yen for US dollars, as outlined in Note 14 of the Consolidated Financial Statements. A 10% change in exchange rates would not have a material effect on the Company's consolidated financial position, liquidity, cash flows or results of operations.

Elan's primary interest rate risk exposure arises on the investment of surplus funds in high grade US debt securities. The value of these securities varies primarily with changes in US interest rates. During 1998 US federal reserve effective rates averaged 5.36%. During the first five months of 1999, US federal reserve effective rates averaged 4.75%. While it is difficult to predict future movements in interest rates, management anticipates that US interest rates will remain stable over the next 12 months.

Elan's primary foreign exchange risk relates to movements in rates between the US dollar and the Irish pound and between the US dollar and the Japanese yen on expenses in Irish pounds and revenues in Japanese yen, respectively.

During 1998, average rates were IR£0.7022=US\$1 while during the first five months of 1999 average rates were IR£0.7176=US\$1. Elan sells US dollars to buy Irish pounds in order to pay for Irish pound costs. The strengthening of the US dollar against the Irish pound will result in a lower reported cost related to Elan's Irish pound cost base in 1999 compared to 1998. While it is difficult to predict future movements in foreign currency exchange rates, management anticipates that the Irish pound will be at similar or weaker levels against the US dollar during 1999.

During 1998, average rates were ¥130.7=US\$1 while during the first five months of 1999 average rates were ¥118.0=US\$1. Elan sells Japanese yen to buy US dollars out of revenues derived in Japanese Yen. The strengthening of the Japanese yen against the US dollar will result in higher reported revenues related to Elan's Japanese yen revenues in 1999 compared to 1998. While it is difficult to predict future movements in foreign currency exchange rates, management anticipates that the Japanese yen will strengthen against the US dollar during 1999.

In December 1998 and November 1997, the Company issued the 2018 LYONs and the Notes, respectively. The interest rate on these securities is fixed and therefore not subject to interest rate risk.

All of the potential changes noted above are based on sensitivity analyses performed on the Company's financial positions at December 31, 1998. Actual results may differ materially.

Item 10. Directors and Officers of Registrant.

The following table provides information concerning the current directors and officers of Elan.

<u>Name</u>	<u>Position with Elan</u>	<u>Age on May 28, 1999</u>
Donal J. Geaney	Chairman, Chief Executive Officer and Director	48
John Groom	President, Chief Operating Officer and Director	61
Thomas G. Lynch	Executive Vice President, Chief Financial Officer and Director	42
William F. Daniel	Group Vice President, Finance, Group Controller and Principal Accounting Officer	47
Paul Goddard, Ph.D.	President, Elan Pharmaceuticals	49
Lisabeth F. Murphy	Executive Vice President, Intellectual Property and Legal Affairs	42
Mark A. Pearson	Secretary	45
Garo H. Armen, Ph.D.	Director	46
Brendan E. Boushel	Director	69
Laurence G. Crowley	Director	62
Alan R. Gillespie, Ph.D.	Director	48
Kieran McGowan	Director	56
Kevin McIntyre, M.D.	Director	63
Kyran McLaughlin	Director	54
Dennis J. Selkoe, M.D.	Director	55
Richard Thornburgh	Director	66
Daniel P. Tully	Director	67

Donal J. Geaney holds the positions of Chairman and Chief Executive Officer of Elan. Mr. Geaney was appointed Chairman in January 1997 and Chief Executive Officer in January 1995. In April 1992, Mr. Geaney was elected to Elan's Board of Directors and subsequently assumed the positions of President and Chief Operating Officer. From 1989 to 1993, Mr. Geaney held the position of Chief Financial Officer of Elan. Mr. Geaney joined Elan in 1987 as Executive Vice President — Corporate Planning. Prior to joining Elan, Mr. Geaney was a partner in the international accounting firm of KPMG. Mr. Geaney was appointed Chairman of the Board of the Irish Aviation Authority in May 1998.

John Groom joined Elan in July 1996 as Chief Operating Officer and director following its acquisition of Athena where he was President, Chief Executive Officer and a director from 1987. From 1960 to 1985, he was employed by Smith Kline & French Laboratories International, the pharmaceutical division of the former SmithKline Beckman Corporation. He retired as President of Smith Kline & French Laboratories International in 1985. He also served as Chairman of the International Section of the Pharmaceutical Manufacturers Association. Mr. Groom serves on the Boards of Directors of IDEC Pharmaceuticals Corporation and Ligand Pharmaceuticals Incorporated. He is a fellow of the Association of Certified Accountants (UK), and also a public trustee on the Board of Directors of the American Academy of Neurology Education and Research Foundation.

Thomas G. Lynch joined Elan in May 1993 as Executive Vice President and Chief Financial Officer. In June 1997, Mr. Lynch was appointed a director. Prior thereto, Mr. Lynch was a partner in the international accounting firm of KPMG, where he specialized in the provision of international corporate financial services. Mr. Lynch is also a director of Axogen Limited, Warner Chilcott, plc, Nanogen Incorporated and Icon, plc.

William F. Daniel joined Elan in March 1994 as Group Financial Controller. In July 1996, he was appointed Group Vice President, Finance, Group Controller and Principal Accounting Officer. From 1990 to 1992, Mr. Daniel was Financial Director of Xtravision, plc. From 1984 to 1990, Mr. Daniel was Chief Accountant and Chief Financial Officer of the Irish Post Office.

Paul Goddard, Ph.D., joined Elan in August 1998 following its acquisition of Neurex. He was appointed President, Elan Pharmaceuticals, in August 1998. He joined Neurex as Chief Executive Officer in March 1991 and assumed the position of Chairman of the Board in October 1991. Before joining Neurex, he worked at SmithKline Beecham Corporation, and its predecessors, where he was Senior Vice President and Director of the Japan/Pacific region. He is also a director of Molecular Devices Corporation, Ribi ImmunoChem Research, Inc. and Onyx Pharmaceuticals, Inc.

Lisabeth F. Murphy was appointed Executive Vice President, Intellectual Property and Legal Affairs in January 1999. Ms. Murphy joined Elan as Vice President and General Counsel in July 1996 following Elan's acquisition of Athena where she served as Vice President, Legal Affairs, General Counsel and Secretary since May 1991. Prior to joining Athena, Ms. Murphy was counsel to the law firm of McCutchen, Doyle, Brown & Enersen. She is a director of Cytel Corporation.

Mark A. Pearson was appointed the Secretary of Elan in December 1996. Mr. Pearson is a partner in the Irish law firm of McCann FitzGerald and specializes in the area of company and corporate law. Mr. Pearson, who qualified as a solicitor in 1979, joined McCann FitzGerald in 1976.

Garo H. Armen, Ph.D., was appointed a director of Elan in February 1994. He has been Chairman and Chief Executive of Antigenics, LLC. since its incorporation in 1994. Dr. Armen also serves as Managing General Partner of Armen Partners, L.P., an investment partnership which specializes in health care companies. Previously, Dr. Armen was with Dean Witter Reynolds as Senior Vice President of Research and with E.F. Hutton & Company as First Vice President, Research.

Brendan E. Boushel was appointed a director of Elan in January 1980. From 1966 until his retirement in 1994, Mr. Boushel was a partner in the Irish law firm of T.T.L. Overend McCarron & Gibbons. Mr. Boushel also holds a number of private company directorships.

Laurence G. Crowley was appointed a director of Elan in March 1996. He is a director of the Bank of Ireland and Executive Chairman of the Graduate Business School of University College, Dublin. He is presently a director of Rothmans International, plc and is Chairman of PJ Carroll & Co., its Irish subsidiary. Before that, he was a partner in the international accounting firm of KPMG.

Alan R. Gillespie, Ph.D., was appointed a director of Elan in March 1996. He is a Managing Director of Goldman Sachs International. Before that, Dr. Gillespie worked at Citicorp in London and Geneva, specializing in capital markets. He is presently Chairman of the Industrial Development Board for Northern Ireland.

Kieran McGowan was appointed a director of Elan in December 1998. From 1994 until his retirement in December 1998, he was Chief Executive of IDA Ireland, having been Managing Director of its predecessor, the Industrial Development Authority, since 1990. He is a director of CRH, plc, Irish Life and Permanent, plc, United Drug, plc, Enterprise Ireland and of An Post National Lottery Company Ltd and is Chairman of the Irish Management Institute.

Kevin McIntyre, M.D., was appointed a director of Elan in February 1984. He is an Associate Clinical Professor of Medicine, Harvard Medical School, and has served as a consultant to the National Academy of Sciences.

Kyran McLaughlin was appointed a director of Elan in January 1998. Since 1985 he has been joint-Chief Executive of Davy Stockbrokers, Ireland's largest stockbroker firm. At Davy Stockbrokers, Mr. McLaughlin is responsible for corporate finance and equity dealing operations.

Dennis J. Selkoe, M.D., joined the Board of Directors of Elan in July 1996 following Elan's acquisition of Athena where he served as a director since July 1995. Dr. Selkoe was a founder of, and consultant to, Athena. Dr. Selkoe, a neurologist, is a Professor of Neurology and Neuroscience at Harvard Medical School where he has been a member of the faculty since 1978. He also serves as co-director of the Center for Neurologic Disease at Brigham and Women's Hospital.

The Honorable Richard Thornburgh was appointed a director of Elan in March 1996. He served as Governor of Pennsylvania for two terms and as Attorney General of the US from 1988 to 1991. He is presently of counsel to the law firm of Kirkpatrick & Lockhart LLP, in Washington D.C.

Daniel P. Tully was appointed a director of Elan in February 1999. He is Chairman Emeritus of Merrill Lynch & Co., Inc., where he served as Chairman of the Board from 1993 to 1997, and was its Chief Executive Officer from 1992 to 1996. He served as vice chairman of the NYSE from 1994 to 1995, vice chairman of the American Stock Exchange from 1984 to 1986 and Chairman of the Board of Governors of the National Association of Securities Dealers.

One third of the directors (excluding the Chairman of the Board) retire annually by rotation. Directors serve until they or their successors have been elected and qualified. Officers serve at the discretion of the Board of Directors. Directors of Elan are compensated at the rate of \$30,000 per annum (with additional payments where directors are members of Board committees) and are reimbursed for travel expenses to and from board meetings.

Item 11. Compensation of Directors and Officers.

For the year ended December 31, 1998, all officers and directors during that year as a group (15 persons) received total compensation of \$3,381,809.

Elan reimburses officers and directors for their actual business-related expenses. For the year ended December 31, 1998, an aggregate of \$152,961 was set aside or accrued by Elan to provide pension, retirement and other similar benefits for directors and officers. Elan maintains a health and medical benefit plan for its employees in which Elan's officers participate along with other employees generally.

Item 12. Options to Purchase Securities from Registrant or Subsidiaries.

At May 31, 1999, there were total options and warrants outstanding to purchase 53,716,612 Ordinary Shares. The exercise prices for these options and warrants ranged from \$4.96 to \$45.00 per share and the expiration dates for exercise were from June 1999 to May 2007. Of the options outstanding at May 31, 1999, 5,400,232 were held as a group by directors and officers of Elan.

The options and warrants outstanding at May 31, 1999 were as follows:

	Options		Warrants	
	Shares	Range	Shares	Range
Outstanding at May 31, 1999	36,463,092	\$4.96-\$38.34	17,253,520	\$14.31-\$45.00

Item 13. Interest of Management in Certain Transactions.

Not applicable.

PART II

Item 14. *Description of Securities to be Registered.*

Not applicable.

PART III

Item 15. *Defaults Upon Senior Securities.*

Not applicable.

Item 16. *Changes in Securities and Changes in Security for Registered Securities.*

On May 14, 1999, the authorized value of Ordinary Shares and 'B' Executive Shares was changed from four Irish pence to five Euro cents. The authorized value of Executive Shares was changed from one Irish pound to 1.25 Euros.

A two-for-one stock split became effective on June 7, 1999 resulting in one additional share being issued to shareholders for each share held by shareholders of record on May 27, 1999.

PART IV

Item 17. *Financial Statements.*

Not applicable.

Item 18. *Financial Statements.*

REPORT OF INDEPENDENT CHARTERED ACCOUNTANTS

To the Directors and Shareholders of Elan Corporation, plc

We have audited the accompanying consolidated balance sheets of Elan Corporation, plc and subsidiaries as of December 31, 1998 and December 31, 1997, and the related consolidated statements of income, comprehensive income, cash flows and shareholders' equity for the years ended December 31, 1998 and 1997, and the nine month period ended December 31, 1996. In connection with our audits of the consolidated financial statements, we have also audited the related financial statement schedule. These consolidated financial statements and financial statement schedule are the responsibility of the Company's directors and management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Elan Corporation, plc and subsidiaries at December 31, 1998 and December 31, 1997, and the results of their operations and their cash flows for the years ended December 31, 1998 and 1997, and the nine month period ended December 31, 1996, in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the related financial statement schedule when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

KPMG
Chartered Accountants

Dublin, Ireland
March 8, 1999 (except for Note 28,
as to which the date is June 7, 1999
and Note 29, as to which the date is
August 4, 1999)

ELAN CORPORATION, plc AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	Notes	At December 31, 1998 \$000s	At December 31, 1997 \$000s
ASSETS			
Current Assets:			
Cash and cash equivalents		819,882	316,739
Marketable investment securities	3	175,857	285,847
Accounts receivable (net)	4	200,062	86,465
Inventories	5	98,674	40,889
Prepayments		20,209	11,159
Total current assets		<u>1,314,684</u>	<u>741,099</u>
Marketable investment securities	3	22,016	13,909
Investments	6	212,474	152,384
Property, plant and equipment (net)	7	196,717	118,372
Intangible assets (net)	8	734,860	188,713
Deferred tax (net of valuation allowance of \$61,362,000; December 31, 1997: \$34,444,000)	9	—	—
Total assets	17	<u><u>2,480,751</u></u>	<u><u>1,214,477</u></u>
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current Liabilities:			
Accounts payable		35,833	30,043
Accrued and other liabilities	10	198,745	35,334
Total current liabilities		<u>234,578</u>	<u>65,377</u>
Other Liabilities:			
Long term debt		73,493	—
3.25% Zero coupon subordinated exchangeable notes	11	863,746	—
4.75% Exchangeable notes	12	325,000	325,000
		<u>1,262,239</u>	<u>325,000</u>
Shareholders' Equity:			
Ordinary shares, par value 4 Irish pence per share; 600,000,000 and 300,000,000 shares authorized at December 31, 1998 and 1997, respectively; 264,047,484 and 208,282,120 shares issued and outstanding at December 31, 1998 and 1997, respectively		16,300	13,170
Executive shares, par value one Irish pound per share; 1,000 shares authorized; 1,000 shares issued and outstanding at December 31, 1998 and 1997	16	2	2
'B' Executive shares, par value 4 Irish pence per share, 25,000 shares authorized; 21,375 shares issued and outstanding at December 31, 1998 and 1997	16	2	2
Additional paid-in capital		2,479,090	1,060,961
Warrant subscription receivable		(4,749)	(8,544)
Equity adjustment from foreign currency translation		(33,872)	(29,206)
Unrealized (loss) gain on available for sale securities (net)	3	(44,948)	44,993
Retained earnings		(1,427,891)	(257,278)
Shareholders' equity		<u>983,934</u>	<u>824,100</u>
Commitments and contingencies (notes 11, 12, 14 and 22)			
Total liabilities and shareholders' equity		<u><u>2,480,751</u></u>	<u><u>1,214,477</u></u>

The accompanying notes are an integral part of these consolidated financial statements.

ELAN CORPORATION, plc AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF INCOME

	Notes	Year ended December 31, 1998 \$000s	Year ended December 31, 1997 \$000s	9 Months ended December 31, 1996 \$000s
Revenues:				
Product sales		342,078	215,486	117,973
License fees		207,473	64,049	34,574
Royalties		31,660	46,857	37,363
Research revenues		95,523	57,789	45,649
Total revenues	17	<u>676,734</u>	<u>384,181</u>	<u>235,559</u>
Costs and expenses:				
Cost of goods sold		137,935	106,182	62,499
Selling, general and administrative		155,869	71,764	41,463
Research and development		143,536	75,160	54,495
Other charges:				
Acquisition of in-process research and development . . .	2	1,311,149	—	571,839
Rationalization and integration	2, 19	41,747	—	—
Loss on sale of business	19, 20	3,322	—	18,026
Contribution to Axogen Limited	19	67,500	—	—
Cost of fundamental restructuring	20	—	—	70,000
Total operating expenses		<u>1,861,058</u>	<u>253,106</u>	<u>818,322</u>
Operating (loss) income	17	<u>(1,184,324)</u>	<u>131,075</u>	<u>(582,763)</u>
Interest and other income		46,457	53,291	22,521
Interest expense		(23,578)	(5,843)	(6,743)
Share of losses from investments accounted for under the equity method		(5,256)	(7,458)	(5,147)
Minority interests		<u>(38)</u>	<u>260</u>	<u>338</u>
(Loss) income before provision for income taxes		<u>(1,166,739)</u>	<u>171,325</u>	<u>(571,794)</u>
Provision for income taxes	9	<u>(3,874)</u>	<u>(1,186)</u>	<u>(774)</u>
Net (loss) income		<u>(1,170,613)</u>	<u>170,139</u>	<u>(572,568)</u>
Basic (loss) / earnings per share	28	<u>(\$4.91)</u>	<u>\$0.86</u>	<u>(\$3.21)</u>
Diluted (loss) / earnings per share	28	<u>(\$4.91)</u>	<u>\$0.77</u>	<u>(\$3.21)</u>

The accompanying notes are an integral part of these consolidated financial statements.

ELAN CORPORATION, plc AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

	Year ended December 31, 1998 \$000s	Year ended December 31, 1997 \$000s	9 Months ended December 31, 1996 \$000s
Net (loss) income	<u>(1,170,613)</u>	<u>170,139</u>	<u>(572,568)</u>
Other comprehensive income:			
Foreign currency translation adjustment	(4,666)	(19,837)	(1,025)
Unrealized (losses) gains on securities	(89,941)	11,409	20,126
Reclassification adjustment for gains included in net income	<u>(5,717)</u>	<u>(3,133)</u>	<u>—</u>
Other comprehensive (loss) income	<u>(100,324)</u>	<u>(11,561)</u>	<u>19,101</u>
Comprehensive (loss) income	<u><u>(1,270,937)</u></u>	<u><u>158,578</u></u>	<u><u>(553,467)</u></u>

The accompanying notes are an integral part of these consolidated financial statements.

ELAN CORPORATION, plc AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Notes	Year ended December 31, 1998 \$000s	Year ended December 31, 1997 \$000s	9 Months ended December 31, 1996 \$000s
Cash flows from operating activities:				
Net (loss) income		(1,170,613)	170,139	(572,568)
Adjustments to reconcile net (loss) income to net cash provided by operating activities:				
Acquisition of in-process research and development	2,19	1,311,149	—	571,839
Loss on sale of business	20	—	—	18,026
Depreciation and amortization		51,097	23,985	18,012
Accrued interest expense on exchangeable notes		1,220	5,201	5,632
(Gain) loss on sale of marketable investment securities		(8,370)	2,409	(761)
Other		5,732	3,764	3,961
Share of losses from investments accounted for under the equity method		5,256	7,458	5,147
Write down of assets		20,412	4,975	—
Gain on disposal of certain product rights		—	(10,066)	—
Net changes in assets and liabilities:				
(Increase) decrease in receivables		(99,193)	(33,191)	5,086
(Increase) decrease in inventories		(32,114)	(22,649)	1,085
(Decrease) increase in accounts payable and accruals		(22,062)	(43,779)	34,013
Net cash provided by operating activities		<u>62,514</u>	<u>108,246</u>	<u>89,472</u>
Cash flows from investing activities:				
Proceeds from disposal of property, plant and equipment		528	4,614	4,173
Purchase of property, plant and equipment		(65,542)	(37,685)	(20,926)
Purchase of investments		(174,605)	(115,548)	(67,995)
Proceeds from disposal of investments		47,487	35,420	—
Purchase of marketable investment securities		(377,249)	(323,915)	(213,448)
Sale and maturity of marketable investment securities		438,231	281,581	165,609
Repayment of short-term loan advanced to Warner Chilcott, plc		—	—	144,370
Purchase of licenses and patents		(189,039)	(21,483)	(7,375)
Minority interest in subsidiaries		—	—	(585)
Acquisition of subsidiaries primarily represented by:				
Goodwill and other intangible assets arising on acquisitions	25	(264,658)	—	(124,353)
Net cash used in investing activities		<u>(584,847)</u>	<u>(177,016)</u>	<u>(120,530)</u>
Cash flows from financing activities:				
Proceeds from sale of share capital		166,274	13,905	3,832
Repayment of loans		(19,000)	(5,026)	(3,880)
Issue of exchangeable notes		840,172	316,875	—
Bank loans		38,085	—	—
Net cash provided by (used in) financing activities		<u>1,025,531</u>	<u>325,754</u>	<u>(48)</u>
Effect of exchange rate changes on cash		(55)	(11,724)	1,377
Net increase (decrease) in cash and cash equivalents		503,143	245,260	(29,729)
Cash and cash equivalents at beginning of year/period		316,739	71,479	101,208
Cash and cash equivalents at end of year/period		<u>819,882</u>	<u>316,739</u>	<u>71,479</u>

The accompanying notes are an integral part of these consolidated financial statements.

ELAN CORPORATION, plc AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

	Number of Shares 000s	Share Capital \$000s	Additional Paid-in Capital \$000s	Warrant Sub. Receivable \$000s	Retained Earnings \$000s	Translation Adjustment \$000s	Unrealized Gain/(Loss) \$000s	Total Amount \$000s
Balance at March 31, 1996	153,676	9,746	351,445	(2,873)	145,151	(8,344)	13,458	508,583
Exercise of stock options and warrants	1,550	100	7,791	—	—	—	—	7,891
Exchange of 5.75% zero coupon subordinated exchangeable notes	3,854	246	34,076	—	—	—	—	34,322
Stock issued as a result of acquisitions	32,428	2,076	511,857	—	—	—	—	513,933
Issue costs	—	—	(4,059)	—	—	—	—	(4,059)
Warrant subscription — Axogen . . .	—	—	14,280	(14,280)	—	—	—	—
Equity adjustment from foreign currency translation	—	—	—	—	—	(1,025)	—	(1,025)
Unrealized gain (net) on available for sale securities	—	—	—	—	—	—	20,126	20,126
Collection of warrant subscription receivable	—	—	—	3,992	—	—	—	3,992
Net loss	—	—	—	—	(572,568)	—	—	(572,568)
Balance at December 31, 1996	191,508	12,168	915,390	(13,161)	(427,417)	(9,369)	33,584	511,195
Exercise of stock options and warrants	1,434	86	9,990	—	—	—	—	10,076
Exchange of 5.75% zero coupon subordinated exchangeable notes	14,202	852	131,626	—	—	—	—	132,478
Stock issued as a result of acquisitions	1,138	68	5,701	—	—	—	—	5,769
Issue costs	—	—	(1,746)	—	—	—	—	(1,746)
Equity adjustment from foreign currency translation	—	—	—	—	—	(19,837)	—	(19,837)
Unrealized gain (net) on available for sale securities	—	—	—	—	—	—	11,409	11,409
Collection of warrant subscription receivable	—	—	—	4,617	—	—	—	4,617
Net income	—	—	—	—	170,139	—	—	170,139
Balance at December 31, 1997	208,282	13,174	1,060,961	(8,544)	(257,278)	(29,206)	44,993	824,100
Exercise of stock options and warrants	19,316	1,088	180,279	—	—	—	—	181,367
Stock issued as a result of acquisitions	36,450	2,042	1,231,740	—	—	—	—	1,233,782
Warrant issued as result of acquisition	—	—	16,400	—	—	—	—	16,400
Issue costs	—	—	(15,040)	—	—	—	—	(15,040)
Warrant subscription — Neuralab . .	—	—	4,750	(4,750)	—	—	—	—
Equity adjustment from foreign currency translation	—	—	—	—	—	(4,666)	—	(4,666)
Unrealized (loss) on available for sale securities (net)	—	—	—	—	—	—	(89,941)	(89,941)
Collection of warrant subscription receivable	—	—	—	8,545	—	—	—	8,545
Net loss	—	—	—	—	(1,170,613)	—	—	(1,170,613)
Balance at December 31, 1998	<u>264,048</u>	<u>16,304</u>	<u>2,479,090</u>	<u>(4,749)</u>	<u>(1,427,891)</u>	<u>(33,872)</u>	<u>(44,948)</u>	<u>983,934</u>

The accompanying notes are an integral part of these consolidated financial statements.

ELAN CORPORATION, plc AND SUBSIDIARIES
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

The accounting policies followed in the preparation of the accompanying consolidated financial statements are in conformity with generally accepted accounting principles in the United States (“US”).

(a) Basis of Consolidation

The consolidated financial statements include the financial statements of Elan Corporation, plc and all of its subsidiaries (“Elan” or the “Company”), and the Company’s share of profits or losses from investments accounted for under the equity method. All significant intercompany profits, transactions and account balances have been eliminated.

(b) Description of Business

Elan is a leading worldwide specialty pharmaceutical company headquartered in Dublin, Ireland. Elan’s principal activities are the discovery, development, manufacturing and marketing of pharmaceutical products and technologies. Elan’s principal research and development, manufacturing and marketing facilities are located in Ireland, the US and Israel. Elan’s shares trade on the New York, London and Irish Stock Exchanges.

(c) Cash and Cash Equivalents

Cash and cash equivalents include cash and highly liquid investments with initial maturities of three months or less.

(d) Marketable Investment Securities

The Company has classified long and short-term marketable investment securities and certain investments as either held to maturity, trading or available for sale in accordance with the terms of Statement of Financial Accounting Standard (“SFAS”) No. 115 “Accounting for Certain Investments in Debt and Equity Securities” and any realized/unrealized gains or losses are recorded in accordance with this statement. Realized gains and losses are determined using specific identification.

(e) Inventories

Inventories are valued at the lower of cost or market value on a first-in, first-out basis. Cost in the case of raw materials and supplies comprises the purchase price and attributable direct costs, less trade discounts. Cost in the case of work-in-process and finished goods comprises direct labor and material costs, and attributable overheads. Cost in the case of product inventory comprises direct materials, labor and external services incurred in connection with the registration of licensable products with regulatory agencies in various jurisdictions.

(f) Investments

An investment is recorded under the cost method unless the Company’s investment in the investee’s voting stock provides the Company with the ability to exercise significant influence over the operating and financial policies of the investee. Significant influence may exist even if the Company owns less than 20%, or may be absent even if the company owns more than 20%, of the investee’s voting stock depending on the existence or lack of factors such as representation on the board of directors of the investee, participation in policy making processes, material intercompany transactions, interchange of managerial personnel or technological dependency. Certain circumstances, such as majority ownership by another company, can offset

ELAN CORPORATION, plc AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

the impact of such factors. The circumstances surrounding an individual investment require a significant level of judgment in determining the use of cost or equity accounting. The percentage of voting stock held by Elan is determined in accordance with Accounting Principles Board Opinion No. 18, which evaluates the percentage of voting securities owned without considering potential effects of other voting securities that may be acquired through the exercise of conversion rights or options. Elan equity accounts for all investments in which it owns 20% or more of the voting interest.

Investments which are accounted for under the cost method are stated at cost, less provisions for other than temporary impairment in value. Investments which are accounted for under the equity method are stated at cost, less provisions for other than temporary impairments in value and adjusted for the Company's share of the earnings or losses of the investee after the date of investment.

Impairment is assessed by reference to the fair value of the securities as determined using established financial methodologies, including quoted market values, where available. The fair value of investments in private entities and non-traded securities of public entities are measured by valuation methodologies including discounted cash flows and option pricing models.

Factors considered in evaluating whether a decline in value is other than temporary include the period of time for which a security has declined in value, the volatility of the security's historical prices, the nature of the public market for similar securities and whether there has been any fundamental change to the assets underlying the securities.

(g) Property, Plant and Equipment

Property, plant and equipment are stated at cost less accumulated depreciation. Depreciation of property, plant and equipment is computed using the straight line method based on estimated useful lives at the following annual rates:

	<u>%</u>
Buildings	2.5 — 3.3
Plant, equipment and other	10 — 25

(h) Intangible Assets

Patents and licenses are stated at the lower of cost or valuation and are amortized over their expected useful lives. Costs incurred in connection with the raising of long-term debt finance are amortized over the period of the financing. Goodwill and other assets arising on acquisition, such as workforce, technology, products rights and customers, are written off over the period during which the benefits are expected to accrue from such assets, which ranges from 6 to 40 years (the weighted average amortization period for goodwill is 18 years). Where events or circumstances are present which indicate that the carrying amount of an intangible asset may not be recoverable, the Company estimates the future undiscounted cash flows expected to result from use of the asset and its eventual disposition. Where future undiscounted cash flow is less than the carrying amount of the asset, the Company will recognize an impairment loss. This impairment loss is measured by comparing the fair value of the asset with its carrying value. Otherwise no loss is recognized.

(i) Taxation

Corporation tax is provided on the results for the year.

The Company applies SFAS No. 109 "Accounting for Income Taxes", which requires the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are

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recognized for the future tax consequences attributable to differences between the financial statements carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which these temporary differences are expected to be recovered or settled.

(j) Derivative Financial Instruments

Derivative financial instruments are utilized to hedge interest rate and currency exposures. Forward currency contracts and options are utilized to hedge against transaction exposures and are recognized in income simultaneously with the net income effect of the related transactions generating such risks. The carrying values of derivative financial instruments are generally reported within other current assets or other current liabilities.

Interest rate futures are utilized within the Company's marketable investment securities portfolio to protect against declines in security values. Unrealized gains or losses are included in income for the period.

(k) Foreign Currencies and Translation of Subsidiaries and Investments accounted for under the Equity Method

Monetary assets and liabilities denominated in currencies other than US dollars are translated into US dollars at exchange rates prevailing at the balance sheet date. Foreign exchange gains and losses are dealt with in the income statement and where material are separately disclosed.

The assets and liabilities of subsidiary undertakings are translated using year-end exchange rates and income is translated at average rates. The cumulative effect of exchange rate movements is included in shareholders' equity.

(l) Revenue Recognition

Revenue is shown net of value added tax and other sales taxes. Non-refundable royalty income and license fees are credited to the statement of income when earned, in accordance with the terms prescribed in each respective license agreement, and when the Company has no future obligations pursuant to that royalty or license fee. Refundable royalties and license fees are treated as deferred income until such time as they are no longer refundable and not subject to future obligations. Revenue from product sales is recognized upon shipment, net of applicable discounts and allowances. Research and development revenues are recognized when earned and non-refundable, in accordance with the terms prescribed in each respective development agreement.

(m) Research and Development

Research and development is charged to expense as incurred.

(n) Stock Based Compensation

Prior to April 1, 1996, the Company accounted for its stock options in accordance with the provisions of Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees", and related interpretations. As such, compensation expense would be recorded only if the current market price of the underlying stock exceeded the exercise price on the date of grant. On April 1, 1996, the Company adopted SFAS No. 123 "Accounting for Stock Based Compensation" ("SFAS No. 123"), which permits entities to recognize as expense over the vesting period the fair value of all stock-based awards on the date of grant. Alternatively, SFAS No. 123 allows entities to continue to apply the provisions of APB Opinion No. 25 and provide pro forma net income and pro forma earnings per share disclosures for employee stock option grants as

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if the fair-value-based method defined in SFAS No. 123 had been applied. The Company has elected to apply the provisions of APB Opinion No. 25 and provide the pro forma disclosure provisions of SFAS No. 123.

(o) Risks and Uncertainties

The Company is subject to certain risks and uncertainties arising from a number of factors including dependence on significant clients and key products, competition, government regulation, no assurance of continued successful licensing and marketing, uncertainty of third party reimbursement, pricing pressure, unpredictability of patent protection, risks related to the identification and development of product candidates and tax reform. Certain pharmaceutical products developed by Elan may face significant exposure from generic competition in the future. It is not possible to predict the impact of possible future competition on sales of Elan's pharmaceutical products.

(p) Use of Estimates

The preparation of the consolidated financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect reported amounts and disclosures in these financial statements. Actual results could differ from those estimates.

(q) Recently Issued Accounting Standards

As of January 1, 1998, Elan adopted SFAS No. 130, "Reporting Comprehensive Income", which establishes standards for reporting comprehensive income and its components. Total comprehensive income includes net income and other comprehensive income which for Elan comprises primarily of net unrealized gains or losses on available for sale securities and equity adjustments from foreign currency translations.

As of January 1, 1998, Elan adopted SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information" which requires disclosure of certain information on reportable segments. The Company operates in two segments, which are pharmaceuticals and drug delivery systems.

In February 1998, the Financial Accounting Standards Board ("FASB") issued SFAS No. 132, "Employers' Disclosures about Pensions and Other Post-retirement Benefits" ("SFAS No. 132") which was adopted by Elan in the financial statements for the year ended December 31, 1998. SFAS No. 132 requires revised disclosures about pension and other post-retirement benefit plans as shown in Note 24.

In June 1998, the FASB issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS No. 133") which becomes effective for Elan's financial statements beginning January 1, 2000. In 1999, the FASB proposed an amendment to defer its effective date to all fiscal quarters of all fiscal years beginning after June 15, 2000. This would be effective for Elan's financial statements beginning January 1, 2001. SFAS No. 133 requires a company to recognize all derivative instruments as assets or liabilities in its balance sheet and measure them at fair value. Elan is currently assessing the impact of this Statement.

2. Acquisitions

(a) Acquisition of NanoSystems LLC

On October 1, 1998 Elan completed the acquisition of all of the assets and liabilities of NanoSystems LLC ("NanoSystems") for \$154,899,000, including the costs of acquisition. The purchase price consisted of \$138,499,000 in cash and the issuance by Elan of warrants with an estimated fair value of \$16,400,000 to

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acquire 1,500,000 Elan American Depositary Shares (“ADSs”) at an exercise price of \$45 per Elan ADSs. The warrants are exercisable until the eighth anniversary of the closing date of the transaction. NanoSystems is engaged in the formulation and manufacturing of enhanced delivery forms of poorly water-soluble drugs using its proprietary NanoCrystal technology. Pharmaceutical and biotechnology companies sometimes terminate drug development projects due to certain drugs being poorly water-soluble. The NanoCrystals’ technology improves a drug’s water solubility by reducing its particle size. The productivity of pharmaceutical and biotechnology companies’ research and development efforts can be improved by the application of the NanoCrystals’ technology as it can reduce the number of drug development projects terminated due to poor water-solubility. NanoSystems is a party to collaborative arrangements with a number of pharmaceutical and biotechnology companies, including Merck & Co., Inc., Warner-Lambert Company, Janssen Pharmaceutica, N.V. and Wyeth-Ayerst Laboratories (“Wyeth”), a division of American Home Products Corporation (“AHP”), to develop improved formulations of both marketed products and new chemical entities. Elan accounted for the acquisition of NanoSystems using purchase accounting. As a result of the transaction, Elan incurred a charge of \$88,500,000 for the year ended December 31, 1998, representing the acquisition of in-process research and development, in accordance with Statement of Financial Accounting Standards No. 2 (“SFAS No. 2”) “Accounting for Research and Development Costs.”

The remaining portion of the purchase price was allocated to acquired technology, net tangible assets and workforce in the amount of \$55,544,000, \$10,355,000 and \$500,000, respectively.

The purchase price of \$154,899,000 for NanoSystems was allocated as follows:

	<u>\$000’s</u>
Property, plant and equipment	11,738
Intangible assets	56,044
Current assets	1,036
Accounts payable	(2,419)
In-process research and development	<u>88,500</u>
Purchase price	<u>154,899</u>

Eleven development stage products were valued as in-process research and development at the date of the acquisition of NanoSystems. These products were NanoCrystal formulations of various pharmaceutical compounds. Technological feasibility of these products was not established at the acquisition date. These products were considered to have no alternative future use other than the therapeutic indications for which they were in development. Eight of these products were in development by licensees. Two products represented approximately \$28,000,000 and \$36,000,000, respectively, of the in-process research and development charge. As both products were in development by licensees, NanoSystems’ costs to completion of these products were expected to be minimal. The first product was in Phase III clinical trials with an estimated launch date during 1999. This product was estimated to be 80% complete, estimated peak revenues to NanoSystems were approximately \$18,000,000 per annum and a discount rate of 24% was used. The second product was in Phase II clinical trials with an estimated launch date during 2001. This product was estimated to be 60% complete, estimated peak revenues to NanoSystems were approximately \$15,000,000 per annum and a discount rate of 24% was used. The work remaining to complete the development products involved research, safety and efficacy studies and the submission of regulatory filings to seek marketing approvals. The principal risks related to the development products were the outcomes of such research, clinical studies and regulatory filings. As pharmaceutical products cannot be marketed without regulatory approvals, Elan will not receive any benefits unless it receives such regulatory approval.

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(b) Acquisition of Neurex Corporation

On August 14, 1998 Elan completed the acquisition of Neurex Corporation (“Neurex”) for approximately \$810,007,000, including the costs of acquisition. Neurex has developed, and is developing, products for pain management and the acute care market, principally in the area of cardiorenal and neurological diseases. In connection with the acquisition, each outstanding share of Neurex common stock was exchanged for 1.02 Elan ADSs, resulting in the issuance of approximately 23,762,360 Elan ADSs valued at \$736,633,000. Options granted by Neurex prior to the acquisition date were converted into options to acquire 3,011,702 Elan ADSs. These options were valued in the determination of the purchase price of Neurex at \$67,147,000. Elan accounted for the acquisition of Neurex using purchase accounting. As a result of the transaction, Elan incurred a charge of \$787,100,000 for the year ended December 31, 1998, representing the acquisition of in-process research and development, in accordance with SFAS No. 2.

The purchase price of \$810,007,000 for Neurex was allocated as follows:

	<u>\$000's</u>
Property, plant and equipment	1,952
Intangible assets	14,505
Current assets	32,889
Accounts payable	(24,281)
Long-term debt	(2,158)
In-process research and development	<u>787,100</u>
Purchase price	<u>810,007</u>

Intangible assets include the value of Neurex’s assembled workforce, developed technology and goodwill. These were valued at \$900,000, \$6,200,000 and \$7,405,000, respectively. The acquired in-process research and development charge of \$787,100,000 represents the value of Neurex’s products in development at the date of acquisition. Technological feasibility of these products was not established at the acquisition date. These products were considered to have no alternative future use other than the therapeutic indications for which they were in development. The development products were estimated to be 67% complete on average, estimated peak sales were approximately \$1,072,000,000 per annum, estimated costs to completion of these products were approximately \$70,000,000 and discount rates of 24% were used. The average time to full completion of the remaining work for the products in development was estimated to be approximately 33 months. The work remaining to complete the products in development involved ongoing safety and efficacy studies and the submission of regulatory filings to seek marketing approvals. The principal risks related to the development products were the outcomes of such clinical studies and regulatory filings. As pharmaceutical products cannot be marketed without regulatory approvals, Elan will not receive any benefits unless it receives such regulatory approval.

(c) Acquisition of GWC Health, Inc.

On May 29, 1998 Elan completed the acquisition of GWC Health, Inc. (“Carnrick”) for approximately \$152,420,000, including the costs of acquisition. The purchase price consisted of \$134,420,000 in cash and the issuance of an \$18,000,000 promissory note. Carnrick markets and distributes a range of products, primarily for neurology and pain management applications, to general practitioners and pain specialists in the US and Puerto Rico. Elan accounted for the acquisition of Carnrick using purchase accounting. As a result of the transaction, Elan incurred a charge of \$19,930,000 for the year ended December 31, 1998, representing the acquisition of in-process research and development in accordance with SFAS No. 2.

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The purchase price of \$152,420,000 for Carnrick was allocated as follows:

	<u>\$000's</u>
Property, plant and equipment	7,105
Intangible assets	101,650
Current assets	41,678
Accounts payable	(16,527)
Long-term debt	(1,416)
In-process research and development	19,930
Purchase price	<u>152,420</u>

Intangible assets include the value of Carnrick's assembled workforce, marketed products and goodwill. These were valued at \$554,000, \$59,728,000 and \$40,670,000, respectively. The acquired in-process research and development charge of \$19,930,000 represents the value of Carnrick's products in development at the date of acquisition. Technological feasibility of these products was not established at the date of acquisition. These products were considered to have no alternative future use other than the therapeutic indications for which they were in development. The development products were estimated to be approximately 63% complete on average, estimated peak sales were approximately \$57,000,000 per annum, estimated costs to completion were approximately \$5,000,000 and discount rates of 22 to 23% were used. The average time to full completion of the remaining work for the products in development was estimated to be approximately 21 months. The work remaining to complete the development products involved continuing formulation activity, ongoing safety and efficacy studies and the submission of regulatory filings to seek marketing approvals. The principal risks relating to the development products were the outcomes of such formulation activity, clinical studies and regulatory filings. As pharmaceutical products cannot be marketed without regulatory approvals, Elan will not receive any benefits unless it receives such regulatory approval.

(d) Acquisition of Sano Corporation

On February 27, 1998, Elan completed the acquisition of Sano Corporation ("Sano") for approximately \$434,650,000, including the costs of acquisition. Sano primarily develops proprietary transdermal drug delivery systems. In connection with the acquisition, each outstanding share of Sano common stock was exchanged for 1.20 Elan ADSs, resulting in the issuance of approximately 12,721,722 Elan ADSs valued at \$377,040,000. Options granted by Sano prior to the acquisition date were converted into options to acquire 2,216,850 Elan ADSs. These options were valued in the determination of the purchase price of Sano at \$53,015,000. Elan accounted for the acquisition of Sano using purchase accounting. As a result of the transaction, Elan incurred a charge of \$445,065,000 in the year ended December 31, 1998, \$404,918,000 of which represented the acquisition of in-process research and development and \$40,147,000 of which represented the cost of integrating and rationalizing certain activities.

The purchase price of \$434,650,000 for Sano was allocated as follows:

	<u>\$000's</u>
Property, plant and equipment	17,128
Intangible assets	9,873
Current assets	20,633
Accounts payable	(10,101)
Long-term debt	(7,801)
In-process research and development	404,918
Purchase price	<u>434,650</u>

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Intangible assets include the value of Sano's assembled workforce, developed technology and goodwill. These were valued at \$589,000, \$1,537,000 and \$7,119,000, respectively. The acquired in-process research and development charge of \$404,918,000 represents the value of Sano's products in development at the acquisition date. Technological feasibility of these products was not established at the date of acquisition. These products were considered to have no alternative future use other than the therapeutic indications for which they were in development. The development products were estimated to be 65% complete on average, estimated peak sales were approximately \$618,000,000 per annum, estimated costs to completion were approximately \$31,000,000 and discount rates of 20% were used. The average time to full completion of the remaining work for the products in development was anticipated to be approximately 33 months. The work remaining to complete the development products involved continuing formulation activity, safety and efficacy studies and the submission of regulatory filings to seek marketing approvals. The principal risks to the development products were the outcomes of such formulation activity, clinical studies and regulatory filings. As pharmaceutical products cannot be marketed without regulatory approvals, Elan will not receive any benefits unless it receives such regulatory approval.

(e) Acquisition of Advanced Therapeutic Systems, Limited

As set forth in the bye-laws of Advanced Therapeutic Systems, Limited ("ATS"), Elan, as the holder of the Special Shares of ATS, possessed the right to purchase all of the outstanding shares of ATS at a fixed price prior to October 31, 1996. A special committee of Elan's Board of Directors was appointed to determine the appropriateness of exercising the purchase option. This committee considered a valuation of ATS prepared by an independent investment bank in its decision of acquire ATS. Other items discussed included whether to use cash or Elan ADSs as consideration and the impact on Elan in the event Elan failed to exercise the purchase option. In October 1996, Elan exercised that purchase option. As a result, Elan paid \$141,544,000, including costs of acquisition, in cash for ATS and assumed net liabilities of \$12,904,000 as full consideration for the purchase of all the outstanding share capital of ATS. The acquisition of ATS in October 1996 gave rise to a charge of \$154,448,000 representing the acquisition of in-process research and development pursuant to SFAS No. 2. The acquisition of ATS was accounted for using purchase accounting. The principal research and development activities of ATS related to products with delivery or absorption issues, including protein and peptide drugs, highly insoluble drugs and drugs with large molecular structures. These products included proton pump inhibitors, potassium channel blocker drugs and drugs for early stage treatment of pain and cancer. At the date of acquisition, the ATS programs were in development and none had been approved by the FDA for marketing. Technological feasibility of these products was not established at the date of acquisition and it was considered that these products had no alternative future use other than the therapeutic indications for which they were in development. The work remaining to complete the development products involved research, safety and efficacy studies and the submission of regulatory filings to seek marketing approvals. The principal risks related to the development products were the outcomes of such research, clinical studies and regulatory filings. As pharmaceutical products cannot be marketed without such regulatory approvals, Elan would not receive any benefits unless it receives such regulatory approval. The estimated costs to completion of the products were approximately \$100,000,000. Elan subsequently out-licensed a number of these projects. The licensees are responsible for research and development costs on such projects. Approval of these products are expected beginning in 2000, with the initial approval of products being for the treatment of pain. This is approximately one to two years later than expected at the time of acquisition. This delay did not have a material impact on Elan's financial condition, results of operations or liquidity in 1998 or 1997.

(f) Acquisition of Athena Neurosciences, Inc.

On July 1, 1996, Elan acquired Athena Neurosciences, Inc. ("Athena"). The total consideration, which was paid for by the issue of Elan ADSs and has been accounted for as an acquisition, amounted to

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\$537,189,000 and resulted in Elan issuing up to 38,979,800 Elan ADSs valued at \$513,934,000. Options and warrants granted by Athena prior to the acquisition date vested and were converted into options and warrants to acquire 6,346,424 Elan ADSs. These options and warrants were valued in the determination of the purchase price of Athena at \$46,868,000. The acquisition of Athena in July 1996 gave rise to a charge of \$412,591,000, representing the acquisition of in-process research and development pursuant to SFAS No. 2. The purchase price of \$537,189,000 for Athena was allocated as follows:

	<u>\$000's</u>
Property, plant and equipment	5,259
Intangible assets	110,877
Current assets	46,457
Accounts payable	(15,115)
Long-term debt	(22,880)
In-process research and development	412,591
Purchase price	<u>537,189</u>

Intangible assets include the value of Athena's assembled workforce, developed technology and marketed products. These were valued at \$2,153,000, \$34,686,000 and \$74,038,000, respectively. The acquired in-process research and development charge of \$412,591,000 represented the value of Athena's projects in research and development at the acquisition date. Athena's principal research and development projects were focused on Alzheimer's disease, multiple sclerosis and neuromuscular disorders. Technological feasibility of these projects was not established at the acquisition date and it was considered that these projects had no alternative future use other than the therapeutic indications for which they were in research and development. The development projects were estimated to be approximately 40% complete on average and the estimated costs to completion were approximately \$240,000,000. The average time to full completion of the remaining work for the projects in research and development was estimated to be approximately 57 months at the date of acquisition. The work remaining to complete the research and development projects involved research, preclinical studies, safety and efficacy studies and the submission of regulatory filings to seek marketing approvals. The principal risks related to the research and development projects are the outcomes of such research, preclinical studies, safety and efficacy studies and regulatory filings. As pharmaceutical products cannot be marketed without such regulatory approvals, Elan will not receive any benefits unless it receives such regulatory approval.

Alzheimer's disease research projects represented approximately \$250,000,000 of the in-process research and development charge. The work remaining to complete the projects involved research, preclinical studies, safety and efficacy studies, and the submission of regulatory filings to seek marketing approvals. The principal risks related to the development products are the outcomes of such research, preclinical studies, safety and efficacy studies and regulatory filings. As pharmaceutical products cannot be marketed without regulatory approvals, Elan will not receive any benefits unless it receives such regulatory approval. The Alzheimer's projects' estimated peak sales were approximately \$820,000,000 per annum, estimated costs to completion were approximately \$110,000,000 and a discount rate of 24% was used. It was estimated that the projects would take between eight and ten years to complete.

The acquired research and development projects have progressed since the acquisition of Athena. Diastat received FDA approval in 1997. Cumulative Diastat revenues since launch to December 31, 1998, were \$7,900,000 compared to \$17,000,000 per the in-process research and development valuation. However projected peak sales for Diastat remain at the same level as in the in-process research and development valuation report. Neurobloc completed clinical trials and an application for marketing approval was filed with

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the FDA in December 1998. Clinical development of Antegren and research into Alzheimer's disease therapeutics is progressing, although slightly slower than initially expected. This delay did not have a material impact on Elan's financial condition, results of operations or liquidity in 1998 or 1997. Antegren is expected to commence pivotal clinical trials in 1999. IND applications are expected to be filed for two Alzheimer's disease therapeutics in 1999. The estimated aggregate research and development expenditure, at the date of acquisition, for Neurobloc, Antegren and Alzheimers' research for 1998 and 1997 were \$35.4 million and \$32.5 million, respectively, compared to actual amounts spent in 1998 and 1997 of \$43.7 million and \$31.3 million, respectively.

(g) Pro forma information

The pro forma effect in 1998 of significant acquisitions if acquired on January 1, 1998 would have resulted in revenues, net loss before other charges directly attributable to the acquisitions and basic loss per share before other charges directly attributable to the acquisitions of \$681,300,000, (\$2,835,000) and (\$0.01), respectively, for the year ended December 31, 1998. Net loss and basic loss per share for 1998 would have been (\$1,235,000,000) and (\$4.86) respectively. The pro forma effect of these acquisitions if acquired on January 1, 1997 would have resulted in revenues, net income, and basic earnings per share of \$388,925,000, \$121,025,000 and \$0.51, respectively, for the year ended December 31, 1997.

3. Marketable Investment Securities

	At December 31, 1998 \$000s	At December 31, 1997 \$000s
Trading securities		
Debt securities	2,644	141,753
Futures contracts	—	(285)
Equity securities	32,096	5,532
Available for sale securities	126,861	121,875
Held to maturity securities	36,272	30,881
Total marketable investment securities	197,873	299,756
Less non-current held to maturity securities	(22,016)	(13,909)
Marketable investment securities — current	<u>175,857</u>	<u>285,847</u>

(a) Available for sale securities

Available for sale securities at December 31, 1998 and 1997 are analyzed as follows:

	Cost \$000s	Unrealized Gains \$000s	Unrealized Losses \$000s	Fair Value \$000s
As of December 31, 1998:				
Equity securities	<u>171,809</u>	<u>31,791</u>	<u>(76,739)</u>	<u>126,861</u>
As of December 31, 1997:				
Equity securities	<u>76,882</u>	<u>55,732</u>	<u>(10,739)</u>	<u>121,875</u>

The net unrealized loss on available for sale securities of \$44,948,000 (December 31, 1997: \$44,993,000 gain) is shown as a separate component of shareholders' equity. The consolidated statement of cash flows

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includes purchases of available for sale securities during the year ended December 31, 1998 of \$58,380,000 (year ended December 31, 1997: \$55,704,000 and nine months ended December 31, 1996: \$5,000,000), within purchases of marketable investment securities, and sales of available for sale securities during the year ended December 31, 1998 of \$17,443,000 (year ended December 31, 1997: \$10,809,000 and nine-month period ended December 31, 1996: \$Nil) within sales of marketable investment securities. Included in income for the year ended December 31, 1998 is an amount of \$1,047,000 being the movement in unrealized loss on trading securities (year ended December 31, 1997: \$2,409,000, nine month period ended December 31, 1996: \$1,164,000).

(b) Held to maturity securities

The amortized cost and fair values of held to maturity securities at December 31, 1998 and 1997 are as follows:

	<u>Amortized Cost \$000s</u>	<u>Unrealized Gains \$000s</u>	<u>Unrealized Losses \$000s</u>	<u>Fair Value \$000s</u>
As of December 31, 1998:				
US treasury notes	36,272	407	—	36,679
	<u>36,272</u>	<u>407</u>	<u>—</u>	<u>36,679</u>
As of December 31, 1997:				
US treasury notes	24,908	188	(23)	25,073
US corporate commercial paper	5,973	—	—	5,973
	<u>30,881</u>	<u>188</u>	<u>(23)</u>	<u>31,046</u>

The maturities of fixed income securities classified as held to maturity at December 31, 1998 and 1997 are as follows:

	<u>1998 Amortized Cost \$000s</u>	<u>1998 Fair Value \$000s</u>	<u>1997 Amortized Cost \$000s</u>	<u>1997 Fair Value \$000s</u>
Within one year	14,256	15,081	16,972	16,988
One to five years	22,016	21,598	13,909	14,058
	<u>36,272</u>	<u>36,679</u>	<u>30,881</u>	<u>31,046</u>

4. Accounts Receivable

	<u>At December 31, 1998 \$000s</u>	<u>At December 31, 1997 \$000s</u>
Trade receivables (net of provision for doubtful debts of \$2,965,000; December 31, 1997: \$2,116,000)	169,090	71,659
Other non-trade receivables	30,972	14,806
	<u>200,062</u>	<u>86,465</u>

Other non-trade receivables include an amount of \$3,242,000 (December 31, 1997: \$7,369,000) due after more than one year.

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5. Inventories

	At December 31, 1998 \$000s	At December 31, 1997 \$000s
Raw materials	31,716	8,360
Work in process	16,200	8,618
Finished goods	32,978	10,349
Product inventory	17,780	13,562
	<u>98,674</u>	<u>40,889</u>

6. Investments

	At December 31, 1998 \$000s	At December 31, 1997 \$000s
Investments in and loans to companies accounted for under the equity method	11,840	41,373
Other securities	200,634	111,011
	<u>212,474</u>	<u>152,384</u>

Investments accounted for under the equity method includes Ebbisham Limited, owned 50% by Elan, at a cost of \$254,000 after attributable losses, at December 31, 1998. Other investments which are accounted for under the equity method include Marathon Medical Technologies, Inc., Tackson Limited, Innovax Corporation, Endorex Newco Limited, Xairo Corporation, MPS NewCo Limited and DOV NewCo Limited/Nascime Limited.

7. Property, Plant and Equipment

	At December 31, 1998 \$000s	At December 31, 1997 \$000s
Cost		
Land and buildings	85,428	67,255
Plant, equipment and other	178,501	95,609
	263,929	162,864
Less accumulated depreciation	(67,212)	(44,492)
	<u>196,717</u>	<u>118,372</u>

Depreciation expense amounted to \$21,549,000, \$12,457,000, and \$10,122,000 for the years ended December 31, 1998 and 1997, and the nine months ended December 31, 1996, respectively. Property, plant and equipment at December 31, 1998 include assets held under finance lease arrangements of \$37,234,000 (December 31, 1997: \$29,307,000).

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8. Intangible Assets

	At December 31, 1998 \$000s	At December 31, 1997 \$000s
Patents and licenses	614,667	185,226
Goodwill	157,879	27,654
Deferred financing costs	30,974	8,125
	803,520	221,005
Less accumulated amortization	(68,660)	(32,292)
	<u>734,860</u>	<u>188,713</u>

Amortization expense amounted to \$29,548,000, \$11,528,000, and \$7,893,000 for the years ended December 31, 1998 and 1997, and the nine months ended December 31, 1996, respectively.

9. Taxation

The components of income tax expense were as follows:

	Year ended December 31, 1998 \$000s	Year ended December 31, 1997 \$000s	9 months ended December 31, 1996 \$000s
Current:			
Irish corporation tax	1,537	268	272
Foreign taxes	2,337	918	502
	<u>3,874</u>	<u>1,186</u>	<u>774</u>

In the year ended December 31, 1998, the year ended December 31, 1997 and the nine-month period ended December 31, 1996, US taxes in the amount of \$2,702,000, \$Nil and \$868,000, respectively, that otherwise would have been accrued were offset by the benefit of tax loss carryforwards.

The Company's consolidated effective tax rate differed from the statutory rate as follows:

	Year ended December 31, 1998 \$000s	Year ended December 31, 1997 \$000s	9 months ended December 31, 1996 \$000s
Taxes at Irish statutory rate of 32% in 1998, 36% in 1997 and 38% in 1996	(373,356)	64,340	(217,282)
Other charges (1)	442,231	—	250,749
Irish income at reduced rates	(50,052)	(48,661)	(40,222)
Foreign income at reduced rates	(21,290)	(18,811)	(2,640)
Share of investments accounted for under the equity method	1,682	2,722	1,956
Other	4,659	1,596	8,213
Total provision for income taxes	<u>3,874</u>	<u>1,186</u>	<u>774</u>

- (1) Other charges comprise the acquisition of in-process research and development, the loss on sale of a business and the contribution to Axogen Limited in 1998 and to the acquisition of in-process research and development, the cost of fundamental restructuring and a provision for loss on sale of a business in 1996.

ELAN CORPORATION, plc AND SUBSIDIARIES
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In the year ended December 31, 1998 and 1997 and the nine months ended December 31, 1996, substantially all of Elan's net income in Ireland has been exempt from taxation by virtue of relief granted to income arising from patents. The effective tax rate reflected tax at the standard rates (32% from January 1998, 36% from April 1997 to December 1997, and 38% for all prior periods presented) on Irish interest income, and tax at the 10% rate on both Irish manufacturing operations and on income arising from qualifying activities in Elan's Shannon certified subsidiary and tax exempt income and losses in foreign jurisdictions subject to the local standard tax rates.

Total gross deferred tax assets at December 31, 1998 and 1997 amounted to \$126,954,000 and \$59,394,000, respectively, and consisted primarily of US net operating loss carryforwards. Total deferred tax liabilities at December 31, 1998 and 1997 amounted to \$65,592,000 and \$24,950,000, respectively, and consisted primarily of intangible assets arising on acquisitions. The valuation allowance for deferred tax assets at December 31, 1998 and 1997 amounted to \$61,362,000 and \$34,444,000, respectively. The net change in the valuation allowance for the year ended December 31, 1998 was an increase of \$26,918,000. Based on the results of current year US operations and the uncertainty of future realization of the deferred tax assets, the Company does not believe that it is more likely than not that the tax benefits of deferred tax assets will be realized.

At December 31, 1998, certain US subsidiaries had net operating loss carryovers for federal and state income tax purposes of \$226,517,000 and \$49,917,000 respectively, and federal and state tax credit carryforwards of \$12,917,000 and \$4,094,000 respectively. The federal net operating losses and tax credits expire from 2001 to 2013. The state net operating losses expire from 1999 to 2002 and the state tax credit carryforwards are available indefinitely. The Company has had "changes in ownership" as described in the US Internal Revenue Code, Section 382. Consequently, utilization of federal and state net operating loss and credit carryforwards are subject to annual limitations.

The distribution of income (loss) before taxes by geographical area was as follows:

	Year ended December 31, 1998 \$000s	Year ended December 31, 1997 \$000s	9 months ended December 31, 1996 \$000s
Income before taxes:			
Domestic	153,719	122,995	91,150
Foreign	103,260	48,330	(3,079)
Other charges (1)	(1,423,718)	—	(659,865)
	<u>(1,166,739)</u>	<u>171,325</u>	<u>(571,794)</u>

- (1) Other charges comprise the acquisition of in-process research and development, the costs of rationalization and integration, a loss on sale of business and the contribution to Axogen Limited in 1998 and to the acquisition of in-process research and development, the cost of fundamental restructuring and a provision for loss on sale of a business in 1996.

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10. Accrued and Other Liabilities

	At December 31, 1998 \$000s	At December 31, 1997 \$000s
Accrued liabilities	59,554	25,250
Other liabilities	24,875	10,084
Bank loan (1)	35,000	—
Other short term debt (2)	79,316	—
	<u>198,745</u>	<u>35,334</u>

- (1) This loan consists of a reverse repurchase agreement with an external fund manager against US treasury bills as collateral. The borrowing was repaid in January 1999.
- (2) Included in other short term debt is the short term element of a promissory note with an initial amount of \$128,000,000 bearing interest at 7% and repayable in 8 equal installments of \$16,000,000 between October 8, 1998 and July 8, 2000. At December 31, 1998, the balance outstanding, including accrued interest, amounted to \$114,011,000 of which \$66,011,000 was included in other short term debt.

11. 3.25% Zero Coupon Subordinated Exchangeable Notes

In December 1998, Elan Finance Corporation Limited (“Elan Finance”), a wholly owned subsidiary of Elan, issued, at a substantial discount, Liquid Yield Option Notes due 2018 (“2018 LYONs”), in the principal amount of \$1,643,546,000 at maturity. The gross proceeds to the Company amounted to \$862,500,000 issued at a price of \$524.78 per \$1,000 principal amount at maturity. The expenses associated with this transaction amounted to \$22,328,000.

The 2018 LYONs are exchangeable at any time into 13.75 Elan ADSs per each \$1,000 principal amount at maturity, representing an initial exchange price of \$38.17. The securities will be redeemable for cash at any time on or after December 14, 2003.

The original issue discount charged to income in the year to December 31, 1998 amounted to \$1,175,000. At December 31, 1998, the liability represented a price of \$525.54 per \$1,000 principal amount at maturity. At December 31, 1998, the balance outstanding amounted to \$863,746,000.

12. 4.75% Exchangeable Notes

In November 1997, Athena, a wholly owned subsidiary of Elan, issued 4.75% Exchangeable Notes due 2004 (the “Notes”), in the principal amount of \$325,000,000. The expenses associated with this transaction amounted to \$8,646,000.

Interest is payable in cash semi-annually from May 15, 1998 and the Notes will mature on November 15, 2004. The Notes are irrevocably and unconditionally guaranteed by Elan and the guarantee is subordinated to all existing and future senior indebtedness of Elan. Each Note is exchangeable at the option of the holder thereof at any time prior to maturity unless previously redeemed or otherwise purchased, for Elan ADSs, at an exchange rate of 28.1516 Elan ADSs per \$1,000 principal amount of Notes. The Notes may be purchased at the option of Athena, at the redemption prices (expressed as a percentage of the principal amount) set forth below:

<u>Year beginning</u>	<u>Redemption Price</u>
November 15, 2000	102.70%
November 15, 2001	102.00%
November 15, 2002	101.40%
November 15, 2003	100.70%

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All remaining notes at November 15, 2004 will be redeemed in cash at 100% of the principal amount.

Interest charged in the year ended December 31, 1998 amounted to \$15,508,000 (December 31, 1997: \$2,091,000).

13. 5.75% Zero Coupon Subordinated Exchangeable Notes

In October 1992, Elan International Finance Limited (“EIF”), a wholly owned subsidiary of Elan, issued, at a substantial discount, Liquid Yield Option Notes due 2012 (the “2012 LYONs”) in the principal amount of \$431,250,000 at maturity. The gross proceeds to the Company amounted to \$138,780,563 issued at a price of \$321.81 per \$1,000 principal amount at maturity. The expenses associated with this transaction amounted to \$4,676,000.

In November 1997, EIF redeemed all the outstanding 2012 LYONs. During 1997 up to redemption on November 30, 1997 a total of 14,202,880 Elan ADSs were issued on exchange of 2012 LYONs in the principal amount of \$326,181,000 at maturity. The remaining 2012 LYONs in the principal amount of \$51,000 were redeemed for cash on November 30, 1997.

The original issue discount charged to income in the year to December 31, 1997 amounted to \$3,110,000 and, in the nine-month period ended December 31, 1996, was \$5,632,000.

14. Financial Instruments

(a) Fair value of financial instruments

The following methods and assumptions were used to estimate the fair value of each material class of financial instrument:

Cash, cash equivalents and accounts receivable — carrying amount approximates fair value due to the short-term nature of these instruments.

Investments — the fair values of investments are estimated for quoted equity securities utilizing quoted market prices and taking account of current market conditions, for debt securities by utilizing current market interest rates for loans with similar risk and duration profile and for material unquoted equity investments by using established financial methodologies.

Marketable investment securities — the fair values of marketable investment securities, including interest rate futures, are estimated based on quotes obtained from brokers for these and similar instruments.

Other creditors and current bank loans — carrying amount approximates fair value due to the short-term nature of these instruments.

3.25% zero coupon subordinated exchangeable notes — fair value was assessed based on the quoted market price.

4.75% exchangeable notes — fair value was assessed based on the quoted market price.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The fair value of financial instruments at December 31, 1998 and December 31, 1997 was as follows:

	At December 31, 1998		At December 31, 1997	
	Carrying Value \$000s	Fair Value \$000s	Carrying Value \$000s	Fair Value \$000s
Financial assets:				
Cash and cash equivalents	819,882	819,882	316,739	316,739
Accounts receivable and prepayments	220,271	220,271	97,624	97,624
Investments	212,474	397,242	152,384	169,381
Marketable investment securities	197,873	198,280	299,756	299,921
Financial liabilities:				
Accounts payable, accrued and other liabilities	308,071	308,071	65,377	65,377
3.25% zero coupon subordinated exchangeable notes	863,746	933,698	—	—
4.75% exchangeable notes	325,000	383,305	325,000	325,000

(b) Derivative financial instrument risk

The Company uses derivative financial instruments to reduce exposures to market risks resulting from fluctuations in foreign exchange rates and interest rates on its marketable investment securities. The Company does not enter into derivative financial instruments for trading or speculative purposes. The Company only enters into contracts with parties that have at least an “A” or equivalent credit rating. The counterparties to these contracts are major financial institutions. Management believes that the risk of any net loss is remote and in any event would not be material to the Company.

The Company’s external fund manager entered into interest rate futures contracts in order to reduce the duration and interest rate sensitivity of trading fixed income securities in accordance with the Company’s treasury policy. Market risk for interest rate futures results from fluctuations in US interest rates. The cash requirements on interest rate futures require net settlement based on fluctuations in US interest rates. At December 31, 1997, interest rate future contracts had a nominal value of \$20,900,000 and a negative fair value of \$285,013. The company had also entered into an interest rate forward agreement with a nominal value of \$5,000,000 and fair value of \$1,000 at December 31, 1997. No interest rate futures contracts were outstanding at December 31, 1998.

Elan’s functional currency is the US dollar. Elan has a number of foreign exchange exposures as a result of costs incurred and revenues earned in currencies other than US dollars. Market risk for foreign exchange contracts principally arises from fluctuations in exchange rates between the US dollar and the Irish pound and Japanese yen respectively. These exposures relate primarily to Irish pound costs as a result of Elan’s facilities in Ireland and revenues earned in Japanese yen from royalties and product sales to Japanese customers. Elan enters into forward foreign exchange contracts and foreign currency options to cover forward (up to 24 months ahead but usually no more than 12 months ahead) a percentage (minimum 50% but generally between 50% and 80%) of the anticipated cash flows related to these foreign currency exposures. Elan’s objective is to reduce the level of foreign exchange risk by improving the level of certainty with respect to future non-dollar cash flows. Forward foreign exchange contracts and foreign currency options are included in the balance sheet within other assets or liabilities and gains and losses are included in income for the period reported.

At December 31, 1998, Elan had entered into a number of forward foreign exchange contracts and foreign currency options at various rates of exchange in the normal course of business. The nominal value of forward foreign exchange contracts to sell Japanese yen for US dollars at that date was \$12,964,000 and these contracts

ELAN CORPORATION, plc AND SUBSIDIARIES
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

had a fair value gain of \$1,201,000. These contracts expire on various dates up to and including September 2000. The nominal value of forward foreign exchange contracts to sell US dollars for Irish pounds at December 31, 1998 was \$32,500,000 and these contracts had a fair value gain of \$1,353,000. These contracts expire on various dates up to and including December 1999. The nominal value of currency options to sell US dollars for Irish pounds at December 31, 1998 amounted to \$20,000,000 and these options had a fair value gain of \$709,000. These options expire on various dates up to and including December 1999.

As at December 31, 1998, the cash requirements of Japanese yen forward contracts require Elan to sell ¥1,597,802,000 and receive US\$12,964,000 at an average exchange rate of US\$1=¥123.25 between January 1999 and September 2000. The cash requirement of Irish pound forward contracts require Elan to sell US\$32,500,000 and receive IR£22,704,500 at an average exchange rate of US\$1=IR£0.6985 between January 1999 and December 1999. Irish pound currency options require a net cash amount payable or receivable if the Irish pound exchange rate against the US dollar is outside certain upper (US \$1=IR£0.6502) and lower (US\$1=IR£0.7513) limits. Derivative financial instruments are marked to market with gains or losses recorded in income.

The fair values of derivative financial instruments at December 31, 1998, were estimated based on quoted market prices.

15. Concentrations of Credit Risk

The Company's revenues derive from the manufacture, development and sale of a range of pharmaceutical products. Approximately 74% of revenues were derived in the US in the year ended December 31, 1998. Four clients accounted for approximately 35% of total revenues. These companies have strong credit ratings and therefore credit risk is considered to be minimal.

The Company invests excess cash in a variety of securities with strong credit ratings. These securities are all investment grade and primarily have at least an "AA" or "AAA" credit rating. As such they bear minimal credit risk and the Company has not experienced any losses related to these investments due to bankruptcy or failure.

16. Share Capital

The Executive Shares do not confer on the holders thereof the right to receive notice of, attend or vote at any meetings of the Company, or the right to be paid a dividend out of the profits of the Company save such dividend as the directors may from time to time determine.

The 'B' Executive Shares confer on the holders thereof the same voting rights as are enjoyed by the holders of Ordinary Shares. The 'B' Executive Shares do not confer on the holders thereof the right to be paid a dividend out of the profits of the Company, save such dividend as the directors may from time to time determine.

ELAN CORPORATION, plc AND SUBSIDIARIES
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

17. Analysis of Revenue, Operating Income, Major Customers, Assets and Reportable Segments

(a) *The distribution of revenue by geographical area was as follows:*

	Year ended December 31, 1998 \$000s	Year ended December 31, 1997 \$000s	9 months ended December 31, 1996 \$000s
Ireland	292,317	185,749	153,063
Rest of Europe	22,506	7,749	6,049
United States	315,229	166,739	70,557
Other	46,682	23,944	5,890
	<u>676,734</u>	<u>384,181</u>	<u>235,559</u>

The distribution of export revenues from Ireland was as follows:

	Year ended December 31, 1998 \$000s	Year ended December 31, 1997 \$000s	9 months ended December 31, 1996 \$000s
United States	188,480	119,857	73,818
Other	69,730	50,743	73,839
Total revenue	<u>258,210</u>	<u>170,600</u>	<u>147,657</u>

(b) *The distribution of operating income (loss) by geographical area was as follows:*

	Year ended December 31, 1998 \$000s	Year ended December 31, 1997 \$000s	9 months ended December 31, 1996 \$000s
Ireland	166,868	133,739	91,185
Rest of Europe	934	(2,590)	(1,053)
United States	65,968	10,906	2,007
Other	16,001	(2,152)	(3,389)
	<u>249,771</u>	<u>139,903</u>	<u>88,750</u>
Corporate, general and administrative expenses	(10,377)	(8,828)	(11,648)
Other charges (1)	<u>(1,423,718)</u>	<u>—</u>	<u>(659,865)</u>
Total operating (loss) income	<u>(1,184,324)</u>	<u>131,075</u>	<u>(582,763)</u>

- (1) Other charges comprise the acquisition of in-process research and development, the costs of rationalization and integration, a loss on sale of a business and the contribution to Axogen Limited in 1998 and to the acquisition of in-process research and development, the cost of fundamental restructuring and provision for loss on a sale of a business in 1996.

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(c) The distribution of consolidated total assets by geographical area was as follows:

	At December 31, 1998 \$000s	At December 31, 1997 \$000s
Ireland	611,181	209,657
Rest of Europe	119,005	8,983
United States	617,185	222,801
Other	20,499	5,310
Corporate assets	1,112,881	767,726
Total assets	<u>2,480,751</u>	<u>1,214,477</u>

(d) In the periods set out below four clients accounted for the percentage of total revenue as follows:

	Year ended December 31, 1998	Year ended December 31, 1997	9 months ended December 31, 1996
Client A	14%	10%	4%
Client B	9%	—	—
Client C	7%	4%	—
Client D	5%	12%	24%

(e) Analysis by reportable segment

Elan's business can be analyzed as to two segments consisting of a pharmaceuticals business ("EP") and a drug delivery business ("EPT"). EP discovers, develops and markets therapeutic products for neurological disorders, acute care and pain management, and diagnostic services for neurological disorders. EPT develops, markets and licenses to clients drug delivery products based on Elan's drug delivery systems.

The accounting policies used for segmental reporting are the same as those defined in Note 1.

	EP			EPT			Total		
	Year Ended 12/31/98 \$000s	Year ended 12/31/97 \$000s	Nine Months Ended 12/31/96 \$000s	Year Ended 12/31/98 \$000s	Year Ended 12/31/97 \$000s	Nine Months Ended 12/31/96 \$000s	Year Ended 12/31/98 \$000s	Year Ended 12/31/97 \$000s	Nine Months Ended 12/31/96 \$000s
Total revenues	350,743	162,887	60,999	357,714	224,932	186,147	708,457	387,819	247,146
Intersegment revenues	(2,296)	(131)	(105)	(30,628)	(4,608)	(11,482)	(32,924)	(4,739)	(11,587)
External revenues	348,447	162,756	60,894	327,086	220,324	174,665	675,533	383,080	235,559
Other revenue							1,201	1,101	—
Total reported revenue							676,734	384,181	235,559
Operating income	57,264	26,570	2,544	189,709	104,837	77,048	246,973	131,407	79,592
Intersegment (loss)/income	19,907	3,547	6,956	(11,439)	2,757	(6,915)	8,468	6,304	41
External income	77,171	30,117	9,500	178,270	107,594	70,133	255,441	137,711	79,633
Total assets	465,005	199,327	179,630	739,269	214,616	195,071	1,204,274	413,943	374,701
Depreciation and amortization	23,472	10,532	7,780	26,295	12,440	10,091	49,767	22,972	17,871
Capital expenditure (1)	271,096	32,912	112,977	346,687	32,333	26,153	617,783	65,245	139,130

- (1) Included in capital expenditure for 1998 are amounts for goodwill, license and patents arising from purchase business combinations during the year of \$140,367,000 for EP and \$81,535,000 for EPT, respectively. Included in capital expenditure for 1996 are amounts for license and patents arising from purchase business combinations during the period of \$103,619,000 for EP and \$12,547,000 for EPT, respectively.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(i) Reconciliation of net (loss)/income

	<u>1998</u> <u>\$000s</u>	<u>1997</u> <u>\$000s</u>	<u>1996</u> <u>\$000s</u>
Segmental external income	255,441	137,711	79,633
Other losses (1)	(16,047)	(6,636)	(2,531)
Other charges (2)	(1,423,718)	—	(659,865)
Operating (loss)/ income	(1,184,324)	131,075	(582,763)
Interest and other income	46,457	53,291	22,521
Interest expense	(23,578)	(5,843)	(6,743)
Share of losses from investments accounted for under the equity method . . .	(5,256)	(7,458)	(5,147)
Minority interest	(38)	260	338
(Loss)/ income before provision for income taxes	<u>(1,166,739)</u>	<u>171,325</u>	<u>(571,794)</u>

- (1) Other losses consist of corporate expenses incurred, not specific to any reportable segment. The increase in expenses is due to the general growth in the company.
- (2) Other charges comprise the acquisition of in-process research and development, costs of rationalization and integration, the loss on a sale of business and the contribution to Axogen in 1998, and to the acquisition of in-process research and development, the cost of fundamental restructuring and a provision for loss on a sale of business in 1996.

(ii) Reconciliation of total assets

	<u>1998</u> <u>\$000s</u>	<u>1997</u> <u>\$000s</u>	<u>1996</u> <u>\$000s</u>
Total segmental assets	1,204,274	413,943	374,701
Corporate assets including investments (1)	258,747	184,039	93,696
Interest bearing assets	1,017,730	616,495	297,503
	<u>2,480,751</u>	<u>1,214,477</u>	<u>765,900</u>

- (1) Corporate assets including investments excludes interest bearing assets which are disclosed separately.

(iii) Reconciliation of depreciation and amortization

	<u>1998</u> <u>\$000s</u>	<u>1997</u> <u>\$000s</u>	<u>1996</u> <u>\$000s</u>
Total segmental depreciation and amortization	49,767	22,972	17,871
Corporate costs—depreciation	1,330	1,013	144
	<u>51,097</u>	<u>23,985</u>	<u>18,015</u>

(iv) Reconciliation of capital expenditure

	<u>1998</u> <u>\$000s</u>	<u>1997</u> <u>\$000s</u>	<u>1996</u> <u>\$000s</u>
Segmental capital expenditure	617,783	65,245	139,130
Corporate	20,338	4,528	148
	<u>638,121</u>	<u>69,773</u>	<u>139,278</u>

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18. Research and Development Arrangements

Neuralab Limited (“*Neuralab*”): In January 1998, Elan and Neuralab, a newly formed research and development company, consummated a private placement of 1,250,000 units, each unit consisting of one common share of Neuralab, one initial warrant to purchase two Elan ADSs at an exercise price of \$65.01 for two Elan ADSs, and one additional warrant to purchase two Elan ADSs, the exercise price of which will be determined based on future trading prices of Elan ADSs and the exercisability of which is contingent upon future events. On January 14, 1999, the units separated into the underlying securities. The initial warrants are exercisable at \$65.01 for two Elan ADSs from January 15, 1999 until January 14, 2003. The additional warrants are exercisable at a 20-day average of the last sales price per Elan ADS prior to the second separation date or the occurrence of certain events, primarily the acquisition or merger of Elan into another entity. The net proceeds of the private placement amounted to approximately \$47,000,000, substantially all of which is being used to fund payments to Elan under a development agreement between Elan and Neuralab. Total net revenues received from Neuralab in 1998 amounted to \$18,554,000.

Under the development and license agreement between Elan and Neuralab, Elan has agreed to use diligent efforts to conduct research and development for Neuralab to identify potential therapeutic compounds for each of the research projects relating to Alzheimer’s disease (the “*Neuralab Projects*”).

Payments to Elan under the development and license agreement for research and other costs of the Neuralab Projects (the “*Development Costs*”) are determined on a funding rate per dedicated Full Time Equivalent (“*FTE*”). This rate is based on a “*Scientific Year*” which represents 1,880 employee hours per year of scientific work on the Neuralab Projects carried out by Elan employees at the level of research assistant (generally, having a baccalaureate degree, or its academic equivalent, in science) or above. The pricing structure based on the FTE rate is considered by Elan to be consistent with contractual relationships it has or had with other third parties. Neuralab makes monthly payments to Elan, based on invoices for all of the Development Costs incurred by or on behalf of Elan during the preceding month.

Neuralab owns all right, title and interest in the world, excluding certain Asian countries (the “*Territory*”), to know-how and patent rights discovered or developed by Elan during the term of and as a result of work funded by Neuralab on the Neuralab Projects. Patent rights include both pending applications and issued patents. Elan has, however, reserved rights to use this know-how and these patent rights in the Territory for the sole purpose of work on the Neuralab Projects and, following expiration of the development agreement to make, have made and use Alzheimer’s disease therapeutic products for sale outside the Territory.

Elan granted to Neuralab a non-exclusive, royalty-free license in the Territory to make, have made, use and sell all know-how and patent rights existing on January 14, 1998 owned or licensed from third parties by Elan, which Elan has the right to sublicense and, subject to the terms and conditions of any relevant license, for the purpose of furthering the development of the Neuralab Projects. However, to the extent Elan has the right to receive revenue from persons other than Neuralab under non-exclusive licenses to these existing patent rights, Elan, not Neuralab, will receive that revenue. In addition, any additional know-how or patent rights relating to the Neuralab Projects with respect to which, during the term of the development agreement, Elan obtains licensing rights in the Territory, will be offered to Neuralab on the same terms and conditions. Elan’s and Neuralab’s respective research and funding commitments under the development agreement will terminate upon the payment to Elan of Neuralab’s funds.

Under the services agreement between Elan and Neuralab, Elan provides management and administrative services to Neuralab for a quarterly fee of \$100,000. The services agreement terminates one year after the termination of the purchase option described below. Neuralab may terminate the services agreement at any time upon 60 days’ notice to Elan.

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Elan has a purchase option for Neuralab. This purchase option was established at the time of Neuralab's private placement in 1998 and represents the outcome of a negotiation between Elan and lead investors. Elan believes that the purchase option price represents fair value as it was determined by a negotiation between independent parties. The purchase option is an exclusive, irrevocable option to purchase all, but not less than all, of the issued and outstanding Neuralab common shares. The purchase option became exercisable on January 14, 1998 and will be exercisable at any time until the earlier of (i) December 31, 2001 or (ii) the 90th day after the date Neuralab provides Elan with quarterly financial statements of Neuralab showing cash or cash equivalents of less than \$2,000,000; provided, however, that if Elan before such 90th day provides written confirmation to Neuralab that Elan will use commercially reasonable efforts, at no expense to Neuralab (beyond substantially all of the net proceeds of the Neuralab unit offering and any other revenues received and interest thereon, less working capital to be retained by Neuralab of \$500,000), to continue to develop the Neuralab Projects, the purchase option shall continue in effect through such date for so long as Elan continues to use commercially reasonable efforts, but in no case beyond December 31, 2001.

The purchase option exercise price per share is as follows:

	<u>Purchase Option Exercise Price</u>
Before February 1, 2000	\$61.01
On or after February 1, 2000 and on or before December 31, 2000 . . .	\$75.35
On or after January 1, 2001 and on or before December 31, 2001	\$93.05

The purchase option exercise price may be paid in cash, fully registered Elan ADSs or in any combination of the foregoing, at Elan's sole discretion. The Elan ADSs will be valued based upon the average of the closing prices for Elan ADSs on the New York Stock Exchange for the twenty trading days immediately preceding the date of notice from Neuralab of cash or cash equivalents of less than \$2,000,000. Elan will retain the right, however, to use cash in lieu of Elan ADSs in the event the 20-day average trading price of Elan ADSs is less than the closing price of Elan ADSs on the trading day immediately prior to that notice. In the event the 12,000 special shares of Neuralab owned by Elan are transferred to a party other than Elan or its affiliates, the purchase option exercise price may be paid only in cash.

Axogen Limited ("Axogen"): In November 1996, Elan concluded a development and license agreement (the "Development Contract") and a services agreement with Axogen to develop therapeutic products for the treatment of neurological disorders. Also in November 1996, a public offering of 5,290,000 units was completed by Axogen. Each unit was comprised of one common share of Axogen and one warrant to purchase two Elan ADSs. The net proceeds to Axogen of the offering amounted to approximately \$89,030,000. On December 31, 1998 the units separated into the two underlying securities. The warrants are exercisable at \$37.54 for two Elan ADSs from January 1, 1999 until December 31, 2001. The proceeds of the offering and the additional contribution are being used primarily to make payments to Elan under the Development Contract. Total net revenues from Axogen in 1998 and 1997 amounted to \$82,554,000 and \$39,307,000, respectively.

Pursuant to the Development Contract and subject to the Elan Option (as defined below), Elan granted to Axogen an option to acquire an exclusive license to sell and otherwise market and sublicense to market in the US certain products (the "Axogen Products"), on a product-by-product basis, and in the case of any Axogen Product for which Elan has manufacturing rights, a license to manufacture or obtain manufacturing for an Axogen Product (the "License Option"). Elan is the owner or existing licensee, as the case may be, of the Axogen Products. Product rights are often transferred by license in the pharmaceutical industry. In the event that Axogen exercises the License Option, Elan retains its respective ownership of, or license to, the Axogen Product. However, Axogen acquires certain economic interests by virtue of its license to the Axogen Product as discussed below. The License Option will be exercisable by Axogen with respect to any Axogen Product within

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90 days after the time that such Axogen Product is approved for marketing in the US by the FDA. If the License Option is exercised as to any Axogen Product, Axogen will acquire an exclusive license with respect to the rights described above for the License Period (as defined below) and a non-exclusive, royalty-free license thereafter. The License Option is not terminable by either Elan or Axogen. Certain of the Axogen Products are subject to supply arrangements with third parties other than Elan which will be assigned or licensed to Axogen to the extent necessary for Axogen to commercialize the licensed product in connection with the exercise of the License Option. Elan will have the right to terminate a license in the event that Axogen does not market such Axogen Products within nine months from the date of marketing approval by the FDA.

During the License Period, Axogen will make the following payments to Elan in the event of the exercise of the License Option with respect to each relevant Axogen Product:

(a) if the Axogen Product is sold by Axogen, base royalties in an amount equal to 60% of the net sales of the relevant Axogen Product received by Axogen, multiplied by a fraction the numerator of which is the aggregate development costs and expenses incurred by Elan (including expenses incurred by Athena prior to the acquisition of Athena by Elan in July 1996) prior to October 31, 1996 in connection with the development of the relevant Axogen Product and the denominator of which is the sum of (x) the amount representing the aggregate development costs and expenses incurred by Elan (including expenses incurred by Athena) prior to October 31, 1996 in connection with the development of the relevant Axogen Product plus (y) the aggregate amount of Development Costs in connection with the development of the relevant Axogen Product incurred pursuant to the Development Contract and any expenses incurred by Axogen in connection with the development of the relevant Axogen Product, other than pursuant to the Development Contract (such fraction, the “Fee Formula”); and

(b) an amount equal to any sublicensing fees or income received by Axogen pursuant to any licensing arrangement entered into by Axogen relating to the relevant Axogen Product and any “front-end” fees, prepaid royalties or similar one-time, infrequent, not in the ordinary course or special payments received by Axogen in respect of any such sublicensing arrangement (collectively, “Ancillary Fees”) multiplied by the Fee Formula.

During the License Period, Elan will make the following payments to Axogen in the event of the exercise of the License Option with respect to each relevant Axogen Product: (a) if the Axogen Product is sold by Elan or an Elan affiliate in any country of the world other than the US, 4% of the net sales in respect of sales of any relevant Axogen Product, as received by Elan or its affiliate; and (b) 30% of Ancillary Fees received by Elan or an Elan affiliate in respect of any country of the world other than the US.

Elan will have the right to reject Axogen’s exercise of the License Option within 60 days of Axogen providing notice of its exercise thereof (the “Elan Option”) upon payment by Elan, at the option of Axogen, of either (a) a one-time cash fee of \$25,000,000 or (b) base royalties of 10% of the net sales of the relevant Axogen Product during the License Period; provided, however, the Elan Option may only be exercised as to one Axogen Product. The determination of the one-time fee of \$25,000,000 for Elan’s rejection of Axogen’s exercise of the license option was considered in 1996, in negotiations with the lead investor groups, to be a reasonable approximation of what fair value would potentially be at the date such option would be exercised.

Elan has agreed to use diligent efforts to conduct clinical development, final development, including US regulatory approval, and commercialization of the Axogen Products. Axogen is paying, and will pay, to Elan substantially all of the net proceeds of the Axogen offering, interest earned thereon and, if designated by Axogen, any licensing or marketing income earned by Axogen or cash payments received in connection with the Elan Option, less working capital to be retained by Axogen of \$1,000,000.

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Development Costs consist of (i) direct research expenses (including direct research salaries, benefits and supplies), which are billed at a rate of cost plus 60% of costs; provided, however, that services provided by third parties will be billed at a rate of cost plus 15% of costs; (ii) indirect research costs (including general research management and support services) at a fixed rate of direct research salary expenses plus 10%; (iii) general and overhead expenses billed at a fixed rate of direct research salary expenses less 20%; and (iv) reimbursement of out-of-pocket costs incurred by Elan including the cost of research materials and external consulting services. The premium or discount applied to direct research salary expenses is intended to cover costs incurred by Elan which are not separately identified by its cost recording systems and include the depreciation of physical assets, amortization of intangible assets, direct and supervisory labor costs, insurance and a contribution to its general and administrative costs.

Under the services agreement, Elan will provide management and administrative services to Axogen for a quarterly fee of \$100,000. The services agreement terminates one year after the termination of the Purchase Option. Axogen may terminate the services agreement upon 60 days' notice to Elan.

Elan has an option, exercisable at Elan's sole discretion, to purchase, according to a pre-determined formula, all (but not less than all) of the outstanding common shares of Axogen. The purchase option became exercisable on November 19, 1996 and will be exercisable at any time until the earlier of (i) December 31, 2001 or (ii) the 90th day after the date Axogen provides Elan with quarterly financial statements of Axogen showing cash or cash equivalents of less than \$4,000,000. If the purchase option is exercised, the purchase price calculated on a per share basis will be as follows:

	<u>Purchase Option Exercise Price</u>
Before January 1, 2000	\$34.56
On or after January 1, 2000 and on or before December 31, 2000	\$45.04
On or after January 1, 2001 and on or before December 31, 2001	\$61.04

The purchase option exercise price may be paid in cash, in Elan ADSs or Ordinary Shares or in any combination thereof at Elan's sole discretion. The purchase option price was established at the time of Axogen's initial public offering and represents the outcome of a negotiation between Elan and the lead investors. Elan believes that the purchase option price represents fair value as it was determined by a negotiation between independent parties.

On December 18, 1998, Elan made a contribution of \$67,500,000 to Axogen.

(c) Relationship with Advanced Therapeutic Systems, Limited ("ATS")

From July 1993 through October 1996, Elan had a research and development arrangement with ATS to further develop drug delivery systems utilizing Elan's proprietary electro-transport, biodegradable enhanced and micro-particulate drug delivery technologies. The net proceeds to ATS of the August 1993 rights offering were used primarily to make payments to Elan under a research and development agreement. Revenues from ATS in the period ended December 31, 1996 were \$51,790,000. These revenues were recorded as research revenues and license fees as appropriate. In October 1996, Elan exercised its option to acquire all outstanding shares of ATS as more fully explained in Note 2.

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19. Other charges for the year ended December 31, 1998

Elan incurred other charges during 1998 of \$1,423,718,000 as set out below:

The acquisitions of Neurex, Sano, NanoSystems and Carnrick in 1998 primarily gave rise to a charge of \$1,311,149,000, representing the acquisition of in-process research and development pursuant to SFAS No. 2 (see Note 2).

Following the acquisition of Sano, a developer of transdermal drug delivery products, Elan commenced a plan to integrate Sano into its drug delivery activities and to rationalize both Sano's and Elan's drug delivery businesses. Costs incurred during 1998 included asset write-downs of \$21,804,000 and other costs of \$3,152,000 arising from the acquisition of Sano and the transfer of transdermal activities from Elan's Athlone, Ireland facility to Sano's Miramar, Florida facility. Costs to close certain drug delivery departments amounted to \$2,758,000. Costs of \$5,956,000 were incurred to rationalize and terminate certain Sano and pre-existing drug delivery division research and development projects. Costs of \$6,477,000 were incurred to terminate certain Sano license and supply agreements. Costs of \$1,600,000 were incurred to rationalize and integrate Elan's diagnostic business. These amounts resulted in a charge of \$41,747,000.

A charge of \$3,322,000 was incurred resulting from a loss on disposal of an investment and loan note, which were acquired as proceeds from a sale of a business.

A charge of \$67,500,000 was incurred resulting from a contribution by Elan to Axogen (see Note 18).

20. Other charges for the period ended December 31, 1996

As a result of the acquisitions of Athena and ATS, and the acquisition by Warner Chilcott, plc of a division of Warner-Lambert Company, in 1996, Elan incurred a charge of \$571,839,000 representing the acquisition of in-process research and development pursuant to SFAS No. 2 (See Note 2).

In July 1996, the Company commenced a fundamental restructuring of its business resulting in a restructuring charge of \$70,000,000. The charge for restructuring resulted from the acquisition of Athena, a re-assessment of the existing Elan business and the required measures to integrate the businesses. The restructuring charge included \$33,000,000 for the restructuring and rationalization of manufacturing operations, \$23,500,000 for integration and rationalization of research and development activities, \$4,500,000 for integration and rationalization of corporate functions, and asset write-offs of \$9,000,000.

Restructuring of manufacturing operations included incremental efforts arising from regulatory compliance activities and also cost management and cost cutting activities. The acquisition of Athena resulted in an increased number of products in research and development and a significant increase in research and development expenditure. This necessitated a review of both Elan's and Athena's research and development efforts to focus resources more strategically. The restructuring provision was fully utilized by the third quarter of 1997 with \$31,733,000 and \$38,267,000 being utilized during the year to December 31, 1997 and the nine-month period to December 31, 1996 respectively.

In December 1996, the Company committed to disposing of its medical nutrition business to an unrelated public company, Nutrition Medical, Inc. In January 1997, the Company signed the definitive legal sale agreement. The net book value of the assets disposed of amounted to \$22,337,000 including goodwill of \$16,205,000, other intangible assets of \$3,675,000, fixed assets of \$1,010,000, inventories of \$839,000 and other items at \$608,000. At December 31, 1996 a provision for loss on disposal of this business amounting to \$18,026,000 was charged to the income statement based on the expected loss on disposal. This provision was fully utilized in 1997.

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21. Share Options and Warrants

Under the terms of the 1986 and 1989 Elan employee stock option plans, options to purchase 3,668,368 Ordinary Shares were outstanding at December 31, 1998. Under the 1989 plan, options to purchase a further 9,534,006 shares were available for grant at December 31, 1998. No options could be granted under the 1989 plan after February 14, 1999 and no options were granted under this plan between December 31, 1998 and February 14, 1999. Options granted under these plans were granted at prices equal to market value at date of grant and will expire on a date not later than eight years after their grant. Options generally vest as to one fifth each year commencing on the first anniversary of the date of grant. In 1995, options to purchase 3,650,000 Ordinary Shares were issued to certain executive officers and employees which become exercisable as to one third each year from the third anniversary from the date of grant. Under the terms of the 1996 Elan employee and consultants stock option plans, options to purchase 16,917,650 Ordinary Shares were outstanding at December 31, 1998. Options to purchase a further 2,082,350 shares were available for grant at December 31, 1998. Under the terms of the 1998 Elan employee stock option plan, options over 5,382,228 Ordinary Shares were outstanding at December 31, 1998. Options to purchase a further 617,772 shares were available for grant at December 31, 1998. All options granted under the 1996 and 1998 plans were granted at prices equal to market value at date of grant and will expire on a date not later than eight years after their grant. Options generally vest as to one third each year commencing on the third anniversary of the date of grant.

In connection with the Axogen offering, Elan issued 5,290,000 warrants to purchase 10,580,000 Elan ADSs in November 1996. The warrants are exercisable at \$37.54 for two Elan ADSs from January 1, 1999 to December 31, 2001. In connection with the Neuralab offering, Elan issued 1,250,000 units in January 1998. Each unit consists of one Common Share of Neuralab, one initial warrant to purchase two Elan ADSs at an exercise price of \$65.01 for two Elan ADSs, and, contingent upon the occurrence of certain future events, one additional warrant to purchase two Elan ADSs at a price to be determined based on future trading prices of Elan ADSs. The warrants are exercisable at \$65.01 for two Elan ADSs from January 14, 1999 to January 14, 2003.

As a result of the acquisition of Athena on July 1, 1996, options and warrants granted by Athena prior to the acquisition date vested and were converted into options and warrants to acquire 6,346,424 Elan ADSs. These options and warrants were valued in the determination of the purchase price of Athena at \$46,868,000. As a result of the acquisition of Sano on February 27, 1998, options granted by Sano were converted into a total of 2,216,850 options to acquire Elan ADSs. These options were valued in the determination of the purchase price of Sano at \$53,015,000. Arising from the acquisition of Neurex on August 14, 1998, options granted by Neurex were converted into a total of 3,011,702 options to acquire Elan ADSs. These options were valued in the determination of the purchase price of Neurex at \$67,147,000. Arising from the acquisition by Elan of all the assets and liabilities of NanoSystems on October 1, 1998, Elan granted 750,000 warrants to purchase 1,500,000 Elan ADSs. The warrants are exercisable at \$45.00 per share from February 1, 1999 to October 1, 2006. These warrants were valued in the determination of the purchase price of Nanosystems at \$16,400,000.

In August 1993, a rights offering to shareholders of 3,922,766 units (the “Units”) was completed. Each Unit comprised one common share in Advanced Therapeutic Systems Limited, and one warrant to purchase four Elan ADSs. On August 12, 1995 the Units separated into the two underlying securities. The warrants were exercisable at \$9.815 per share from August 12, 1995 until August 12, 1998, and all warrants were either exercised or expired during the period to December 31, 1998.

The Company applies APB Opinion No. 25 in accounting for its plans and, accordingly, no compensation cost has been recognized for its stock options in the financial statements. Had the Company determined compensation cost based on the fair value at the grant date for its stock options under SFAS No. 123, the

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Company's net income and earnings per share would have been reduced by \$41,200,000 or \$0.18 per share in the year ended December 31, 1998 and by \$22,200,000 or \$0.11 per share in the year ended December 31, 1997.

The weighted average fair value of the individual options granted during the years ended December 31, 1998 and 1997 and the nine months ended December 31, 1996 is estimated as \$11.26, \$8.72 and \$5.54, respectively, on the date of grant. The fair value for these options was estimated using the Black-Scholes option-pricing model with the following weighted average assumptions for the year ended December 31, 1998: dividend yield of nil; expected volatility of 32.62%; risk free interest rate of 4.6%; and expected life of 5.0 years. The weighted average assumptions used for the year ended December 31, 1997 were: dividend yield of nil; expected volatility of 31.51%; risk free interest rate of 5.9%; and expected life of 5.1 years. The weighted average assumptions used for the period ended December 31, 1996 were: dividend yield of nil; expected volatility of 29.56%; risk free interest rate of 6.4%; and expected life of 5.2 years.

Pro forma net income and earnings per share reflects only options granted on or after April 1, 1995. Therefore, the full impact of calculating compensation cost for stock options under SFAS No. 123 is not reflected in the pro forma net income amounts presented above because compensation cost is reflected over the options' vesting period of 3-5 years and compensation cost for options granted prior to April 1, 1995 is not considered.

The share options and warrants outstanding and exercisable were as follows:

	Options		Warrants	
	Shares	Weighted average exercise price	Shares	Weighted average exercise price
Outstanding at March 31, 1996	10,816,160	\$ 8.25	15,687,100	\$ 9.82
Arising on acquisition	4,939,320	14.32	1,407,104	14.32
Exercised	(952,696)	11.21	(597,412)	14.27
Granted	9,963,928	14.30	10,580,000	18.77
Expired	(653,988)	8.93	—	—
Outstanding at December 31, 1996	24,112,724	11.85	27,076,792	13.45
Exercised	(2,430,002)	10.25	(101,128)	11.92
Granted	4,150,628	22.44	—	—
Expired	(1,266,100)	14.77	(543,912)	14.32
Outstanding at December 31, 1997	24,567,250	13.65	26,431,752	13.44
Arising on acquisition	5,228,552	30.43	1,500,000	45.00
Exercised	(3,703,498)	17.22	(15,610,092)	9.82
Granted	10,698,114	30.55	2,500,000	32.51
Expired	(943,716)	19.85	(16,984)	9.82
Outstanding at December 31, 1998	35,846,702	20.61	14,804,676	23.68
Exercisable at December 31, 1998	8,906,616	19.49	10,804,676	18.68

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At December 31, 1998, the range of exercise prices and weighted average remaining contractual life of outstanding options was as follows:

<u>Range (\$)</u>	<u>4.96-14.24</u>	<u>14.25-24.99</u>	<u>25.00-30.99</u>	<u>31.00-45.00</u>	<u>Total</u>
Options:					
Number of shares outstanding	7,299,102	13,152,400	8,362,094	7,033,106	35,846,702
Weighted average exercise price — \$.	8.80	15.77	29.27	31.60	20.61
Weighted average remaining contractual life (years)	4.05	4.87	6.16	4.88	5.01
Number of exercisable options	2,848,174	2,101,456	1,531,466	2,425,520	8,906,616
Weighted average exercise price of exercisable options — \$	8.04	14.36	29.64	31.00	19.49
Warrants:					
Number of shares outstanding	—	10,804,676	—	4,000,000	14,804,676
Weighted average exercise price — \$.	—	18.68	—	37.19	23.68
Weighted average remaining contractual life (years)	—	2.97	—	5.43	3.63
Number of exercisable options	—	10,804,676	—	—	10,804,676
Weighted average exercise price of exercisable options — \$	—	18.68	—	—	18.68

22. Commitments and Contingencies

The Company and its subsidiaries occupy certain facilities under lease arrangements and lease certain equipment. Rentals amounted to \$7,220,000, \$4,795,000 and \$2,104,000 in the year ended December 31, 1998, the year ended December 31, 1997, and the nine month period ended December 31, 1996, respectively.

Future minimum rental commitments for operating leases with non-cancelable terms in excess of one year are as follows:

	<u>Minimum Rental Payments</u>		
	<u>Premises \$000s</u>	<u>Other \$000s</u>	<u>Total \$000s</u>
1999	8,330	843	9,173
2000	8,009	537	8,546
2001	7,862	319	8,181
2002	7,650	52	7,702
2003	7,392	34	7,426
Later years	20,930	—	20,930
	<u>60,173</u>	<u>1,785</u>	<u>61,958</u>

As of December 31, 1998, the following capital commitments for the purchase of property, plant and equipment had been authorized by the directors:

	<u>At December 31, 1998 \$000s</u>	<u>At December 31, 1997 \$000s</u>
Contracted for	19,130	2,834
Not contracted for	1,429	388
	<u>20,559</u>	<u>3,222</u>

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During 1998, 1997, and 1996 the Company disposed of plant and equipment with a net book value of \$16,129,000, \$8,764,000 and \$31,218,000, respectively, and subsequently leased the plant and equipment back under 15 year leases. The Company also entered into an arrangement with a third party bank, the substance of which allows the Company to insist on a net settlement of its obligations under the leases. The related assets and liabilities have been offset in these financial statements in the amount of \$41,571,000 and \$25,421,000 as at December 31, 1998 and December 31, 1997, respectively.

Capital grants totaling \$6,321,000, in aggregate, have been received from the Industrial Development Authority, an Irish government agency. Normally such grants would become repayable if the Company ceased to trade or where the grant-aided assets are sold within a period generally defined as ten years after receipt of last payment under the relevant grant agreement.

At December 31, 1998, Elan had commitments to invest \$9,000,000 in two healthcare managed funds.

During 1998, the Company entered into an agreement with Ligand Pharmaceuticals Incorporated (“Ligand”), a biopharmaceutical company engaged in the discovery and development of small molecule drugs. Elan agreed to (i) purchase \$20,000,000 of Ligand common stock; (ii) purchase up to \$110,000,000 in issue price of Ligand’s zero coupon convertible senior notes due 2008, which are convertible into Ligand common stock; and (iii) enter into a license agreement providing for a license to Ligand in the United States and Canada of Elan’s proprietary product Morphelan for the oncology and HIV markets. Morphelan, a once-daily solid oral dosage form of morphine, is currently in Phase III clinical trials.

In 1998, the Company completed its purchase of Ligand’s common stock and purchased \$30,000,000 in issue price of Ligand’s zero coupon convertible senior notes due 2008. The license agreement provides that, under certain circumstances, Ligand may co-promote Morphelan in Europe and Elan may co-promote Morphelan in the United States. In connection with the license agreement, Ligand paid to Elan a non-refundable license fee of \$15,000,000, which Elan recognized as revenue, in the form of additional shares of Ligand common stock of \$5,000,000 and additional zero coupon convertible senior notes of \$10,000,000. In addition, Ligand will make future milestone payments to Elan upon filing of an NDA with the FDA and upon FDA approval of Morphelan for marketing in the US.

Elan has a remaining commitment to purchase additional zero coupon convertible senior notes of Ligand with an aggregate issue price of up to \$70,000,000 on or before December 31, 1999.

In October 1998, the Company licensed from Vanguard Media Group, plc (“Vanguard”) exclusive North American sales and distribution rights for frovatriptan, which had completed Phase III efficacy studies in patients with migraine. The Company paid \$10,000,000 to Vanguard to acquire new ordinary shares of Vanguard and as part of the licensing collaboration. The terms of the license provide that Elan will make milestone payments of up to \$50,000,000 and will pay royalties on future sales. To date, \$15.0 million of these milestone fees have been made. In January 1999, an NDA for frovatriptan was filed with the FDA.

In September 1998, Elan re-acquired the US and Canadian rights to its Naprelan and Verelan products from AHP. Under the terms of the agreement with AHP, Elan may be liable to make future contingent cash payments amounting to a maximum of \$30,000,000 depending on the amount and timing of launches of generic competitive products.

23. Post Balance Sheet Events

In February 1999, the Company entered into a \$325,000,000 senior unsecured revolving credit facility with a group of financial institutions, as lenders, and Merrill Lynch International, as lead arranger. The credit

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facility provides for revolving borrowings by Elan and certain of its subsidiaries from time to time. Borrowings under the credit facility bear interest at LIBOR, the London Interbank Offered Rate, plus a borrowing margin of between 0.4% and 2.0% depending on Elan's credit rating at the time of any such borrowing or, in certain circumstances, on the date of repayment of the borrowing. The credit facility will expire on February 3, 2002, unless terminated sooner upon an event of default. The expiration date of the credit facility may be extended by mutual agreement of Elan and the lenders under the credit facility. Borrowings under the credit facility are guaranteed by Elan and certain of its subsidiaries. The credit facility contains customary covenants that restrict Elan and its subsidiaries from taking certain actions and that require Elan to achieve and maintain certain financial ratios.

A two-for-one stock split became effective on June 7, 1999 resulting in one additional share being issued for each share held to shareholders of record on May 27, 1999. All share and related information (such as per share information, options and warrants) and EPS data have been restated to give effect to the stock split (see Note 28).

24. Pension Plans

The Company funds the pension entitlements of certain employees through defined benefit plans. Two plans are operated for Irish employees. On retirement a member is entitled to a pension calculated at 1/60th of final pensionable salary for each year of pensionable service, subject to a maximum of 40 years. These plans are funded externally and the related pension costs and liabilities are assessed in accordance with the advice of professionally qualified actuaries. The investments of the plans as at December 31, 1998 consisted of units held in independently administered funds.

Change in benefit obligation:

	Year ended December 31, 1998 \$000s	Year ended December 31, 1997 \$000s	9 months ended December 31, 1996 \$000s
Benefit obligation at beginning of year/period . .	7,385	6,369	4,997
Service cost	900	596	323
Interest cost	508	424	301
Plan participants' contributions	854	607	381
Actuarial gain	477	716	149
Benefits paid	(142)	(178)	(199)
Foreign currency exchange rate changes	467	(1,149)	417
Benefit obligation at end of year/period	<u>10,449</u>	<u>7,385</u>	<u>6,369</u>

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Change in plan assets:

	At December 31, 1998 \$000s	At December 31, 1997 \$000s
Fair value of plan assets at beginning of year	9,218	7,159
Actual return on plan assets	987	1,832
Employer contribution	1,665	1,156
Plan participants' contributions	854	607
Benefits paid	(142)	(178)
Foreign currency exchange rate changes	588	(1,358)
Fair value of plan assets at end of year	<u>13,170</u>	<u>9,218</u>
Funded status	2,721	1,833
Unrecognized net actuarial gain / (loss)	288	(94)
Unamortized prior service cost	94	96
Unrecognized transition obligation	130	142
Prepaid benefit cost	<u>3,233</u>	<u>1,977</u>

The net periodic pension cost was comprised of the following:

	Year ended December 31, 1998 \$000s	Year ended December 31, 1997 \$000s	9 months ended December 31, 1996 \$000s
Service cost	900	596	323
Interest cost	508	424	301
Expected return on plan assets	(985)	(1,833)	(341)
Amortization of transition obligation	18	20	16
Asset gain / (loss)	107	1,214	(53)
Amortization of prior service cost	6	6	5
Net periodic pension cost	<u>554</u>	<u>427</u>	<u>251</u>

Weighted-average assumptions:

	At December 31, 1998 \$000s	At December 31, 1997 \$000s
Discount rate	7.0%	7.5%
Expected return on plan assets	9.0%	9.0%
Rate of compensation increase	5.0%	5.5%

In addition, Elan operates a number of defined contribution pension plans, primarily for employees outside of Ireland. The costs of these plans are charged to the profit and loss account in the period in which incurred. The pension cost for these plans was \$2,297,000, \$1,243,000 and \$609,000 in the years ended December 31, 1998 and December 31, 1997, and the period ended December 31, 1996, respectively.

ELAN CORPORATION, plc AND SUBSIDIARIES
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

25. Supplemental Schedule of Non-Cash Investing Activities

The following schedule summarizes the impact of the acquisitions outlined in Note 2, on the Company's cash flow:

	Year ended December 31, 1998 \$000s	Year ended December 31, 1997 \$000s	9 months ended December 31, 1996 \$000s
Cash paid for the capital stock	264,658	—	124,353
Liabilities assumed	74,207	—	63,618
Total cash consideration	338,865	—	187,971
Shares and warrants issued in exchange for the capital stock	1,250,235	—	516,746
Payments accrued at balance sheet date	23,783	—	—
Fair value of assets acquired	<u>1,612,883</u>	<u>—</u>	<u>704,717</u>

26. Supplemental Disclosures of Cash Flow Information

	Year ended December 31, 1998 \$000s	Year ended December 31, 1997 \$000s	9 months ended December 31, 1996 \$000s
Cash paid for:			
Interest	18,388	337	125
Income taxes	2,084	434	312
	<u>20,472</u>	<u>771</u>	<u>437</u>

27. Litigation

There are no material pending legal proceedings to which Elan is a party or to which any of its property is subject.

28. Earnings Per Share

During the year ended December 31, 1997, the Company adopted SFAS No. 128 "Earnings Per Share" which required a change in the method used to compute earnings per share ("EPS"). Under this standard, primary and fully diluted earnings per share were replaced with "Basic" and "Diluted" EPS. Basic EPS is based on the income available to common stockholders divided by the weighted-average number of common shares outstanding during the period. Diluted EPS is based upon the income available to common stockholders divided by the weighted-average number of common shares outstanding during the period and adjusted for the effect of all dilutive potential common shares that were outstanding during the period. Earnings per share in 1996 have been restated to give effect to the adoption of the standard. A two-for-one stock split became effective on June 7, 1999 resulting in one additional share being issued for each share held by shareholders of record on May 27, 1999. All share and related information (such as per share information, options and warrants) and EPS have been restated for all periods presented to give effect to the stock split.

ELAN CORPORATION, plc AND SUBSIDIARIES
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The following table sets forth the computation for basic and diluted EPS:

	Year ended December 31, 1998 000s	Year ended December 31, 1997 000s	9 months ended December 31, 1996 000s
Numerator			
Numerator for basic EPS — net income/(loss)	(\$1,170,613)	\$170,139	(\$572,568)
Adjustment for interest on exchangeable debt	—	\$3,268	—
Numerator for diluted EPS	(\$1,170,613)	\$173,407	(\$572,568)
Denominator			
Denominator for basic EPS — weighted-average shares	238,304	198,704	178,330
Effect of dilutive securities — options and warrants	—	19,236	—
Effect of dilutive securities — exchangeable debt	—	8,220	—
Denominator for diluted EPS	238,304	226,160	178,330
Basic EPS (US\$)	(\$4.91)	\$0.86	(\$3.21)
Diluted EPS (US\$)	(\$4.91)	\$0.77	(\$3.21)

29. Restatement

Elan has restated its consolidated financial statements for a change in the method used to account for two investments made in 1997. These investments were accounted for under the cost method in 1997 and the equity method in 1998. The financial statements have been restated to use the equity method to account for these investments in 1997. The accounting method used in 1998 is unchanged.

The effect of this restatement on the 1997 consolidated income statement is a decrease in revenue of \$4,975,000. This results in a decrease in net income of \$4,975,000, from \$175,114,000 to \$170,139,000, in the 1997 consolidated income statement. Basic and diluted earnings per share decrease from \$0.88 to \$0.86 and from \$0.79 to \$0.77, respectively, in the 1997 consolidated income statement.

The effect of this restatement on the consolidated balance sheets for 1997 and 1998 is to decrease investments by \$4,975,000 and to decrease retained earnings by \$4,975,000.

The accompanying financial statements have been restated to reflect the above changes.

SCHEDULE II**ELAN CORPORATION, plc AND SUBSIDIARIES**
VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

	Balance at beginning of period \$000s	Arising on acquisitions \$000s	Charged to costs and expenses \$000s	Written off to accounts receivable \$000s	Balance at end of period \$000s
April 1, 1996 to December 31, 1996					
Reserve for doubtful accounts receivable	<u>314</u>	<u>2,635</u>	<u>890</u>	<u>(1,500)</u>	<u>2,339</u>
January 1, 1997 to December 31, 1997					
Reserve for doubtful accounts receivable	<u>2,339</u>	<u>—</u>	<u>1,742</u>	<u>(1,965)</u>	<u>2,116</u>
January 1, 1998 to December 31, 1998					
Reserve for doubtful accounts receivable	<u>2,116</u>	<u>96</u>	<u>1,132</u>	<u>(379)</u>	<u>2,965</u>

Item 19. Financial Statements and Exhibits

(a) Financial Statements

(1) Financial Statements of Elan Corporation, plc and Subsidiaries

Report of Independent Chartered Accountants

Consolidated Balance Sheets at December 31, 1998 and December 31, 1997

Consolidated Statements of Income for the years ended December 31, 1998 and December 31, 1997 and the nine months ended December 31, 1996

Consolidated Statements of Comprehensive Income for the years ended December 31, 1998 and December 31, 1997 and the nine months ended December 31, 1996

Consolidated Statements of Cash Flows for the years ended December 31, 1998 and December 31, 1997 and the nine months ended December 31, 1996

Consolidated Statements of Shareholders' Equity

Notes to the Consolidated Financial Statements

(2) Financial Statement Schedule of Elan Corporation, plc and Subsidiaries

Schedule II — Valuation and Qualifying Accounts and Reserves

(b) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
1.-(a)	Memorandum of Association of Elan Corporation, plc (as amended by all Special Resolutions up to and including May 14, 1999)
2.-(a)	1998 Long-Term Incentive Plan
2.-(b)	1999 Stock Option Plan
23.0	Consent of KPMG with respect to Registration Statements No. 333-07361, No. 333-07136, No. 33-03834, No. 333-09284, No. 333-09644, No. 333-09746 and the Athena Neurosciences, Inc. Registration Statement No. 333-8356

SIGNATURES

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the Registrant certifies that it meets all of the requirements for filing on Form 20-F and has duly caused this annual report to be signed on its behalf by the undersigned, thereunto duly authorized.

ELAN CORPORATION, PLC

/s/ THOMAS G. LYNCH

Thomas G. Lynch
Chief Financial Officer, Executive
Vice President and Director

August 26, 1999