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William Blair & Company
Limited Liability Company

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XOMED SURGICAL PRODUCTS, INC.

(XOMD)

April 23, 1999
Basic Report

(99-040)

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Price: $38 7/8 ($15 13/16–$41 7/8)
Fiscal Year Ends: December

Fiscal Year	Earnings Per Share	Price/Earnings Ratio
1998	$0.78	49.8x
1999E	$1.02	38.1x
2000E	$1.27	30.6x
2001E	$1.64	23.7x

Earnings Per Share Growth		Return on Average Equity	
1996-1998*	45%	1998	9%
Long-term	25%	2001E	14%
Book Value Per Share (December 1998):	$9.45	Dividend:	None
Insider Ownership:	8.3%	Common Shares:	12.1 million
Sales (1999E):	$118 million	Market Value:	$470 million

* Excluding one-time charges

Investment Opinion: Long-term Buy

Xomed is the leading supplier of ENT (ear, nose, and throat) surgical devices. We expect this market to be more than $450 million in 1999, versus about $400 million in 1998, and to grow 14% annually. Approximately $265 million of the market should be in the United States and growing 11% annually. While the ENT market historically appears to have been underserved and overlooked, it is important medically. For example, the top two medical procedures for children under the age of 15—insertion of an ear tube for chronic ear infections and tonsillectomies—are ENT procedures. In fact, middle-ear infections are the most common medical condition leading children to visit physicians and the most frequent reason for children to be prescribed antibiotics. For adults, chronic sinusitis—swelling of the sinuses—another ENT-associated illness, is the second-most-common medical condition after orthopedic impairments. In 1998, we estimate that Xomed had a 19% share of the global market, up from 16% in 1996, and it should continue to gain share. The company has the broadest product line; the only large, dedicated salesforce; and, in our opinion, exceptional senior management members, who either founded or significantly influenced three of the top four device companies in the ENT market. Xomed's superior ENT market position and other strengths should allow it to achieve at least 25% earnings per share growth for the foreseeable future. Consequently, we would recommend purchase of stock in this high-quality medical device company.

Xomed Surgical Products, Inc.—Long-term Buy

Xomed is the leading supplier of medical devices to the market for ENT surgical procedures—focusing on procedure-specific, proprietary products and emphasizing disposable and implantable devices. The company has captured 19% market share worldwide in 1998, with sales of almost $92 million. We expect earnings per share growth of at least 25% annually over the next three to five years, driven by revenue increases of more than 20% each year combined with gross margin and operating expense leverage.

Summary Income Statement
($ in millions)

	1997	% Revenue	1998	% Revenue	1999E	% Revenue	2000E	% Revenue	2001E	% Revenue
Revenue	**$77.2**	**100%**	**$91.4**	**100%**	**$120.5**	**100%**	**$146.1**	**100%**	**$179.1**	**100%**
COS	$30.5	39%	35.3	39%	46.5	39%	55.8	38%	68.0	38%
Gross Profit	**$46.8**	**61%**	**$ 56.1**	**61%**	**$ 74.0**	**61%**	**$ 90.3**	**62%**	**$ 111.1**	**62%**
SG&A	$30.3	39%	34.3	38%	44.8	37%	52.1	36%	62.6	35%
R&D	$4.1	5%	4.7	5%	5.8	5%	8.5	6%	10.2	6%
Amortization	$2.4	3%	2.4	3%	2.8	2%	3.2	2%	3.6	2%
Total Operating Expense	$36.8	48%	41.4	45%	53.4	44%	63.9	44%	76.5	43%
Operating Income	**$9.9**	**13%**	**$ 14.7**	**16%**	**$ 20.6**	**17%**	**$ 26.4**	**18%**	**$ 34.6**	**19%**
Other Income, Net	$0.1	0%	0.6	1%	0.8	1%	1.0	1%	1.3	1%
Earnings Before Income Taxes	**$10.1**	**13%**	**$ 15.3**	**17%**	**$ 21.4**	**18%**	**$ 27.4**	**19%**	**$ 35.9**	**20%**
Provision for Income Taxes	$4.0	5%	5.9	6%	8.1	7%	10.4	7%	13.6	8%
Net Income	**$6.1**	**8%**	**$ 9.4**	**10%**	**$ 13.3**	**11%**	**$ 17.0**	**12%**	**$ 22.3**	**12%**
EBITDA	$15.2		$20.4		$27.0		$33.3		$42.4	
EPS	**$0.55**		**$0.78**		**$1.02**		**$1.27**		**$1.64**	
Shares Outstanding	11,268		12,088		13,086		13,366		13,646	

Year-over-year growth

	1997	1998	1999E	2000E	2001E
Revenue	18%	18%	32%	21%	23%
Gross Profit	18%	20%	32%	22%	23%
Operating Income	45%	47%	40%	28%	31%
Net Income	94%	53%	42%	28%	31%
EPS	48%	42%	31%	25%	29%

Summary of Balance Sheet
($ in millions)

	1997	1998	1999E	2000E	2001E
Cash and Cash Equivalents	$1.7	$4.3	$1.7	$7.9	$17.4
Working Capital	$26.1	32.5	36.7	54.6	76.6
Long-term Debt	-	13.1	-	-	-
Shareholders' Equity	$86.5	$114.2	$127.4	$144.8	$167.5

Summary of Cash Flows
($ in millions)

	1997	1998	1999E	2000E	2001E
Net Cash Provided by Operations	$6.1	$9.1	$11.6	$12.5	$15.3
Net Cash Used in Investing	($2.2)	($40.7)	($1.8)	($5.3)	($6.0)
Net Cash Provided by Financing	($3.0)	$33.5	($12.4)	($0.9)	$0.1
Net Cash Increase (Decrease)	$0.9	$1.9	($2.6)	$6.3	$9.4

Quarterly EPS

	1998	1999E	2000E
1Q	$0.15	$0.20A	$0.27
2Q	$0.19	$0.25	$0.30
3Q	$0.18	$0.24	$0.29
4Q	$0.26	$0.33	$0.41
Year	$0.78	$1.02	$1.27

Source: FactSet; Company financials; William Blair & Company, L.L.C. estimates

Contents

Summary of Investment Recommendation: Long-term Buy

Xomed is the leading supplier to the market for ENT surgical devices. We expect the global market to be more than $455 million in 1999 and to grow 14% per year. We believe that approximately $265 million of this market is in the United States and growing an estimated 11% per year. Currently, Xomed has 19% share of the worldwide market, and we believe it is growing faster than the market, thus gaining share. The company has the broadest product line; the only large, dedicated salesforce; and, in our opinion, exceptional senior management members, who either founded or significantly influenced three of the top four device companies in the ENT market. Xomed's superior ENT market position and other strengths should allow it to achieve at least 25% earnings per share growth for the foreseeable future.

While the ENT market historically appears to have been underserved and overlooked, it is important medically. For example, the top two medical procedures for children under 15—insertion of an ear tube for chronic ear infections and tonsillectomies—are ENT procedures. In fact, middle-ear infections are the most common medical condition leading children to visit physicians and the most frequent reason for children to be prescribed antibiotics. For adults, chronic sinusitis—swelling of the sinuses—another ENT-associated illness, is the second-most-common medical condition after orthopedic impairments.

Xomed currently derives more than 80% of its revenue from the ENT market, and we forecast this proportion to rise to more than 85% by 2001. Its ENT business is divided into three broad product lines, essentially covering the ENT subspecialties. These include sinus and rhinology, 43% of revenue; head and neck, 23%; and otology, 17%. We anticipate that sinus and rhinology should increase to about 55% of revenue, and otology should decline to 10% by 2001. Xomed's products include ventilation tubes for middle-ear infections, the Powerforma™ surgical drill, the XPS® shaver systems for removing hard and soft tissue, the NIM® nerve-monitoring system, and the LandmarX™ image-guided surgery (IGS) system. The remaining revenue comes primarily from its Solan ophthalmologic business, which sells precision surgical hand instruments, microkeratomes for use in corrective laser surgery, and fast-wicking, lint-free sponges for eye surgery, such as cataract removal.

Our investment recommendation for Xomed is based on the following five key factors.

1) **We believe that the market for ENT medical devices is attractive.**
   In our opinion, the market seems favorable due to its structure and dynamics, as well as its relative size and growth rate. First, the market appears historically underserved, with many techniques unchanged for the past 60 years. Second, the medical needs driving the various ENT conditions appear significant and sustainable; they typically are caused by improper anatomy arising through genetics, trauma, or environmental causes, such as bacteria, smoking, or dust. Lastly, we believe that there is a barrier to entry arising from specialization of Xomed's direct salesforce and marketing efforts to the ENT arena, as well as the subspecialties of otology (ears), rhinology (nose), and laryngology (throat). We estimate the market to be more than $455 million currently, growing 14% compounded annually, which would lead to a market of more than $800 million globally by 2003. This market growth derives from an approximately $265 million U.S. market growing 11% annually, and an international market approaching $200 million, growing a faster 18%. Increases in diagnosis, treatment, and use of surgical procedures should contribute to this growth.

2) **Xomed is the market share leader, and we view it as the ENT device leader.**
   We believe Xomed is the clear market leader in market share and breadth and depth of product offering. *It is the only major competitor focused predominantly on the ENT medical device market.* The company's extensive and innovative product lines most often offer improvements to *current procedures—rather than new approaches* to learn.

In our opinion, the products also are easy to use and offer valuable and innovative features that result in better outcomes, while increasing surgical efficiency. Xomed also appears to have the best distribution, with the only direct salesforce covering all ENT subspecialties, with 65 reps in the United States and 34 internationally. We believe the company also maintains exceptional relationships with customers and ENT opinion leaders through informal and formal arrangements such as programs to develop new, surgeon-driven products. We believe that its market share, innovative products, focused sales-and-marketing efforts, and customer relationships position it well to take advantage of the opportunities in the ENT market.

3) **The senior management of Xomed is exceptional, in our opinion.**
Senior management members have been involved in founding or significantly influencing three of the top four companies that supply ENT medical devices. In addition, management has a proven history of success developing the arthroscopy (minimally invasive joint surgery) market. Also, the broader management team is deep and highly experienced, having had key positions in such firms as Zimmer, Linvatec, and Stryker.

4) **The company should experience at least 25% annual earnings per share growth.**
We expect revenue to grow more than 20% annually, faster than the 14% market growth rate, leading to a share increase from 19% to 25%. This rise should come predominantly from innovative new products such as the XPS®-powered surgical system and the LandmarX™ IGS system, which both should take share as well as *expand the primary market*. Xomed's gross margin should increase 60 basis points by 2001, from 61.4% in 1998 to 62% in 2001, due to operating leverage as well as use of lower-cost manufacturing techniques such as molding versus machining implants. Also, operating expenses should decline about 3% of revenue, from 45.3% to 42.7%, as the direct salesforce becomes more levered. Taxes should remain essentially stable, at about 38. The combined revenue growth and expense improvements should lead to a net-income increase of 33% compounded annually through 2001, with earnings growing a modestly lower 28%—accounting for some dilution principally due to the exercise of stock options.

5) **As earnings rise, we expect concomitant stock-price appreciation, as the current valuation premium appears justified.**
Our valuation analysis shows that Xomed historically seems to have been valued with comparable companies that participate in the market for ENT medical devices and have similar market capitalizations. This would imply a 2000 forward price-to-earnings ratio somewhat less than the forward growth rate. However, in recent months, Xomed has experienced P/E-multiple expansion. We believe that this expansion is justified on the basis of Xomed's past record, superior position in a focused market, and innovative new products, as well as the underlying growth of the ENT market. Consequently, if this premium is maintained, the shares still should appreciate substantially due to an anticipated EPS growth rate of at least 25%.

Risks

Pharmaceutical versus surgical treatment. As with most medical conditions, ENT ailments can be treated with various medicines or procedures. For example, both the first-line treatments for otitis media and sinusitis are antibiotics. Surgery is performed only when the pharmaceutical approach does not work. For some procedures, such as various tumors or polyps, the surgical approach is tried first, but this may change in the future as new medicines are developed. For some procedures, such as middle-ear reconstructions or deviated septa caused by genetic variability, surgery should remain the standard of care.

Slower market penetration of new procedures. A major driver of Xomed's growth is the increased use of minimally invasive surgical techniques in ENT procedures. The first minimally invasive, powered surgical approach to functional endoscopic sinus surgery occurred

in 1993. While it appears that these approaches have gone beyond early adopters and are becoming mainstream—the current penetration is more than 50%—the ultimate penetration of the techniques may be significantly less than 100%. This could slow both the capital equipment placements, as well as the disposable use.

Fewer procedures due to a change in clinical practice. Standards of care may change over time because of the perceived benefits versus costs of treatment, both direct and indirect. This may be driven explicitly, through new information gleaned from clinical trials, or implicitly, based on changes to reimbursement or beliefs of medical or political opinion leaders. A relevant example for the ENT market is the relative popularity of tonsillectomies and adenoidectomies. In the 1970s, tonsillectomies came under fire as neither medically necessary nor worth the cost. Since that time, the indications for which they are performed have been refined, and costs reduced. For instance, tonsillectomies no longer are performed to treat chronic otitis media, although adenoidectomies are may be. Also, the facility cost of tonsillectomies in a surgery center is only about $500, versus $1,000 for hospitals, where they were performed before, improving the cost/benefit ratio. Cost/benefit issues similar to those illustrated by this example could face other ENT surgical procedures in the future.

Attractive Market

The market appears to be attractive due to its structure and dynamics, as well as its relative size and growth rate. We believe the structure and dynamics of the market seem favorable for three reasons: 1) the market historically appears to have been underserved; 2) the medical needs driving the various ENT conditions are significant and appear sustainable; and 3) we believe that there are barriers to entry due to Xomed's focus on the ENT specialty and its subspecialties. While the ENT market appears to have been underserved and overlooked, it is an adequate size and important medically. We estimate the total worldwide market to be $455 million, currently growing 14% compounded annually, which would lead to a market of more than $800 million globally by 2003. Increases in diagnosis, treatment, and use of surgical procedures should contribute to this growth.

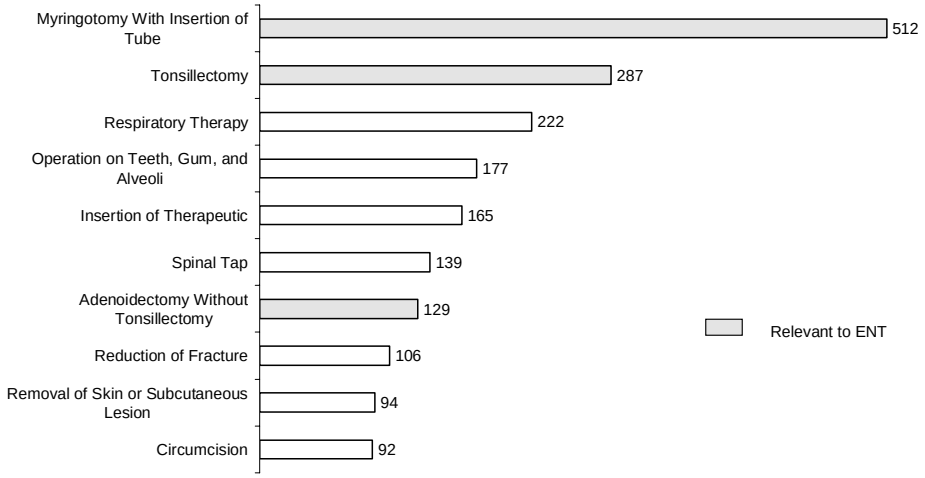
Structure and Dynamics of the Market Appear Favorable

First, the market appears historically underserved, with many surgical techniques unchanged for the past 60 years. For example, sinus surgery has used a procedure with the unappealing moniker "snare and tear," which comprises manually inserting a hand instrument into the sinus and ripping out the offending tissue. This technique is painful and often ineffective, and it results in heavy post-operative bleeding. Another example is the Caldwell-Luc procedure of creating a hole in the bottom of a sinus and "scraping" the inside in the hope that the sinus will drain. It is now recognized by ENT surgeons that the cilia in the sinuses move fluid *up*, so that creating a new hole on the bottom is most often ineffective because it tries to work against the body's own anatomy. We expect these types of highly invasive procedures should be replaced by minimally invasive procedures—which often could use powered instruments—leading to more-efficient surgery with significantly better outcomes. This is analogous to the development of minimally invasive arthroscopic procedures, which now constitute 80% to 90% of techniques applied to joints.

Second, the medical needs driving the various ENT conditions appear significant and sustainable. For example, as figure 1 shows, the top two medical procedures for children under 15—insertion of an ear tube for chronic ear infections and tonsillectomies—are ENT procedures—in this case otology and laryngology procedures. In fact, as seen in figure 2, otitis media (middle-ear infections) are the most common medical condition that lead children to visit physicians and the most frequent reason for children to be prescribed antibiotics. For adults, chronic sinusitis or swelling of the sinuses—another ENT associated illness, in this case rhinology—is the second-most-common medical condition after orthopedic impairments, as shown in figure 3, on page 8. Currently, the American Academy of Otolaryngology–Head

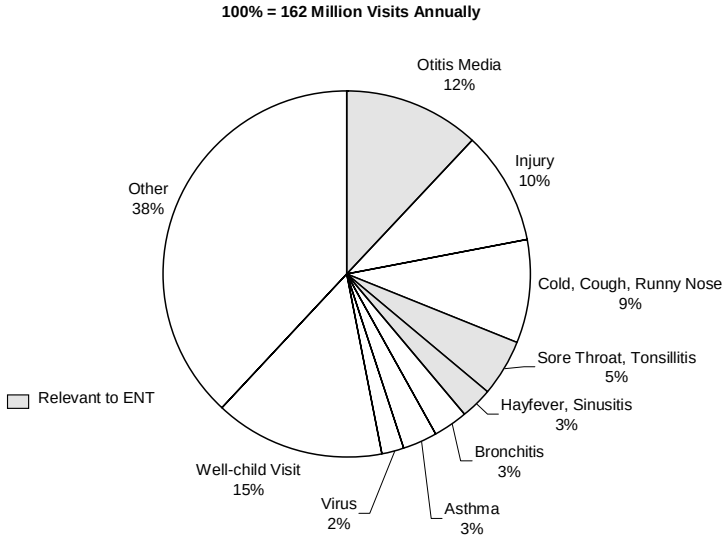
and Neck Surgery estimates that chronic sinusitis affects 35 million, or about 15% of Americans each year and results in 15 million physician office visits. Yet, this condition currently only results in about 500,000 surgical procedures annually. Other procedures are also medically serious, such as the removal of cancerous tumors, the reconstruction of a middle ear to restore hearing, or the removal of polyps on vocal chords. The conditions typically are caused by genetic defects in anatomy, trauma, or environmental causes such as bacteria, smoking or dust. Most of these procedures require very delicate and precise techniques because the surgical sites are most often within millimeters of the brain, the eyes, delicate facial nerves, or blood vessels that supply these organs.

Figure 1
Xomed Surgical Products, Inc.
Top 10 Medical Procedures for Children Under 15 Years Old
1996



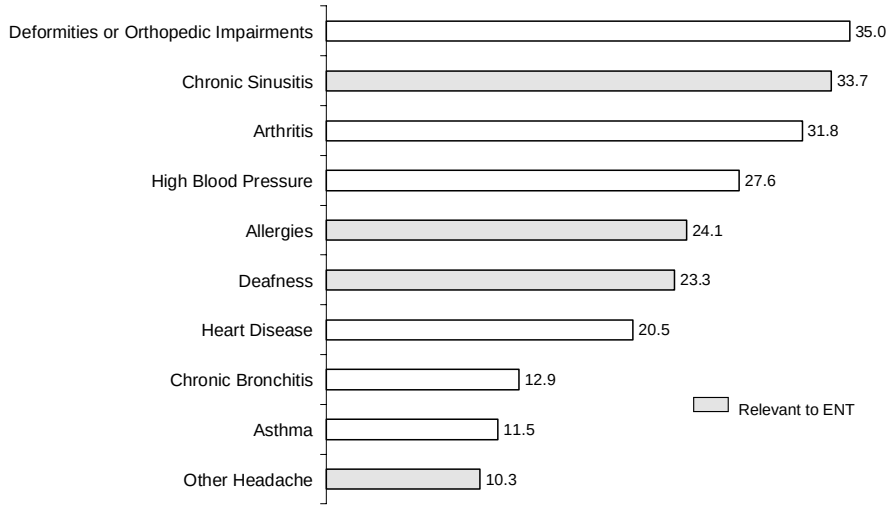
Source: National Center for Health Statistics; William Blair & Company, L.L.C.

Figure 2
Xomed Surgical Products, Inc.
Principal Diagnosis of Doctor Visits by Children



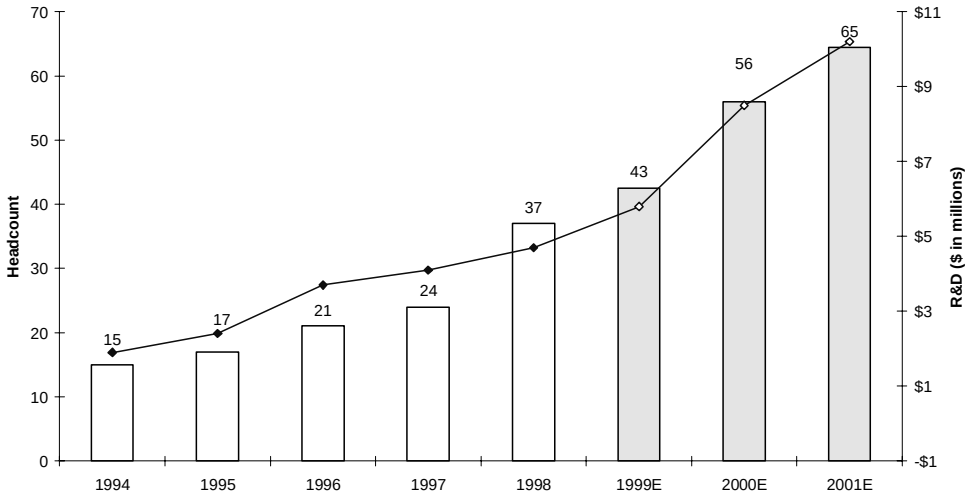
Source: NCHS; William Blair & Company, L.L.C. estimates

Figure 3
Xomed Surgical Products, Inc.
1992* U.S. Prevalence of Chronic Diseases
(in millions)



*Most recent data available
Source: NCHS; William Blair & Company, L.L.C. estimates

Figure 4
Xomed Surgical Products, Inc.
R&D Headcount and Expenditures



Source: Company interviews; William Blair & Company, L.L.C. estimates

Lastly, we believe there is a barrier to entry arising from the specialization and innovation of Xomed's product line, direct salesforce, and marketing efforts to the ENT arena. We believe that only two major competitors, Xomed and Smith & Nephew, have a focused medical device effort directed toward ENT. While Xomed derives more than 80% of its sales from ENT, Smith & Nephew's effort is part of a broader organization covering orthopedics, endoscopy, and wound management. Thus, Smith & Nephew derives less than 5% of its sales from ENT. Other competitors such as Karl Storz, Stryker, and CONMED serve the market predominantly with products and sales organizations focused on other specialties like arthroscopy, and they derive less than 5% of sales from ENT. Furthermore, Xomed has the broadest product line and greatest market share, compared with even Smith & Nephew, as

we discuss more fully in the "ENT Leader" section. These products cover the spectrum of ENT subspecialties: otology, rhinology, and laryngology. For example, most heads of academic ENT departments are otologists, so Xomed's strength in this subspecialty—the smallest—provides leverage across all subspecialties. Consequently, this helps drive its ability to reach opinion leaders and get its devices used in the institutions that train new ENT specialists. Its product line breadth allows broader, deeper access to all ENT surgeons, allowing opportunities for cross-selling and gathering new product ideas. As mentioned later, its dominant and focused direct salesforce dwarfs other competitors' efforts in this arena. Its dedicated research and development (R&D) effort with 37 people and a greater than $5 million budget in 1998, as shown in figure 4, on the previous page, also should provide an entry barrier, as other competitors spend much less on ENT product development or simply sell products designed for other specialties.

A large number of ENT procedures should lead to an almost $500 million worldwide market in 1999, growing at an estimated 14% annually.

Currently, *we estimate there are almost 4 million total ENT procedures performed in the United States annually,* illustrated in table 1. To put in context, this represents about half the number of orthopedic procedures performed annually. Of the ENT procedures, only about 14% are performed on an inpatient basis, with 18% performed at freestanding ambulatory surgery centers (ASCs). The remaining 68%, are performed on an outpatient basis in hospitals, as shown in figure 5, on the following page. As table 1 details, there are a wide variety of relevant procedures with significant volume, including about 1 million insertions of ear ventilation tubes, more than 700,000 tonsillectomies or adenoidectomies, almost 500,000 sinus surgeries, about 400,000 facial cosmetic procedures, and about 400,000 nose reconstructions (septoplasties or rhinoplasties). It is important to note that about 30% of ENT surgeons perform plastic reconstructive procedures. Overall, we forecast that the number of ENT surgical procedures in the United States will grow about 5% per year.

Table 1
Xomed Surgical Products, Inc.
Relevant ENT Procedure U.S. Volume
(in thousands)

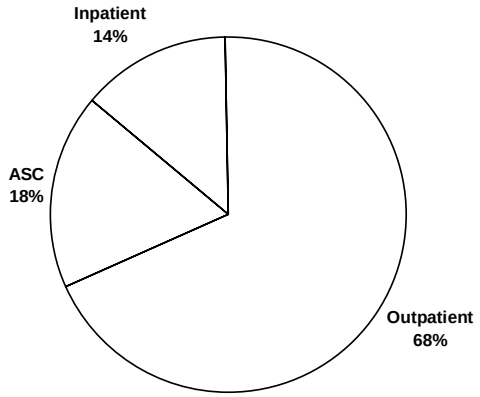
ENT Specialty	Indication	Procedure	1998E
Sinus/rhinology	Chronic sinusitits	Sinus surgery	461
	Cosmetic reconstruction	Septoplasty/rhinoplasty	394
	Trauma	Reconstruction	176
Head and Neck	Chronic infection	Adenotonsillectomy	720
	Vocal cord lesion	Surgical removal	78
	Acoustic neuroma\mastoid infection	Skull base surgery	110
	Tumors	Surgical removal	216
	Facial cosmetic augmentation	Face lifts, other	420
	Sleep apnea\snoring	Uvulopharyngoplasty	135
Ear	Acute otitis media	Myringotomy with tubes	972
	Hearing loss	Middle-ear reconstruction	143
Total			3,826

Source: National Center for Health Statistics; AAO-HNS; AAFPRS; ASPRS; MDI; Dorland; Xomed; William Blair & Company, L.L.C. estimates

We estimate the market value in the United States to be $265 million in 1999 and growing 11% compounded annually, leading to a market of more than $425 million by 2003, as illustrated in figure 6, on the following page. The market value should grow at roughly 2 times the rate of procedure growth for three reasons: 1) innovative products that have a higher price; 2) minimally invasive surgical (MIS) techniques and powered instruments should continue to increase penetration, leading to capital equipment purchases and increased use of disposable versus reusable hand instruments; and 3) new technology—such as Xomed's LandmarX™ IGS system or NIM® nerve-monitoring system—should result in surgery for more difficult types of cases that are low-volume but high-revenue. Additionally, less than one-quarter of most of

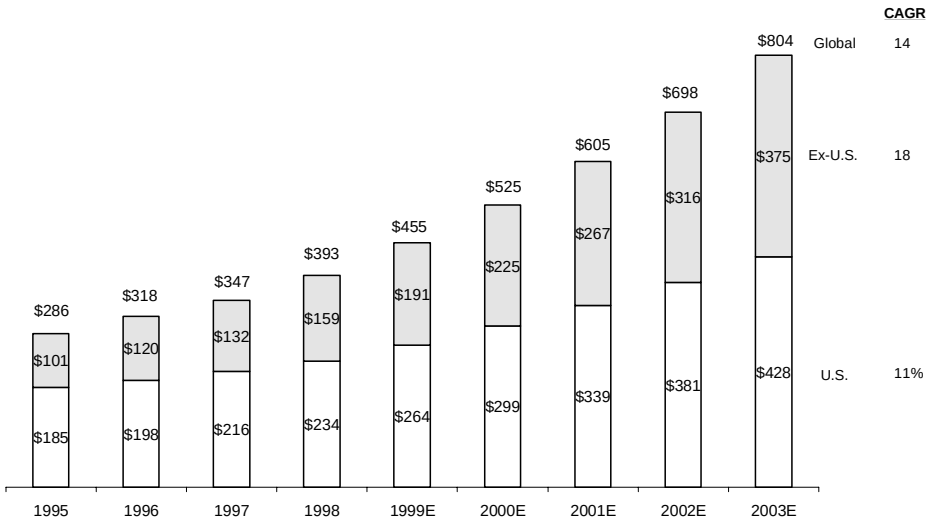
the approximately 9,000 ENT physicians' revenue is derived from surgery. The majority of this revenue is from office visit fees, however, this percentage should shift more toward surgery, as barriers to using surgical approaches fall with the advent of MIS and powered surgical techniques that are more efficient and appealing to patients due to faster surgery, lower pain, less blood, and improved results.

Figure 5
Xomed Surgical Products, Inc.
U.S. 1998 Location of ENT Surgery



Source: National Center for Health Statistics; AAO-HNS; AAFPRS; ASPRS; MDI; Dorland; Xomed; William Blair & Company, L.L.C. estimates

Figure 6
Xomed Surgical Products, Inc.
ENT Market Growth
($ in millions)



Source: Company financials; Doorland; Start-Up; MDI; Clinica; Arthrocare, VTI; Investor Direct; *Investor's Business Daily*, William Blair & Company, L.L.C. estimates

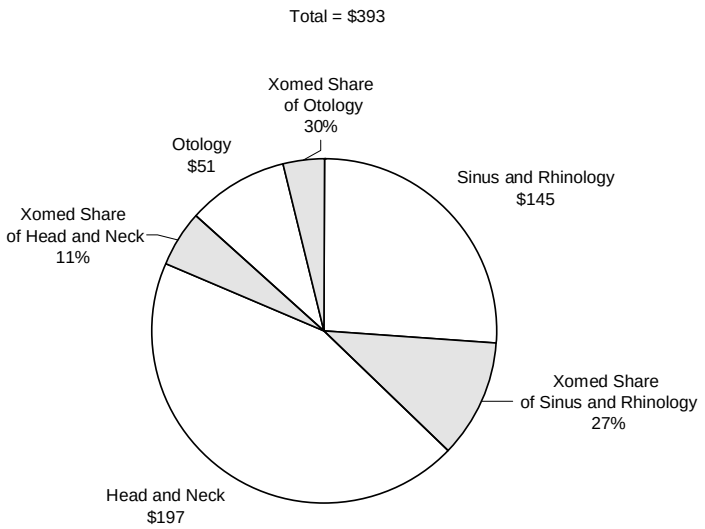
The market value for ENT devices is driven by the price and unit volume of implants, disposables, and capital equipment. For example, a standard plastic vent tube (implant) would be priced at $8 to $15, but an antibacterial tube would be $18 to $20, leading to double the value per procedure. Similarly, the cost of MIS disposable blades range from

$100 to $200, and 1 to 3 blades per surgery might be used. In addition, the capital equipment such as an XPS® shaver system costs about $10,000. Thus, using a MIS procedure would add a value of $150 to $200 to each relevant procedure, such as endoscopic sinus surgeries or adenoidectomies.

We approximate that the international ENT market for medical devices should be more than $190 million in 1999, growing at 18% annually. We believe the ENT market outside the United States is less developed in terms of procedure volume and, more importantly, the use of disposables and MIS techniques. International physicians in general tend to use more reusable surgical instruments. However, infection control concerns are driving increases in disposable use outside the Untied States. We believe that the penetration of powered instruments, and consequently MIS techniques, is significantly lower internationally, but that improved cost, convenience and outcome should lead to higher penetration as it has domestically. Definitive diagnosis of sinusitis also was hampered historically due to lower access to CT scanners, which are 70% to 100% diagnostically effective for sinusitis, versus 20% to 50% effectiveness for plain x-rays. Thus, we anticipate higher procedure volume growth and faster growth of the market value as new, disposable products and MIS techniques are adopted by the 16,000 ENT specialists outside the United States.

The overall ENT market comprises three basic subspecialties: otology (ears), rhinology (nose), and laryngology (throat). Figure 7 details our estimates of the size of each market and Xomed's share in each market. Head and neck, including laryngology, is the largest at almost $200 million, with Xomed's share of 11% having significant upside potential, in our view. Xomed's share in this subspecialty is somewhat underreported, because the XPS® system sales, at about $10,000 per placement, are always reported in sinus and rhinology. About one-third of these procedures are cancer (tumor) related, one-third neck or laryngeal related, and one-third voice related. Sinus and rhinology is second largest, with a value of almost $150 million, with Xomed's share at 27%, and otology is the smallest market, at about $50 million, with Xomed having a 30% share.

Figure 7
Xomed Surgical Products, Inc.
1998 ENT Subspecialty Global Market Segments
and Xomed's Estimated Share
($ in millions)

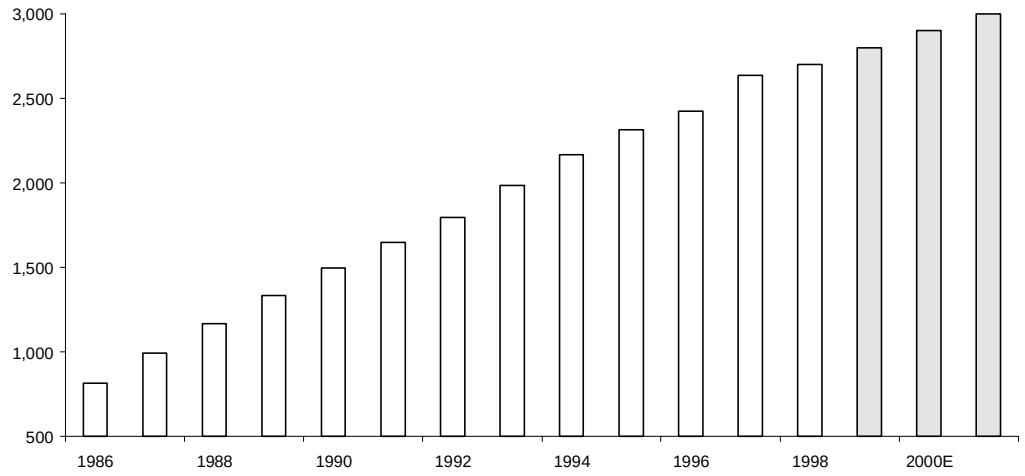


Source: Company financials; Doorland; Start-Up; MDI; Clinica; Arthrocare, VTI; Investor Direct; *Investor's Business Daily*, William Blair & Company, L.L.C. estimates

In addition to increasing disposable revenue, *capital equipment sales should expand in the ENT market*. Xomed's revenue model is driven predominantly by disposables, accounting for about three-quarters of revenue, but much of the disposable volume is due to parts that are used in conjunction with a piece of capital equipment, such as the NIM® system or XPS® shaver system. In addition, while the LandmarX™ system should generate annual service contracts revenue and software upgrades, the bulk of the revenue for these types of systems are generated by the equipment sale. The number of sites for capital equipment is currently large, underpenetrated, and continues to grow. To begin with, virtually all hospitals have ENT departments and thus likely would benefit from powered surgical or other equipment, both in- and outpatient, creating potential demand for at least 5,000 placements of each product more if procedure volume warrants. In addition, there are about 2,700 freestanding ASCs, most of which are multispecialty and should be locations for ENT capital equipment. Unfortunately, at this point, many office-based procedures are not reimbursed, which actually helps drive the growth of ASCs.

ASCs are worth emphasizing, because they seem to be growing in importance for most surgical specialties, including ENT. Currently, about 6.5% of ENT-only procedures and 12% of plastic surgery procedures are performed in these centers. Figure 8 shows the explosive growth of these centers as reimbursement improved, and they became more accepted by patients, providers and insurers. In 1970, the first center opened; in 1971, the American Medical Association (AMA) endorsed the concept; and in 1982, Medicare first approved payments for 200 procedures performed at these locations. By 1998, Medicare had approved payments for 2,300 procedures. In general, patients are more satisfied with surgeries in ASCs than hospitals. When this satisfaction is combined with the additional greater satisfaction and reduced risk patients perceive for MIS procedures, such as those developed and disseminated by Xomed, patients seem to be more willing to undergo ENT surgery. This leads to benefits for the patient and the ENT surgeons. In addition, insurers like these centers because facility costs are typically at least 30% to 50% lower than those for a hospital. For example, Blue Cross Blue Shield estimates that tonsillectomies only cost on average $464 in an ASC, versus $998 in hospitals.

Figure 8
Xomed Surgical Products, Inc.
Ambulatory Surgery Centers in the United States

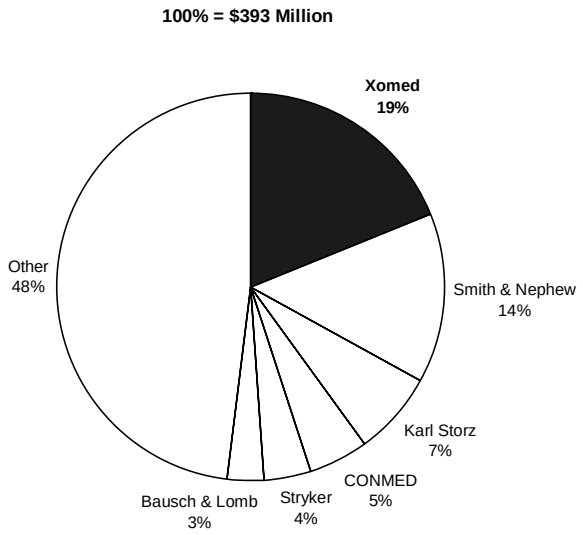


Source: SMG Marketing Group; SAMBA; Healthsouth; FASA; William Blair & Company, L.L.C. estimates

ENT Leader

Xomed commands an estimated market-leading 19% of the $393 million global market in 1998 for ENT surgical products, as shown in figure 9. We believe Xomed's position as the ENT leader is attributable to 1) the innovative and broadest medical device offering dedicated to the ENT specialty; 2) an unparalleled distribution system that squarely targets the ENT market; and 3) prime positioning.

Figure 9
Xomed Surgical Products, Inc.
1998 ENT Worldwide Market Shares



Source: Clinica; MDI; Start Up; Company Reports; Industry Interviews; SMG Marketing Group; SAMBA; Healthsouth; FASA; William Blair & Company, L.L.C. estimates

Broad, Innovative and ENT-focused Product Line

Xomed's more-than-4,000 SKU product line is, in our opinion, the broadest in the industry, covering the full range of instruments and supplies, from $5 implantable ventilation tubes to the $150,000 LandmarX™ IGS system, as shown in table 2, on the following page. The company should continue to lead the competition by continually developing and introducing new products. Nineteen ninety-eight was marked by the increase in R&D staff to 37, as shown in figure 4, on page 8, and the introduction of more than 200 new products—including product-line extensions and accessories, the most notable of which was the LandmarX™ IGS system. As figure 10 illustrates, the company's new products provided 34% of revenue in 1998, up from only 14% of revenue in 1995, a testament to the success of Xomed's development efforts.

All of Xomed's products are designed with the improvement of current procedures in mind. The majority of ENT specialty practitioners use procedures more than 60 years old and well entrenched. The snare-and-tear technique for sinus surgery has been targeted by Xomed as the beachhead for powered surgery conversion of ENT, as various knee procedures were in arthroscopy. By offering improvements to, rather than radical replacement of, procedures, doctors are allowed a less-steep learning curve, and the conversion process requires less "missionary" work on the part of Xomed. For example, adenoidectomies, which historically have been done "blind" with curettes, can be performed faster with more accurate and complete tissue removal using the XPS® shaver system. The company's innovative products offer ENT physicians several appealing features such as improved results and reduced procedure time, leading to increased throughput. Use of Xomed's Activent® antimicrobial ventilation tubes has reduced the incidence of post-operative otorrhea, or

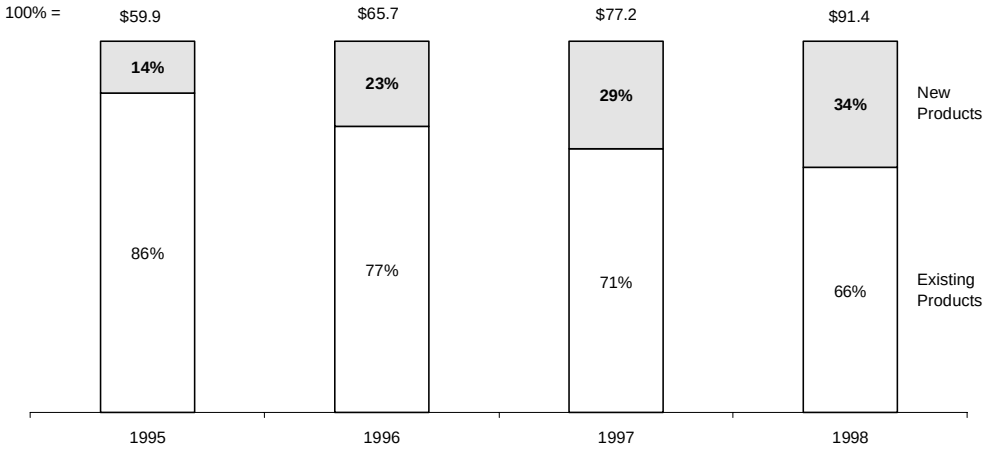
fluid production of the ear, by 60%. The use of powered instruments, such as the XPS® StraightShot® with RAD blades, reduced the operating room time for an endoscopic sinus surgery procedure from 3.5-4 hours to 45 minutes, and lowered morbidity by up to 40%. Similar results appear possible using this system for adenoidectomies. Surgery time could be reduced from 45 minutes to 3 to 4 minutes, with more complete tissue removal. The use of the StraightShot® also allows doctors to remove tissue more easily, allowing for more-effective surgeries. This eliminates the need to perform additional surgeries often required if insufficient tissue is removed. There also should be facility expense savings of $200 to $500 by reducing surgical time 1 to 2 hours.

Table 2
Xomed Surgical Products, Inc.
Competitor Product Lines

Company	Powered Tissue Removal	Electrosurgery	Implantable Devices	Nerve Monitoring	Sinus Packing	Endoscopy/ Visualization	Hand Instruments	Image-guided Surgery
Xomed	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Smith & Nephew	X		X	X	X	X	X	
Karl Storz	X					X	X	
CONMED	X	X				X		
Stryker	X					X		
Bausch & Lomb (Storz)							X	
Wolf						X		
Visualization Technology								X
Brain Labs								X
Radionics								X
Arthrocare		X						
Somnus		X						
Influence			X					
Micromedics			X					
Ultracell					X			
Pharmacia & Upjohn					X			

Source: Company Financials; FDA; Industry Interviews; William Blair & Company, L.L.C. estimates

Figure 10
Xomed Surgical Products, Inc.
Revenue Contribution of New Products*
($ in millions)



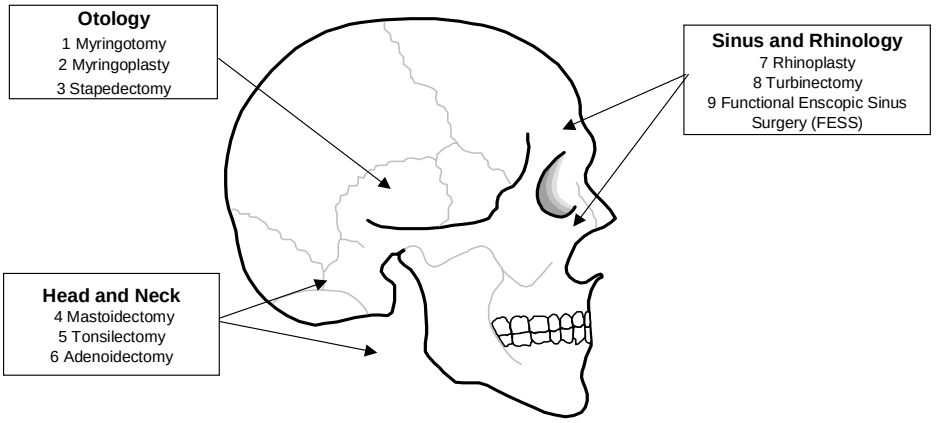
* less than 3 years old

Source: Company financials; William Blair & Company, L.L.C. estimates

As shown in figure 11, Xomed provides products covering the entire ENT specialty, from otologists to sinus and rhinologists, to laryngologists and head and neck surgeons. The products are often subspecialty or procedure-specific. Certain components might span specialties such as the visualization and powered surgical equipment, but many of the

disposable components are tailored to fit the needs of particular subspecialists. For instance, the XPS® StraightShot® powered surgical shaver is used in head and neck, as well as sinus and rhinology procedures, two of the subspecialties within ENT shown in figure 11. The shaver provides a platform from which procedure-specific disposables may be provided. For head and neck procedures, the company sells the RADenoid™ and RAD™ Airway blades, with extended lengths' designed to reach down the throat to remove adenoids and polyps. For sinus and rhinology, the curved RAD 40™ blade is well suited to be guided up and around the sinus cavities, while the aggressive RAD 55™ Bur may be used to effectively bore through hard tissue. The RAD 60 X-Treme™ curved blade is curved 60%, the greatest curve available, to access the frontal sinuses, and the very small 2.9 millimeter Silver Bullet™ blade provides the delicate capabilities needed for pediatric applications. The development of blades for the XPS® system to be used in head and neck liposuction procedures will broaden the range of services offered by the portion of ENT doctors who also perform plastic surgery, providing increased practice revenue.

Figure 11
Xomed Surgical Products, Inc.
Major Ear, Nose and Throat Procedures by Subspecialty and Relevant Xomed Products



Otology	Head and Neck	Sinus and Rhinology
Activent Antimicrobial Ventilation Tubes (1)	NIM-2XL Interoperative Nerve Monitor (3)	XPS StraightShot Shaver System (2,3,4,5,6,7,8,9)
Stapes Prostheses (2,3)	PowerForma Surgical Drill (4,5,6)	RAD 40 Blade (8,9)
	RADenoid Blade (5,6)	RAD 55 Bur (8,9)
	RAD Airway Blade (5,6)	Autoclavable Endoscopes (9)
	EMG Endotracheal Tubes (5,6)	Merocel Sinus Packing (7,8,9)

(Procedures using product)

Source: NCHS; Xomed; William Blair & Company, L.L.C.

The LandmarX™ image guided surgery (IGS) system is easy to use and integrates familiar Xomed products such as the StraightShot® and Powerforma™ into a powerful software and visualization tool for ENT surgeons. The LandmarX™ will enable surgeons to handle complicated cases more effectively, such as trauma cases or tumors near critical nerves or blood vessels, as well as to do preoperative planning. Often ENT surgeons work along side neurosurgeons in trauma cases to correct such critical conditions as cerebral spinal fluid leaks. The LandmarX™ also has significant advantages compared with the other major ENT IGSs, supplied by competitor VTI. The VTI IGS system requires a disposable, fixed-size, *$125 headband* to register a CT image with the actual structures of a patient's head and neck. Combined with the system's resolution, the VTI IGS system also is not intended for use with patients younger than *16 years old*. In contrast, the LandmarX™ does not require the cost nor inconvenience of a headband or other artificial registration devices, and combined with its resolution, is indicated for use with patients as young as *18 months old*.

To help prevent injuring one of the ubiquitous nerves in the head and neck regions, which could cause facial paralysis or other serious complications, Xomed supplies the NIM-2® nerve integrity monitor. The NIM Response®, a new four-channel NIM nerve monitoring system, soon will launch—the first full-featured monitor to allow doctors to observe four separate nerves rather than the current two.

Xomed also has state-of-the-art, sinus packing material, including lint-free MeroCel™ and the upcoming MeroGel™ product. MeroGel™, licensed from Fidia Advanced Biopolymers, brings *bioresorbable* technology to the surgical packing area. It is a material that absorbs up to 10 times its weight in liquids as it gradually changes into a gel. We believe this is the first new product to eliminate the painful step of removing packing material put in place to control bleeding, because MeroGel™ dissolves in about two weeks.

Strong, Focused Distribution System

Xomed is the sole company to have an entire direct salesforce dedicated to the ENT market. Globally, Xomed has 99 direct sales representatives, with 65 in the United States. These reps are employees of Xomed, rather than the agents used by other competitors. The company's closest competitor, Smith & Nephew, has only 15 ENT direct specialists, relying on others such as their orthopedics reps to make ENT sales calls when in hospitals. Although CONMED has expressed a renewed focus on sales of powered surgical equipment to the ENT market through its 40-person Hall Powered surgical division, it plans to focus only 60% of its time on this effort, or only 24 full-time equivalents. These sales reps will be focused only on powered surgery. A key differentiator is Xomed's reach to ENT physicians who practice *all* the various subspecialties and procedures, not just those, for example, known to use powered instruments or those who perform endoscopic procedures. To illustrate, Stryker's orthopedic representatives call on ENT departments in hospitals, yet are only able to offer powered instruments and products related to endoscopy.

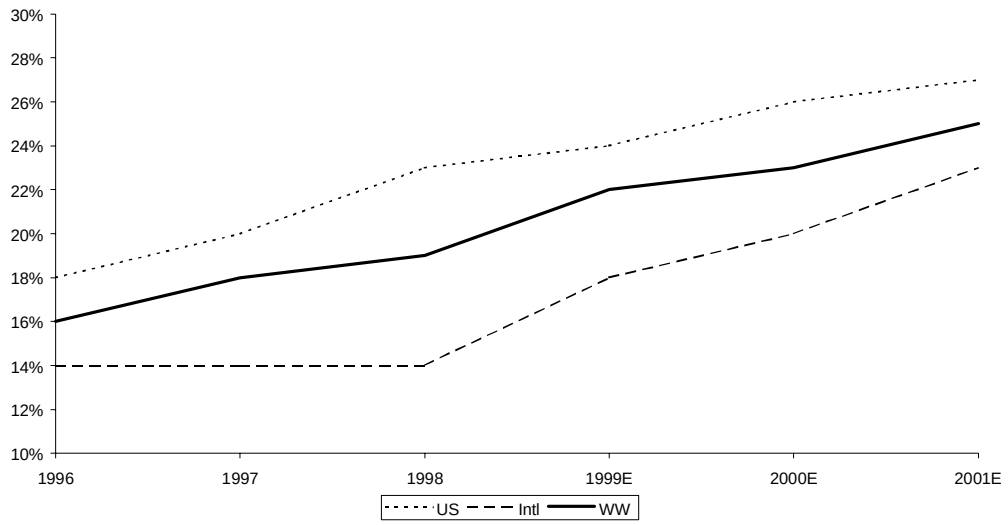
Internationally, Xomed serves France, Germany, Australia, Canada, and the United Kingdom with a direct salesforce of 34 and uses a network of 120 distributors to service the rest of the globe. Additionally, the recent acquisition of MicroFrance's facilities will provide the company more needed infrastructure for continued international growth.

Well Positioned

Xomed's market-leading 19% worldwide market share is just one measure of its leading position. In our opinion, the company has built upon surgeon relationships to form a loyal customer base and great brand association. Xomed has formal and informal relationships with ENT opinion and thought leaders at such highly regarded institutions as University of Pennsylvania, Johns Hopkins, Washington University in Saint Louis, the Shey Clinic in Memphis, and the Georgia Clinic in Savannah. The company routinely provides video production equipment and assistance at no cost to doctors who wish to create teaching materials that use Xomed products, and it sponsors the Xomed/Otolaryngology Research Society of the United Kingdom ENT award as well. Xomed's position has allowed it to capture an estimated market share in the United States of 23% in 1998, increasing from 18% in 1996, as depicted in figure 12.

The recent acquisition of MicroFrance, a small French ENT manual instrument company, further enhances Xomed's image and position globally. MicroFrance's instruments long have been considered the premier line of hand tools available for ENT surgeons, with many asserting the importance of the "MicroFrance feel" these high-quality tools possess, justifying the premium that doctors are willing to pay for them. Xomed hopes to broaden the global reach of these products by making them available through its wide distribution system. As figure 12 shows, we estimate that the addition of MicroFrance will increase Xomed's international share to 18% in 1999 from 14% in recent years. Furthermore, we forecast that Xomed will be able to build on this base to increase its international share to 23% by 2001.

Figure 12
Xomed Surgical Products, Inc.
Geographic Market Shares



Source: Company financials; Industry Interviews; Doorland; Start-Up; MDI; Clinica; Arthrocare, VTI; Investor Direct; Investor's Business Daily, William Blair & Company, L.L.C. estimates

In our opinion, Xomed possesses the necessary design and manufacturing competencies to maintain its leadership. It has the ability to design the electronics for its powered surgical systems and build them in-house. It also can either micromachine or mold parts, depending on the circumstances, which enhances product quality and optimizes cost of goods. These capabilities, built through its development of the broadest ENT product line available, also allow it to leverage surgeon-driven product concepts, as well as to transfer concepts from other surgical specialties into the ENT marketplace.

Xomed was selected by Sofamor Danek Group (SDG) as its partner to distribute its LandmarX™ image-guided surgery (IGS) system for the ENT market. We believe that SDG, a division of Medtronic, is the leader in the IGS field, and the company recognized Xomed as the best distribution vehicle for this product to the ENT market. The LandmarX™ also provides Xomed with the opportunity to cross-sell various integrated products, such as the powered shaver systems. ENT software sales by Xomed to existing and future owners of SDG's Stealth IGS systems allows the company exposure to new clients that may be in need of other Xomed products. The initial cost for the system is $150,000, with $12,000-$15,000 annual service contracts and $40,000-$50,000 software sales to upgrade placed systems add continuing revenue. The LandmarX™ system was launched in December 1998.

Exceptional Company Management

Xomed's senior management team has a record of building a successful business in the area of ENT. It also possesses a proven record linked to the history of several of the leading medical device firms that participate in both the ENT and minimally invasive surgical (MIS) products markets.

Family Ties and History Bind Xomed to ENT Market

CEO Jim Treace, along with brothers John (vice president of Sales) and Dan (vice president of Regulatory Affairs and Quality Assurance), father Harry, and COO Barry Bays, have been involved in the medical device industry for MIS and ENT procedures since 1956 and have founded or been involved with three of the top four device firms that participate in the ENT market. Figure 13 traces the movement of these individuals and their companies. In 1956, Harry Treace hand carved the first prosthetic replacement bone for the middle ear and later went on to become president of Richards Medical (now a division of Smith & Nephew), an orthopedics company with a significant ENT product line. Richards Medical was also home to Jim and John Treace and Mr. Bays, where they held senior management positions through 1979. In 1981, Jim Treace and Mr. Bays left Richards for Concept, an eclectic medical device firm that manufactured products for a number of various specialties without any particular direction. Under this new management, Concept was focused on the orthopedic device market, particularly in the area of arthroscopy and MIS, increasing the company's business from $10 million in 1981 to $50 million in 1989. Concept's arthroscopy products helped drive the conversion of knee surgery to minimally invasive and powered arthroscopic procedures to approximately 90% penetration of procedures by the end of a 10-year period.

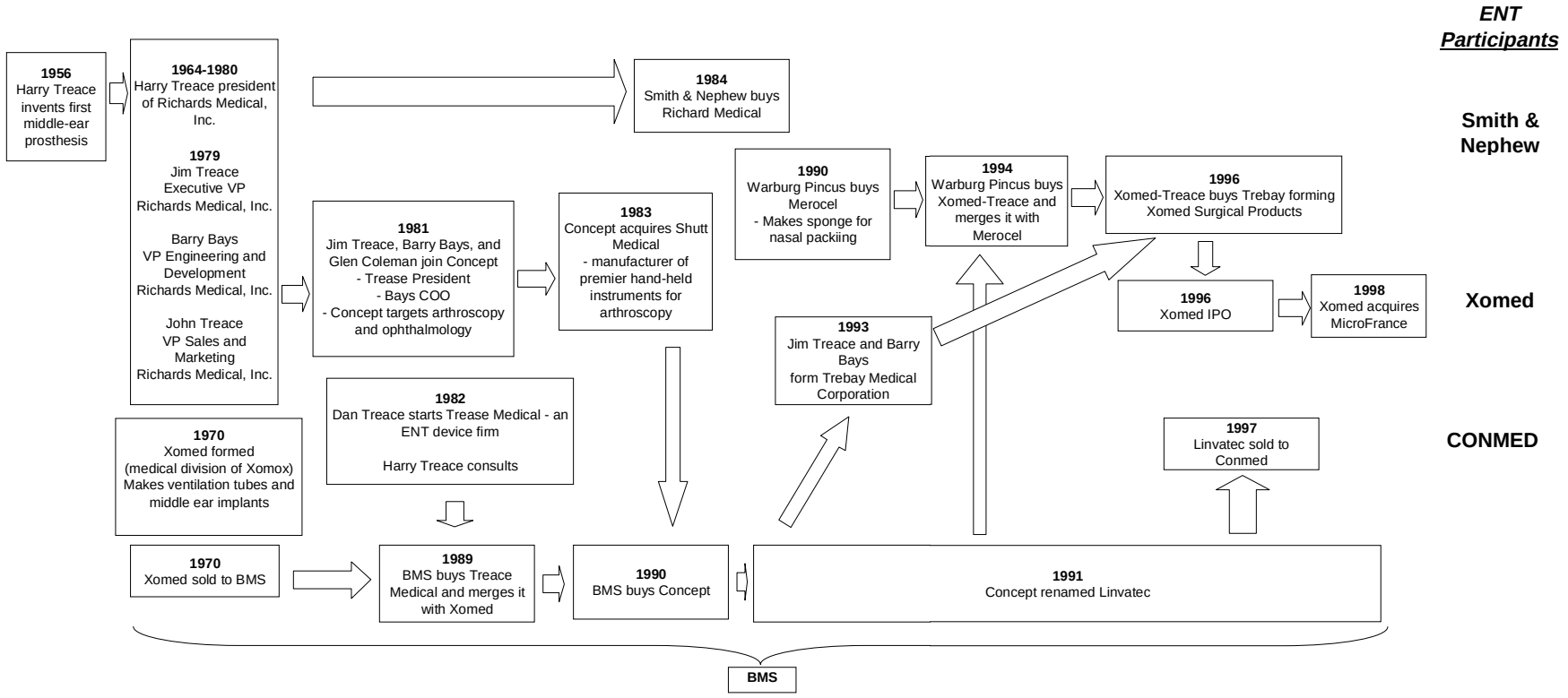
While Messrs. Treace and Bays worked at Richards Medical and Concept, Bristol-Myers Squibb (BMS) was busy building up its Zimmer orthopedic business. In 1979, BMS acquired Xomed, then a manufacturer of ventilation tubes and inner-ear implants, and in 1989 acquired Treace Medical, an ENT device company founded by Dan Treace. In 1990, Concept's success in the arthroscopy market attracted BMS, and the pharmaceutical company soon acquired it. Concept's name changed to Linvatec—"Least Invasive Techniques"—rounding out BMS' device portfolio. Jim Treace and Mr. Bays left Linvatec in 1993 and founded TreBay Medical Corporation to further explore the application of MIS techniques to ENT and orthopedics. Not long after their departure, BMS began to divest itself of its device holdings as it refocused on its pharmaceuticals business. Xomed was sold to Warburg Pincus group in 1994, which merged the company with its Merocel Corporation, which made surgical packing materials for ENT procedures. Arthroscopy powerhouse Linvatec eventually was sold to medical device manufacturer CONMED in 1997. Warburg purchased TreBay in 1996, merging it with Xomed, thus reuniting Jim Treace and Mr. Bays with Dan Treace and the growing franchise in the ENT market shown in table 3 and figure 13.

Table 3
Xomed Surgical Products, Inc.
Company History

1970	Xomed Founded
1979	Acquired by Bristol-Myers Squibb
1994	Acquired by Warburg, Pincus
1996	TreBay Acquisition
1996	IPO
1997	XPS system launched
1998	Fidia alliance (Merogel(TM) product line)
1998	Sofamor Danek aliance (LandmarX(R) image-guided surgery system
1998	Follow-on offering and 3-for-2 stock split
1998	MicroFrance acquisition

Source: Company financials; William Blair & Company, L.L.C. analysis

Figure 13
Xomed Surgical Products, Inc.
Management History



Source: Various Company Filings; Interviews; In-Vivo; William Blair & Company, L.L.C. analysis

Prior Experience Leads to Successful Cultivation of ENT Niche

While at Concept, Xomed's management gathered significant experience with the conversion of arthroscopy to minimally invasive procedures in the area of knee surgery. They recognized that similar opportunities should exist in other underserved medical specialties. This led Jim and Barry Treace back to ENT, a medical specialty ripe for innovation.

Xomed has been able to bring various technologies used in other medical specialties to the area of ENT. Antimicrobial ventilation tubes allow lower infection rates. Unique materials such as Merocel, a highly absorbant packing material formerly used in eye surgeries and in limited applications in the semiconductor industry, and the recently announced MeroGel™, a bioresorbable packing material, effectively eliminate what is considered by some to be the most painful part of sinus surgery, the removal of the surgical packing material used to control post-operative bleeding. MIS powered surgical equipment such as the XPS® StraightShot® and the Powerforma™ systems, have their roots in other surgical specialties. The XPS® StraightShot® origins may be traced to the surgical shaver systems used in arthroscopic procedures. The Powerforma™ system for head and neck operations derives from systems used in neurology and spine procedures. The launched LandmarX™ IGS system originally was developed for use in the spine by SDG. These new products and likely others yet to be disclosed are anticipated to have a large impact on ENT, facilitating safer and more-effective outcomes.

Tenured Management Completes the Rest of Team and Leads to Successful Business

Table 4 shows the rest of the management team. Its collective experience spans many years and various aspects of the medical device landscape. Extensive upper-level experience at Zimmer, Merocel, Linvatec, and TreBay provides the company with an intimate knowledge of the industry's workings, as well as impressions of how competitors have performed in the market for assorted surgical products. Together, management has been able successfully to build Xomed into the market leader in ENT, with more than $90 million in revenue.

Table 4
Xomed Surgical Products, Inc.
Management Team

Name	Position	Age	Prior Experience
James T. Treace	Chairman, President, CEO	52	Co-founder, President, Chairman and Chief Executive Officer of ***TreBay***; President of ***Linvatec Corporation;*** President and Chief Executive Officer of ***Concept***
F. Barry Bays	Senior Vice President - Operations, COO	51	Vice President, Chief Operating Officer, and a Director of ***TreBay***; Executive Vice President and Chief Operating Officer of ***Linvatec***; Executive Vice President and Chief Operating Officer of ***Concept***
Thomas E. Timbie	Vice President - Finance, CFO	40	Vice President, Chief Financial Officer of ***TreBay***; Senior Director-Working Capital and Assistant Controller of ***Linvatec***; Director-Financial Accounting and Reporting of ***Concept***
Guy K. Williamson	Vice President - International	43	Vice President of ***Zimmer International***; General Manager-China and Hong Kong of ***Bristol-Myers Squibb***
John R. Treace	Vice President - U.S. Sales	53	Vice President-Sales and Marketing of ***TreBay***; Product Manager, Director-Marketing and Sales, and Group Vice President-Marketing and Sales of ***Richards Medical Company***
R. Glen Coleman	Vice President - Marketing	43	Vice President-Global Marketing; Vice President-Sales; Vice President and General Manager-Concept Division of ***Linvatec***
Fred B. Dinger, III	Vice President - Research and Development	37	Vice President-Research and Development; Director-New Product Development; Manager-Power Systems Development of ***Linvatec***
Dan H. Treace	Vice President - Regulatory Affairs and Quality Assurance	49	Vice President and Quality Manager of ***TreBay;*** Vice President-Technical Affairs of ***Xomed-Treace;*** President of ***Treace Medical, Inc.***
Mark J. Fletcher	Vice President, Division President - Ophthalmic Products	42	Several Senior Management positions with ***Stryker***, including Executive Vice President-Sales and Marketing
Gerard J. Bussell	Vice President - Operations	49	Director of ***Merocel***; Managing Director of ***The Vertical Group, Inc.***

More Than Twenty-five Percent EPS Growth Expected

Xomed should experience more than 25% compounded annual earnings per share growth over the next several years. This earnings growth should be driven by several factors: revenue growth, improved margins, and declining selling, general, and administrative expense ratios. Therefore, we expect net income as a percentage of revenue to increase from 10.3% to 12.5%.

Revenue should grow more than 20% annually.

Both market growth and new product revenues should drive Xomed's revenue growth. The $455 million market for ENT surgical devices and supplies is forecast to grow 11% annually in the United States and 14% globally. We expect Xomed's internally generated revenue to grow more than 20% for the next several years as shown in figure 14, rising from $91 million in 1998 to $179 million in 2001. Revenue should grow 32% in 1999, with the additional growth attributed to about $8 million derived from the acquisition of MicroFrance at the end of 1998. With the international sales increase due to MicroFrance, as well as anticipated faster market growth outside the United States, we forecast the geographic distribution of revenue to shift from the trend of roughly 30% derived internationally in 1998, to 38% by 2001, as illustrated in figure 15. Table 5 shows Xomed's deriving much its revenue growth in the subspecialties of sinus and rhinology and head and neck, which are expected to grow 37% and 19%, respectively, and should make up 75% of sales by 2001, as seen in figure 16. (Figures 15-17 are on the following pages.)

Table 5
Xomed Surgical Products, Inc.
Product Line Sales Analysis

Annual Revenue

	1995	1996	1997	1998	1999E	2000E	2001E
Sinus & Rhinology	17,062	22,260	28,848	38,981	**55,774**	**74,071**	**99,281**
Head & Neck	14,188	16,088	17,842	21,372	**26,215**	**30,383**	**35,828**
Otology	12,392	13,855	14,444	15,124	**16,108**	**17,045**	**18,134**
Total Core Business	43,642	52,203	61,134	75,477	**98,097**	**121,499**	**153,244**
Opthalmic & Other	16,223	13,461	16,066	15,906	**22,421**	**24,611**	**25,844**
Total Company	59,865	65,664	77,240	91,383	**120,518**	**146,110**	**179,088**

Year-over-year Growth

	1995	1996	1997	1998	1999E	2000E	2001E
Sinus & Rhinology		30%	30%	35%	**43%**	**33%**	**34%**
Head & Neck		13%	11%	20%	**23%**	**16%**	**18%**
Otology		12%	4%	5%	**7%**	**6%**	**6%**
Total Core Business		20%	17%	23%	**30%**	**24%**	**26%**
Opthalmic & Other		-17%	19%	-1%	**41%**	**10%**	**5%**
Total Company		10%	18%	18%	**32%**	**21%**	**23%**

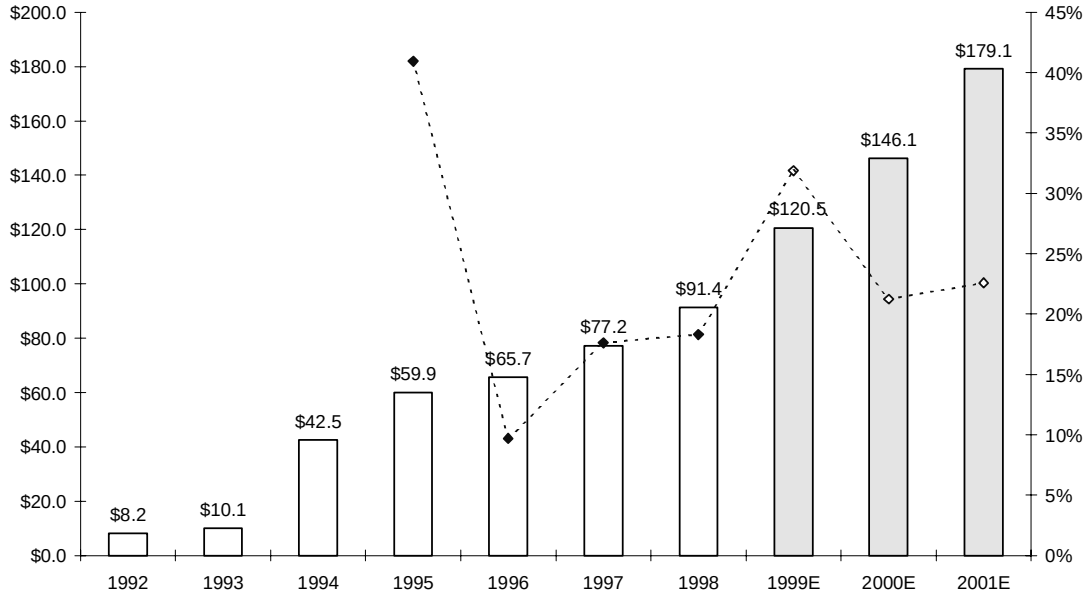
100% Revue Mix

	1995	1996	1997	1998	1999E	2000E	2001E
Sinus & Rhinology	29%	34%	37%	43%	**46%**	**51%**	**55%**
Head & Neck	24%	25%	23%	23%	**22%**	**21%**	**20%**
Otology	21%	21%	19%	17%	**13%**	**12%**	**10%**
Total Core Business	73%	80%	79%	83%	**81%**	**83%**	**86%**
Opthalmic & Other	27%	21%	21%	17%	**19%**	**17%**	**14%**
Total Company	100%	100%	100%	100%	**100%**	**100%**	**100%**

Source: Company financials; William Blair & Company, L.L.C. estimates

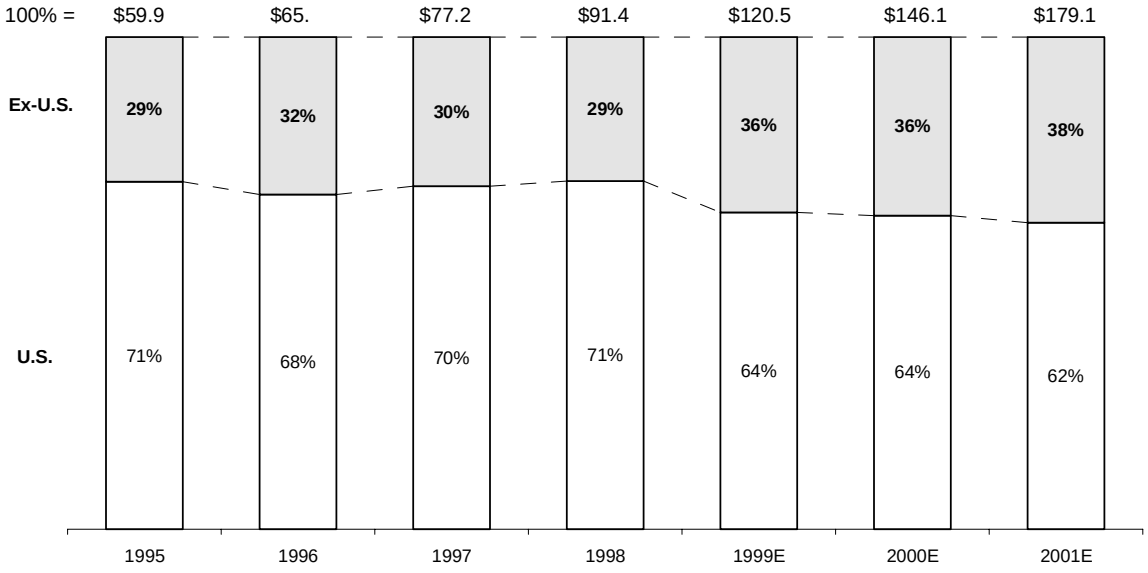
Going forward, Xomed targets revenue from new products to be 30% to 35% of total revenue, illustrated in figure 10. We believe this is attainable due to the company's increasing focus on new products, demonstrated by the introduction of 200 new products in 1998 and at least another 200 planned for 1999. The company plans to leverage its growing installed base of equipment—XPS® and Powerforma™ systems—to drive the demand for disposables, which currently constitute 77% of total revenue. The company had placed more than 2,000

Figure 14
Xomed Surgical Products, Inc.
Revenue and Growth Rate
($ in millions)



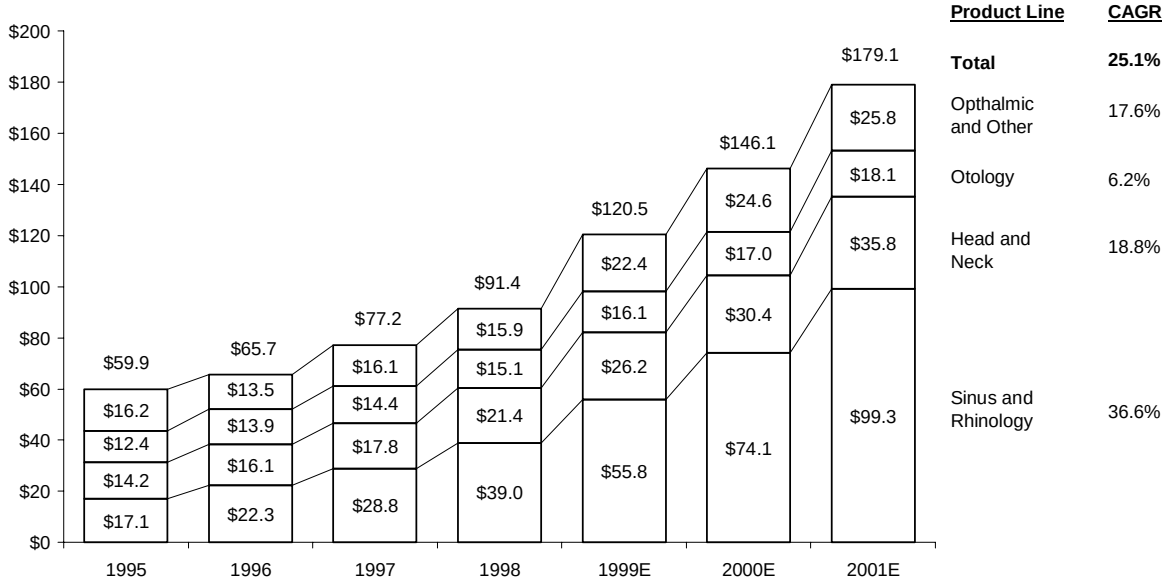
Source: Company financials; William Blair & Company, L.L.C. estimates

Figure 15
Xomed Surgical Products, Inc.
Geographic Sales Distribution
($ in millions)



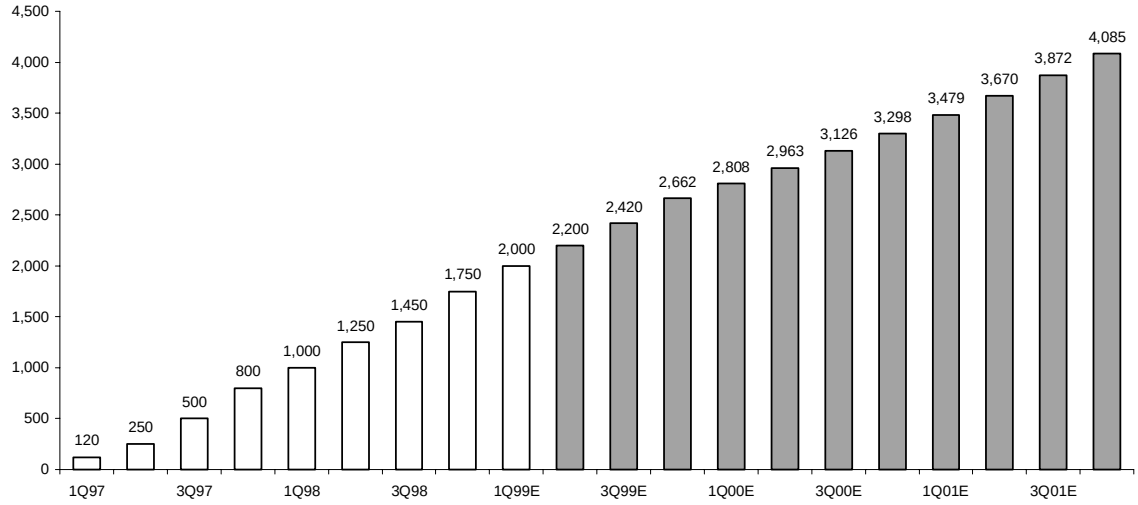
Source: Company financials; William Blair & Company, L.L.C. estimates

Figure 16
Xomed Surgical Products, Inc.
Revenue Mix
($ in millions)



Source: Company financials; William Blair & Company, L.L.C. estimates

Figure 17
Xomed Surgical Products, Inc.
XPS (R) Powered Shaver System Placements



Source: Clinica; MDI; Start Up; Company Reports; Industry Interviews; SMG Marketing Group; SAMBA; Healthsouth; FASA; William Blair & Company, L.L.C. estimates

of the $10,000 XPS® systems by the first quarter of 1999, as shown in figure 17, on the previous page. Each system generates approximately $9,000 in disposable revenue from the sales of blades at an average cost of $100 each and other system-related accessories. Often 2 to 3 blades of different types must be used for one surgical procedure. Lastly, the company's Solan ophthalmologic division also may provide revenue growth upside. Solan's hybrid salesforce, comprising 5 direct reps and 14 distributors, should increase revenue growth through the sales of its Flapmaker disposable microkeratome and newly repackaged instruments and fluid control products used in the increasingly popular laser vision-correction operation, LASIK.

We believe that pricing trends will vary by product category with "physician preference" items commanding modest increases going forward. Consequently, we estimate that the sinus-and-rhinology and head-and-neck markets should see 3% to 4% annually price increases. In contrast, we expect pricing in the otology and ophthalmology markets to remain unchanged. The net impact should be a modest 2% to 3% growth in prices across the entire product line.

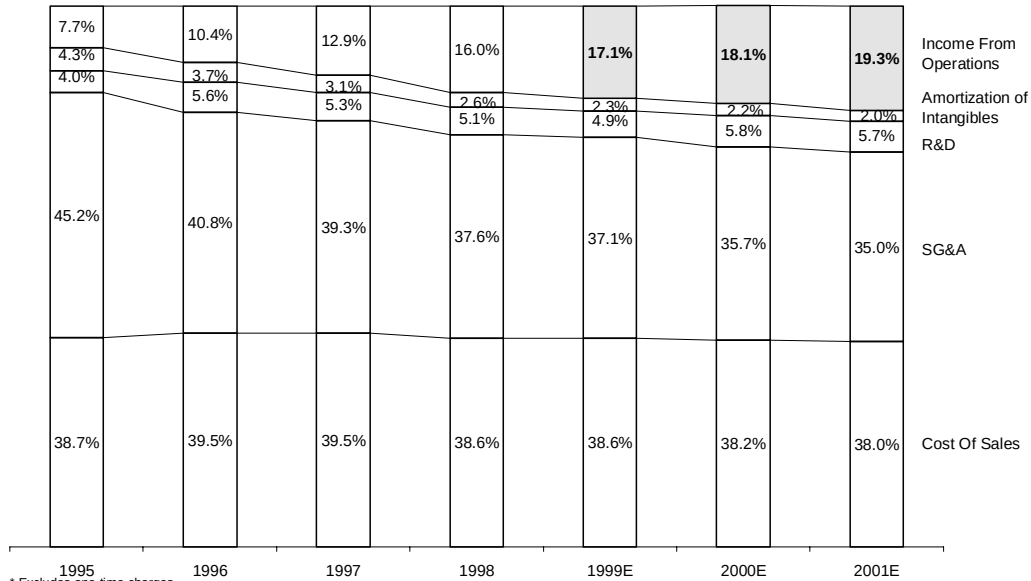
Gross margin should increase 60 basis points to more than 62% by 2001.

The company has consistently been able to increase gross margins historically through improved manufacturing. For example, it appears to be the only company that successfully can injection mold Teflon® into ear vent tubes. Other firms must machine the tubes, a costlier and more time-consuming process. We also expect the realization of efficiencies due to operating leverage as volume increases and the revenue shifts toward the higher-gross-margin disposables side of the business, as well as software for the LandmarX™ system.

Operating expenses should continue to decline 260 basis points to less than 43% of revenue by 2001.

We expect operating expenses as a percentage of revenue to decline over the next few years; launching expenses for such products as the LandmarX™ system will be scaled back after the product is fully introduced this year and the direct selling effort will be further leveraged. R&D expenses should increase as a percentage of revenue from 5.1% in 1998 to 5.7% in 2001. We believe this increase is necessary in light of new product development targets, 30%-35% of revenue.

Figure 18
Xomed Surgical Products, Inc.
Cost of Sales and Operating Expense*



* Excludes one-time charges
Source: Company financials; William Blair & Company, L.L.C. estimates

As a result of these changes in gross margin and operating expenses, we anticipate operating margin to improve from 16% in 1998 to more than 19% in 2001, as shown in figure 18 and table 6. We forecast operating income to increase 33% compounded annually, from $14.7 million in 1998 to $34.6 million in 2001.

Table 6
Xomed Surgical Products, Inc.
Annual Income Statement
($ in thousands)

	1996	1997	1998	1999E	2000E	2001E
Revenue	$65,664	$77,240	$91,383	**$120,518**	**$146,110**	**$179,088**
Cost of sales	25,926	30,475	35,283	**46,480**	**55,825**	**68,026**
Gross profit	39,738	46,765	56,100	**74,038**	**90,286**	**111,061**
Selling, general, and administrative	26,799	30,334	34,335	**44,771**	**52,091**	**62,644**
Research and development	3,659	4,088	4,682	**5,846**	**8,546**	**10,194**
Amortization of intangibles	2,421	2,374	2,417	**2,818**	**3,218**	**3,618**
Total operating expenses	32,879	36,796	41,434	**53,435**	**63,855**	**76,456**
Income from operations	6,859	9,969	14,666	**20,603**	**26,431**	**34,605**
Interest income	(2,205)	(104)	559	**467**	**733**	**1,162**
Other income, net	525	234	69	**320**	**224**	**162**
Earnings before taxes	5,179	10,099	15,294	**21,390**	**27,388**	**35,928**
Income tax expense	2,020	3,969	5,903	**8,099**	**10,375**	**13,611**
Net income (loss)	$3,159	$6,130	$9,391	**$13,291**	**$17,012**	**$22,318**
Net income per share diluted	$0.37	$0.55	$0.78	**$1.02**	**$1.27**	**$1.64**
Shares outstanding	8,535	11,268	12,088	**13,086**	**13,366**	**13,646**
Year-over-year growth						
Revenue		18%	18%	**32%**	**21%**	**23%**
Gross margin		18%	20%	**32%**	**22%**	**23%**
Operating income		45%	47%	**40%**	**28%**	**31%**
Net income		94%	53%	**42%**	**28%**	**31%**
EPS		48%	42%	**31%**	**25%**	**28%**
100% Income statement						
	1996	**1997**	**1998**	**1999E**	**2000E**	**2001E**
Revenue	100.0%	100.0%	100.0%	**100.0%**	**100.0%**	**100.0%**
Cost of sales	39.5%	39.5%	38.6%	**38.6%**	**38.2%**	**38.0%**
Gross profit	60.5%	60.5%	61.4%	**61.4%**	**61.8%**	**62.0%**
Selling, general, and administrative	40.8%	39.3%	37.6%	**37.1%**	**35.7%**	**35.0%**
Research and development	5.6%	5.3%	5.1%	**4.9%**	**5.8%**	**5.7%**
Amortization of intangibles	3.7%	3.1%	2.6%	**2.3%**	**2.2%**	**2.0%**
Total operating expenses	50.1%	47.6%	45.3%	**44.3%**	**43.7%**	**42.7%**
Income from operations	10.4%	12.9%	16.0%	**17.1%**	**18.1%**	**19.3%**
Interest income	-3.4%	-0.1%	0.6%	**0.4%**	**0.5%**	**0.6%**
Other income, net	0.8%	0.3%	0.1%	**0.3%**	**0.2%**	**0.1%**
Earnings before taxes	7.9%	13.1%	16.7%	**17.7%**	**18.7%**	**20.1%**
Income tax expense	3.1%	39.3%	38.6%	**37.9%**	**37.9%**	**37.9%**
Net income (loss)	4.8%	7.9%	10.3%	**11.0%**	**11.6%**	**12.5%**

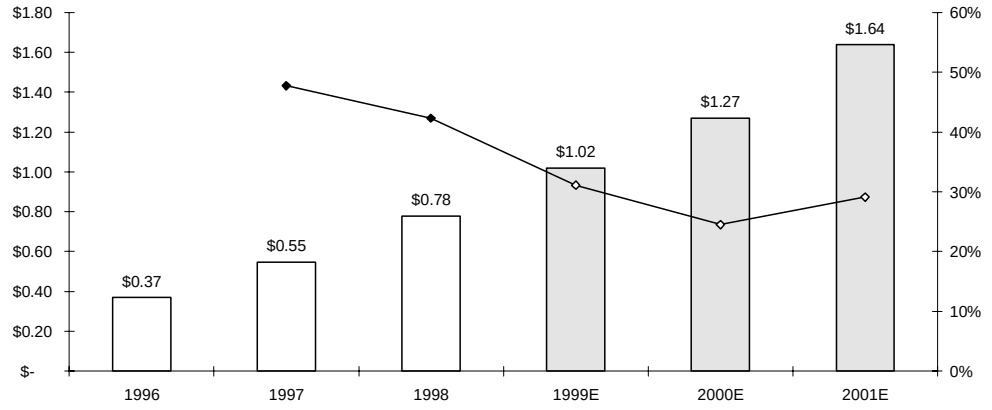
Source: Company financials; William Blair & Company, L.L.C. estimates

Taxes should remain stable, declining slightly from 38.6% in 1998 to 37.9% in 2001.

Net income and earnings per share should grow 33% and 28%, respectively, compounded annually through 2001

The changes in gross margin and operating expense ratios described should result in an increase in net income margin from 10.3%, or $9 million, in 1998 to 12.5%, or $22 million, in 2001, a 32% compounded annual growth rate (CAGR) comparable to the increase in operating income. Therefore, earnings per share should grow from $0.78 in 1998 to $1.64 in 2001, a CAGR of 28% that accounts for dilution attributed to stock option executions. Figure 19 illustrates the five-year EPS trend for Xomed from 1997 to 2001, showing a CAGR of more than 31%.

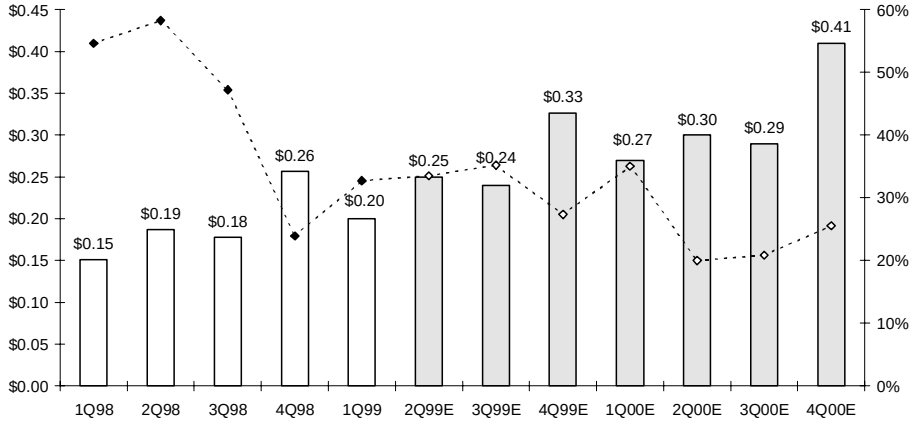
Figure 19
Xomed Surgical Products, Inc.
EPS and EPS Growth



Source: Company financials; William Blair & Company, L.L.C. estimates

Our quarterly estimates are shown in table 7 and figure 20. The well-established pattern of seasonality is explained by the very nature of the ailments treated most often by ENT physicians, allergy-related sinus problems in the second and fourth calendar quarters, as well as ear infections in children during the winter months. It is also worth noting the traditional summer softness related to elective surgical procedures (especially well documented in the orthopedic specialty) includes ENT and is reflected in reduced earnings in the third quarters.

Figure 20
Xomed Surgical Products, Inc.
Quarterly EPS and Year-over-year Growth



Source: Company financials; William Blair & Company, L.L.C. estimates

Xomed's balance sheet and cash flow are healthy and should continue to improve. Xomed currently maintains a strong balance sheet, carrying no debt. The recent MicroFrance acquisition was carried out using proceeds attained from the liquidation of the company's investment portfolio, shown in table 8. Property, plant, and equipment items on the balance sheet have increased in 1998 due to expansion of facilities in Jacksonville, Florida, which is expected to continue as the company continues to grow, illustrated in table 9. Cash should steadily increase, from $7.1 million in 1998 to $17.4 million in 2001. Cash from operating activities also should rise, from $9.7 million in 1998 to $15.3 million in 2001, with cash consumed by investing activities—predominantly capital expenditures—increasing to slightly more than $6 million by 2001.

Table 7
Xomed Surgical Products, Inc.
Quarterly Income Statement
($ in thousands)

	1Q98	2Q98	3Q98	4Q98	1Q99	2Q99E	3Q99E	4Q99E	1Q00E	2Q00E	3Q00E	4Q00E
Sales, net	$20,682	$22,868	$21,912	$25,921	$ 27,608	**$ 29,484**	**$ 28,435**	**$ 34,991**	**$ 32,290**	**$35,293**	**$ 34,193**	**$ 44,334**
Cost of sales	8,063	8,929	8,402	9,889	10,780	**11,350**	**10,962**	**13,388**	**12,388**	**13,499**	**13,093**	**16,845**
Gross margin	12,619	13,939	13,510	16,032	16,828	**18,134**	**17,473**	**21,603**	**19,902**	**21,794**	**21,101**	**27,490**
Selling, general, and administrative	8,085	8,717	8,302	9,231	10,788	**11,019**	**10,433**	**12,531**	**11,667**	**12,628**	**12,276**	**15,521**
Research and development	1,170	1,166	1,195	1,151	1,393	**1,410**	**1,480**	**1,562**	**1,924**	**2,075**	**2,020**	**2,527**
Amortization of intangibles	584	584	616	633	685	**684**	**716**	**733**	**785**	**784**	**816**	**833**
Total operating expense	9,839	10,467	10,113	11,015	12,866	**13,113**	**12,629**	**14,827**	**14,376**	**15,486**	**15,112**	**18,881**
Operating income	2,780	3,472	3,397	5,017	3,962	**5,021**	**4,843**	**6,777**	**5,525**	**6,307**	**5,989**	**8,609**
Interest income (expense)	30	62	210	257	34	**148**	**150**	**135**	**143**	**178**	**208**	**204**
Other income, net	40	28	18	(17)	89	**83**	**77**	**71**	**65**	**59**	**53**	**47**
Earnings before taxes	2,850	3,562	3,625	5,257	4,085	**5,251**	**5,071**	**6,983**	**5,733**	**6,545**	**6,250**	**8,860**
Income tax expense	1,125	1,407	1,414	1,957	1,528	**2,011**	**1,926**	**2,634**	**2,170**	**2,484**	**2,367**	**3,354**
Net income	1,725	2,155	2,211	3,300	2,557	**3,241**	**3,145**	**4,349**	**3,563**	**4,060**	**3,883**	**5,506**
Net income per share diluted	$0.15	$0.19	$0.18	$0.26	$0.20	**$0.25**	**$0.24**	**$0.33**	**$0.27**	**$0.30**	**$0.29**	**$0.41**
Weighted average common shares outstanding	11,448	11,510	12,455	12,867	12,981	**13,051**	**13,121**	**13,191**	**13,261**	**13,331**	**13,401**	**13,471**
Year-over-year growth												
Revenue	16%	19%	17%	20%	33%	**29%**	**30%**	**35%**	**17%**	**20%**	**20%**	**27%**
Gross margin	19%	20%	20%	21%	33%	**30%**	**29%**	**35%**	**18%**	**20%**	**21%**	**27%**
Operating income	57%	54%	50%	37%	43%	**45%**	**43%**	**35%**	**39%**	**26%**	**24%**	**27%**
Net income	59%	62%	62%	41%	48%	**50%**	**42%**	**32%**	**39%**	**25%**	**23%**	**27%**
EPS	55%	58%	47%	24%	31%	**33%**	**35%**	**29%**	**36%**	**23%**	**21%**	**24%**
100% Income statement												
	1Q98	**2Q98**	**3Q98**	**4Q98E**	**1Q99**	**2Q99E**	**3Q99E**	**4Q99E**	**1Q00E**	**2Q00E**	**3Q00E**	**4Q00E**
Sales, net	100.0%	100.0%	100.0%	100.0%	100.0%	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**
Cost of sales	39.0%	39.0%	38.3%	38.2%	39.0%	**38.5%**	**38.6%**	**38.3%**	**38.4%**	**38.2%**	**38.3%**	**38.0%**
Gross margin	61.0%	61.0%	61.7%	61.8%	61.0%	**61.5%**	**61.4%**	**61.7%**	**61.6%**	**61.8%**	**61.7%**	**62.0%**
Selling, general, and administrative	39.1%	38.1%	37.9%	35.6%	39.1%	**37.4%**	**36.7%**	**35.8%**	**36.1%**	**35.8%**	**35.9%**	**35.0%**
Research and development	5.7%	5.1%	5.5%	4.4%	5.0%	**4.8%**	**5.2%**	**4.5%**	**6.0%**	**5.9%**	**5.9%**	**5.7%**
Amortization of intangibles	2.8%	2.6%	2.8%	2.4%	2.5%	**2.3%**	**2.5%**	**2.1%**	**2.4%**	**2.2%**	**2.4%**	**1.9%**
Total operating expense	47.6%	45.8%	46.2%	42.5%	46.6%	**44.5%**	**44.4%**	**42.4%**	**44.5%**	**43.9%**	**44.2%**	**42.6%**
Operating income	13.4%	15.2%	15.5%	19.4%	14.4%	**17.0%**	**17.0%**	**19.4%**	**17.1%**	**17.9%**	**17.5%**	**19.4%**
Interest income (expense)	0.1%	0.3%	1.0%	1.0%	0.1%	**0.5%**	**0.5%**	**0.4%**	**0.4%**	**0.5%**	**0.6%**	**0.5%**
Other income, net	0.2%	0.1%	0.1%	-0.1%	0.3%	**0.3%**	**0.3%**	**0.2%**	**0.2%**	**0.2%**	**0.2%**	**0.1%**
Earnings before income taxes	13.8%	15.6%	16.5%	20.3%	14.8%	**17.8%**	**17.8%**	**20.0%**	**17.8%**	**18.5%**	**18.3%**	**20.0%**
Income tax expense	39.5%	39.5%	39.0%	37.2%	37.4%	**38.3%**	**38.0%**	**37.7%**	**37.8%**	**38.0%**	**37.9%**	**37.9%**
Net income	8.3%	9.4%	10.1%	12.7%	9.3%	**11.0%**	**11.1%**	**12.4%**	**11.0%**	**11.5%**	**11.4%**	**12.4%**

Source: Company financials; William Blair & Company, L.L.C. estimates

Table 8
Xomed Surgical Products, Inc.
Balance Sheet
($ in thousands)

ASSETS	1997	1998	1999E	2000E	2001E
Current assets:					
Cash and cash equivalents	$1,712	$4,256	**$1,657**	**$7,930**	**$17,350**
Accounts receivable	13,277	18,516	**22,989**	**29,128**	**36,621**
Other receivables	620		**700**	**887**	**1,115**
Inventories	16,238	22,368	**27,445**	**34,532**	**43,183**
Prepaid and other assets	1,083	1,586	**704**	**897**	**1,102**
Deferred income taxes	1,404		**1,077**	**793**	**964**
Total current assets	34,334	$46,726	**$54,572**	**$74,166**	**$100,335**
Investments		16,584	**9,204**	**9,204**	**9,204**
Notes receivable from officers	724		**-**	**-**	**-**
Property, plant, and equipment	24,137	33,379	**42,539**	**47,878**	**53,887**
Depreciation	(8,734)	(11,610)	**(14,840)**	**(19,356)**	**(24,439)**
Property, plant, and equipment, net	15,403	21,769	**27,699**	**28,522**	**29,448**
Cost in excess of assets acquired, net	42,399	49,488	**47,105**	**45,677**	**44,249**
Other assets	2,867	7,429	**7,682**	**7,837**	**7,995**
Total assets	$95,727	$141,996	**$146,262**	**$165,406**	**$191,231**
LIABILITIES AND SHAREHOLDERS' EQUITY					
Current liabilities:					
Accounts payable	$3,493	$6,290	**$8,033**	**$10,107**	**$12,639**
Accrued expenses	2,403	4,953	**6,751**	**7,165**	**7,605**
Accrued payroll and commissions	2,332	2,949	**3,130**	**3,322**	**3,526**
Total current liabilities	8,228	14,192	**17,913**	**20,594**	**23,769**
Other long-term liabilities	990	500	**997**		
Long-term debt and capital lease obligations		13,062			
Total liabilities	9,218	27,754	**18,910**	**20,594**	**23,769**
Shareholders' equity:					
Common stock:	73	81	**85**	**89**	**93**
Retained earnings	(3,459)	5,932	**19,223**	**36,236**	**58,553**
Additional paid-in capital	90,264	108,755	**108,886**	**109,016**	**109,147**
Cumulative translation adjustments	(281)	(526)	**(842)**	**(528)**	**(332)**
Total shareholders' equity	$86,509	$114,242	**$127,352**	**$144,813**	**$167,462**
Total liabilities and shareholders' equity	$95,727	$141,996	**$146,262**	**$165,406**	**$191,231**

Source: Company financials; William Blair & Company, L.L.C. estimates

Table 9
Xomed Surgical Products, Inc.
Statement of Cash Flows
($ in thousands)

	1997	1998	1999E	2000E	2001E
OPERATING ACTIVITIES					
Net income (loss)	$6,130	$7,080	**$13,291**	**$17,012**	**$22,318**
Operating activities:					
Depreciation	2,340	2,352	**3,230**	**4,516**	**5,083**
Amortization	2,776	2,709	**2,383**	**1,428**	**1,428**
Loss on disposal of property and equipment	60	876	**0**	**0**	**0**
Translation adjustments	288	(34)	**(316)**	**314**	**197**
Net effect on accounts and other receivables	0	1153	**(5,173)**	**(6,325)**	**(7,722)**
(Increase) decrease in inventories, net	(3,282)	(2,568)	**(5,077)**	**(7,087)**	**(8,651)**
Decrease (increase) in deferred income taxes	(1,563)	(4,825)	**(1,077)**	**284**	**(171)**
Increase (decrease) in other assets	2,002	(1,002)	**629**	**(347)**	**(363)**
Increase (decrease) in accounts payable and accrued expenses	(251)	345	**3,721**	**2,680**	**3,176**
Decrease in accrued restructuring costs	(980)	2,646	**0**	**0**	**0**
Net cash provided by operating activities	$6,365	$9,687	**$11,611**	**$12,475**	**$15,294**
INVESTING ACTIVITIES					
Purchases of property and equipment	(2,426)	(7,706)	**(9,160)**	**(5,339)**	**(6,009)**
Net of effect on marketable securites		(17,428)	**7,380**	**-**	**-**
Purchase of other assets		(15,520)			
Net cash used in investing activities	($2,226)	($40,654)	**($1,780)**	**($5,339)**	**($6,009)**
FINANCING ACTIVITIES					
Proceeds from revolving line of credit	12,302	13,062	**497**	**(997)**	**0**
Payments on revolving line of credit	(15,450)	-	**-**	**-**	**-**
Exercise of stock options	655	292	**-**	**-**	**-**
Issuance of stock		20,157	**135**	**135**	**135**
Net cash used in financing activities	($2,996)	$33,511	**($12,430)**	**($862)**	**$135**
Net increase in cash and cash equivalents	1,083	$2,544	**($2,599)**	**$6,273**	**$9,420**
Cash at beginning of period	$629	$1,712	**$4,256**	**$1,657**	**$7,930**
Cash at end of period	$1,712	$4,256	**$1,657**	**$7,930**	**$17,350**

Source: Company Financials; William Blair & Company, L.L.C. estimates

Valuation Premium Appears Justified

Although Xomed's stock price appears to carry a premium, varied analysis suggests that the company's valuation appears justified. We base this assessment on ratios of forward price-to-earnings multiples versus EPS growth rates for various comparable firms, as well as Xomed's track record, superior market position in a focused market, innovative new products, and underlying growth of the ENT market.

Growth projections and adjustments for P/E-multiple expansion appear to indicate that Xomed is valued fairly. As detailed in table 10, we conducted this analysis by examining Xomed's EPS compounded annual growth rate and three-year-forward P/E relative to a group of companies that participate in the ENT medical device market. We broke this group into large-, mid- and micro-capitalization stocks. Due to data availability, we could not compare the micro-caps. In addition, one of the comparables, Stryker, carries so much larger a capitalization that we placed it with the bellwether large-cap medical device firms. Xomed historically has traded at a P/E multiple of 26.5, as shown in figure 21a, yet has experienced about an 8-point P/E expansion in the last 6 months, which we believe is due in part to events shown in figure 21c. When the current P/E is adjusted for this expansion, bringing Xomed to its historical level, the stock appears fairly valued relative to its ENT midcap competitors, implying a P/E ratio of roughly 1 times the estimated growth rate, shown in figure 22. Comparing this group to the bellwether large-cap medical device stocks implies a 50% to 60% discount for the ENT device firms.

We also compared Xomed to a group of pure-play companies that we consider dominant in their markets. This group of companies, shown in table 10, includes Visx, an ophthalmology company that dominates the U.S. laser vision-correction market; MiniMed, in the U.S. insulin pump market; and Osteotech, the overwhelming leader in the bone graft market. This group of companies trades at a P/E ratio of roughly 1 times their forecast growth rate as well.

We believe that its anticipated more than 25% EPS growth should still allow Xomed's stock to appreciate substantially. Due to its market-leading position and earnings growth potential, we view Xomed as an excellent medical device holding.

Additional information in available upon request.

DJIA:	10689.67
S&P 500:	1356.80
NASDAQ:	2590.50

William Blair & Company, L.L.C. maintains a market in the shares of Xomed Surgical Products, Inc.

The prices of the common stock of other public companies mentioned in this report follow:

Bausch & Lomb	$73 1/4
Pharmacia & Upjohn	$59 13/16

Table 10
Xomed Surgical Products, Inc.
Comparable Company Valuation Analysis

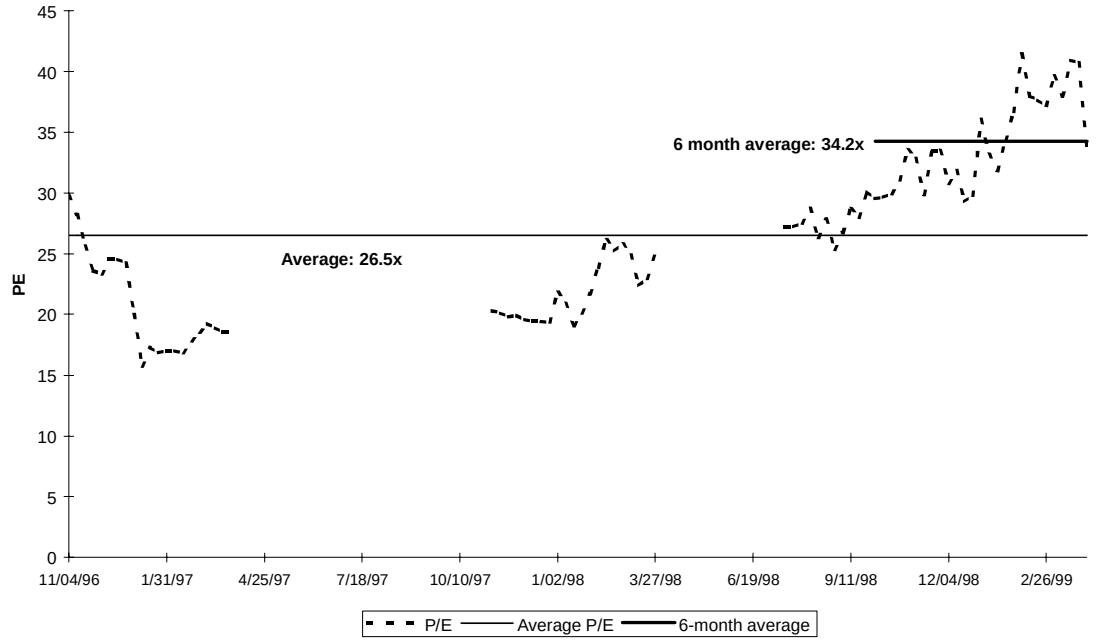
	Name	Ticker	Price 4/23/99	Mkt. Cap.	EPS 1997	EPS 1998	EPS 1999E	EPS 2000E	3-year CAGR	2000P/E	2000P/E / 3-year CAGR	Rating*
	Large-cap Medical Devices											
	Medtronic	MDT	$73.69	$43,180	$1.20	$1.47	$1.76	$2.15	21%	34.3	1.6	2
	Baxter	BAX	$67.50	$19,327	$2.31	$2.54	$2.85	$3.25	12%	20.8	1.7	
	Guidant	GDT	$59.75	$17,995	$0.66	$1.19	$1.37	$1.62	35%	36.9	1.1	2
	Boston Scientific	BSX	$43.25	$17,048	$0.67	$0.85	$1.03	$1.30	25%	33.3	1.3	
	Becton Dickinson	BDX	$41.69	$10,380	$1.25	$1.42	$1.57	$1.79	13%	23.3	1.8	
	Biomet	BMET	$44.81	$5,033	$1.04	$1.20	$1.30	$1.49	13%	30.1	2.4	
	CR Bard	BCR	$54.00	$2,780	$1.79	$1.72	$2.23	$2.57	13%	21.0	1.6	
1	Stryker	SYK	$60.94	$5,883	$1.28	$1.53	$1.63	$2.20	20%	27.7	1.4	
	Mid-small-cap ENT Device Comparables											
2	**Xomed**	**XOMD**	**38.88**	**$472**	**$0.55**	**$0.78**	**$1.02**	**$1.27**	**32%**	**30.6**	**1.0**	**2**
3	CONMED	CNMD	30.25	$459	$1.11	$1.39	$1.75	$2.10	24%	14.4	0.6	2
4	Respironics	RESP	13.75	$437	$1.06	$0.72	$0.99	$1.22	5%	11.3	2.3	
5	ResMed	RESM	28.25	$416	$0.57	$0.83	$1.03	$1.27	31%	22.2	0.7	2
	Micro-cap ENT Device Comparables											
6	Arthrocare	ARTC	16.75	$150	($0.87)	($0.47)	$0.38	$1.03	NM	16.3	NM	
7	Somnus	SOMN	2.34	$41	($0.17)	$0.06	$0.11	$0.25	NM	9.4	NM	
8	Symphonix	SMPX	2.94	$29	($3.10)	($1.24)	($1.30)	($1.20)	NM	NM	NM	
	Median PE/CAGR											
	Large-cap Medical Devices								**13%**	**30.1**	**1.6**	
	Mid-small-cap ENT Device Comparables								**27%**	**18.3**	**0.8**	

Dominant Pure-play Medical Device Companies

Name	Ticker	Price	Mkt Cap	EPS 1997	EPS 1998	EPS 1999E	EPS 2000E	3-year CAGR	2000P/E	2000P/E / 3 year CAGR	Rating
Visx	VISX	$117.69	$3,625	$0.39	$1.19	$2.28	$2.95	96%	39.9	0.4	
Minimed	MNMD	$65.38	$1,840	$0.28	$0.46	$0.69	$0.98	52%	66.7	1.3	
Xomed	**XOMD**	**$38.88**	**$472**	**$0.55**	**$0.78**	**$1.02**	**$1.27**	**32%**	**30.6**	**1.0**	**2**
Osteotech	OSTE	$30.75	$410	$0.43	$0.73	$0.91	$1.23	42%	25.0	0.6	1
Median								**42%**	**30.6**	**1.0**	

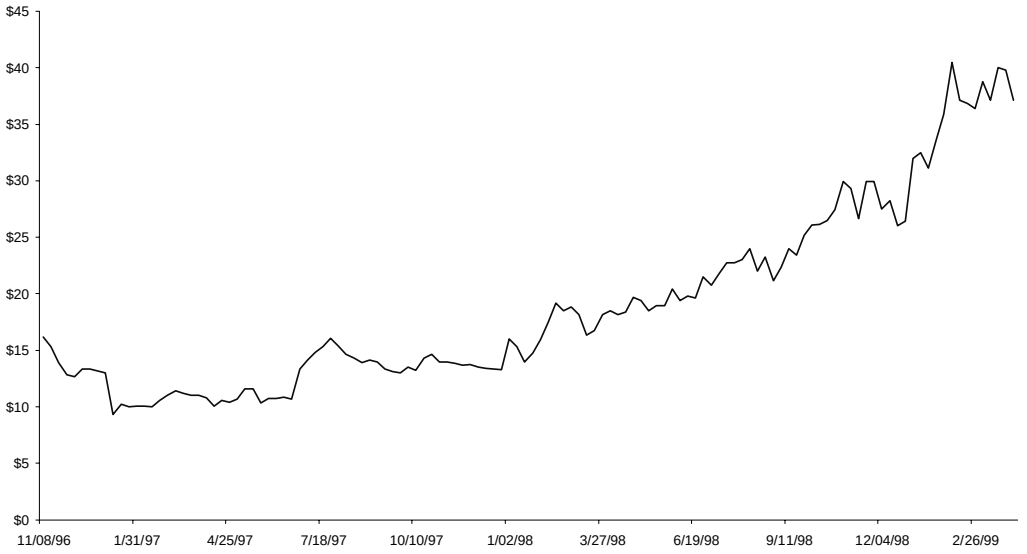
* William Blair & Company, L.L.C. estimates used for Medtronic, Guidant, Xomed, CONMED, and ResMed
Source: First Call; FactSet; Disclosure; Bloomberg; William Blair & Company, L.L.C. estimates

Figure 21a
Xomed Surgical Products, Inc.
Forward-12-months' P/E



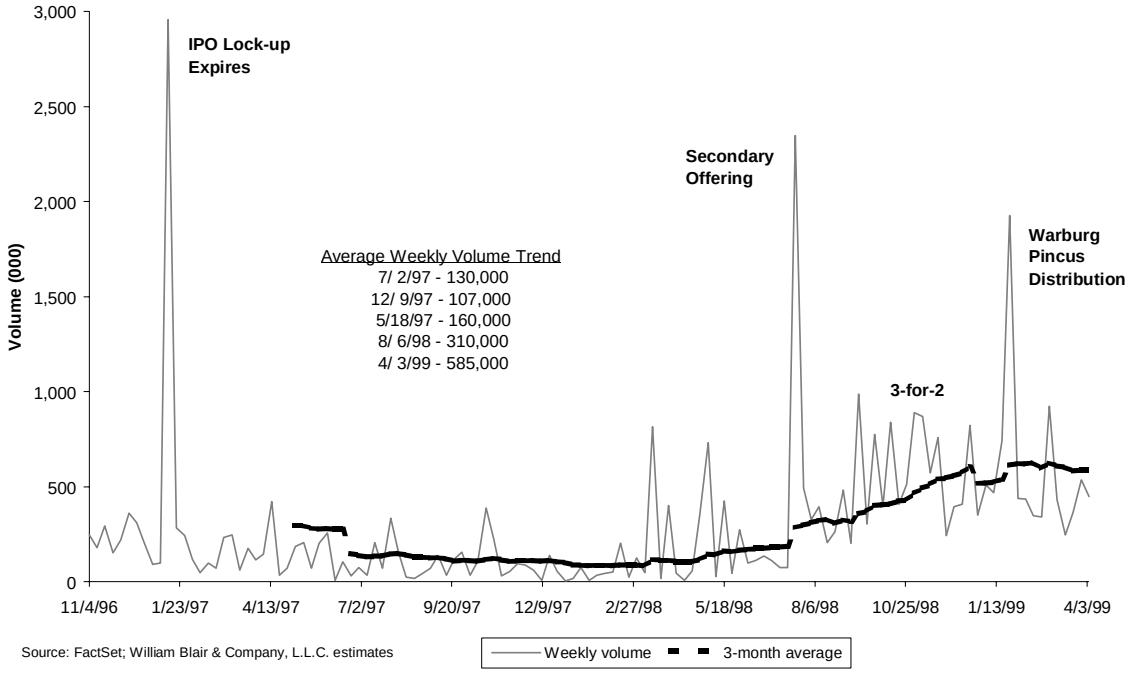
Source: First Call; FactSet; William Blair & Company, L.L.C. estimates

Figure 21b
Xomed Surgical Products, Inc.
Stock Price Performance



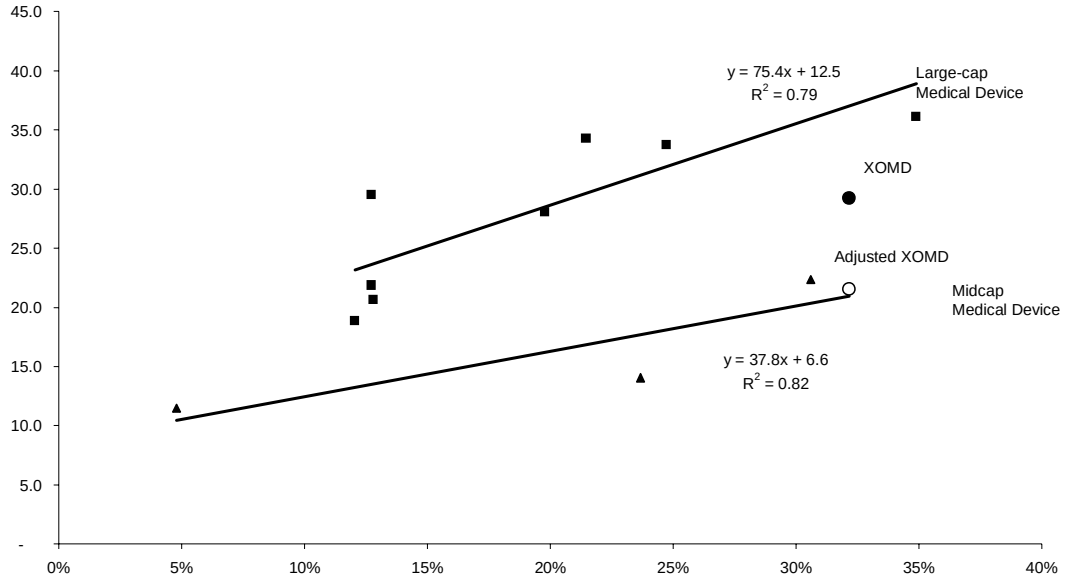
Source: FactSet; William Blair & Company, L.L.C. estimates

Figure 21c
Xomed Surgical Products, Inc.
Weekly Trading Volume



Source: FactSet; William Blair & Company, L.L.C. estimates

Figure 22
Xomed Surgical Products, Inc.
2000 Three-year EPS CAGR Versus 2000 P/E



Source: FactSet; William Blair & Company, L.L.C. estimates

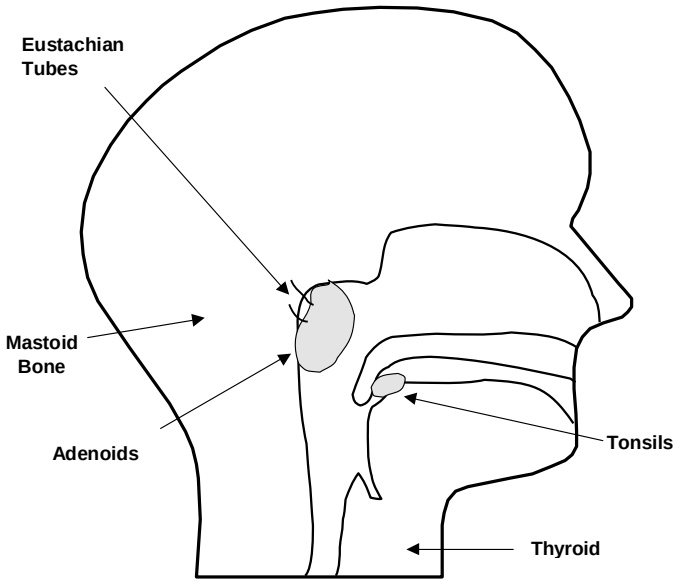
Appendix A: Relevant Medical Conditions/Procedures

Middle-ear Infections (Otitis Media)/Ear Tubes or Adenoidectomy

Otitis media—or as it is more commonly known a middle-ear infection—is especially prevalent in children, accounting for more than 12% of all visits to pediatricians, and it is the most frequent reason for administering antibiotics to children in the United States. Thirty percent of children will have had at least three bouts of otitis media by the age of three. Health economists estimate the total annual direct and indirect cost of ear infections in children to be $5 billion, with the majority of the cost lying in loss of parents' time. Symptoms related to otitis media include pain, effusion of fluid from the ear, vertigo, facial nerve paralysis, and *hearing loss*. The infection is caused by various species of bacteria and viruses most often from an upper respiratory tract infection that progresses to the ear. The bacteria lead to inflammation and pus formation, causing pressure on the tympanic membrane, resulting in pain. Extended pressure on the tympanic membrane could lead to its rupture, and potential hearing damage.

The first line treatment for otitis media is the administration of antibiotics, amoxicillin being the most often prescribed. If after 6 weeks the infection has not subsided, the antibiotics are supplemented with a course of corticosteroids. If after 9 weeks, the disease continues to persist, antibiotics are changed. Finally, at 12 weeks of persistent infection the disease is labeled chronic and surgical intervention should be applied. A myringotomy may be performed, during which the eardrum is cut to allow for the drainage of fluid and the likely insertion of ventilation tubes. These tubes relieve the pressure on the tympanic membrane. An adenoidectomy also may be performed. Removal of the adenoid, whose location is shown in figure 23, is thought to eliminate the bacterial pathogens causing the infection, as well as to improve eustachian tube function by decreasing airway obstruction. Left untreated, otitis media can lead to permanent hearing impairment or loss. Depending on the damage to the inner structure of the ear a tympanoplasty, repair of the tympanic membrane, or a myringoplasty, the replacement of the tympanic membrane, may be required to restore lost hearing.

Figure 23
Xomed Surgical Products, Inc.
Head and Neck Physiology

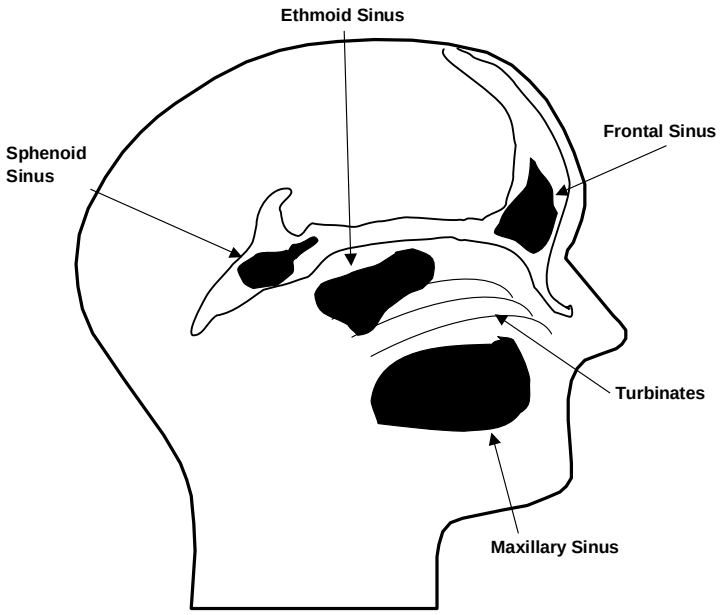


Source: William Blair & Company, L.L.C.

Chronic Sinusitis/Endoscopic Sinus Surgery

The sinuses are a group of four pairs of air filled cavities in the skull, the frontal, ethmoid, sphenoid, and maxillary sinuses, illustrated in figure 24. The sinuses have several postulated functions including: reducing the weight of the skull, providing resonating chambers for the voice, acting as "crumple zones" for the brain, and acting as a form of thermal insulation for the brain from the external temperature. The sinus cavities are lined with ciliated tissue that serves to sweep foreign matter and mucus into the nasal cavity. Inflammation of the sinuses leading to the impairment of proper sinus drainage is known as sinusitis and may be caused by bacterial or viral infection, allergies, or physical obstruction by pollutants such as dust. It also may be exacerbated by differences in individual patient anatomy. Sinusitis occurs more frequently in the maxillary and ethmoid sinuses than in the frontal or sphenoid sinuses. About one in three people will experience sinusitis in their life. Chronic sinusitis is the second most prevalent chronic disease, afflicting close to 35 million patients in the United States annually. As depicted in table 11, sinusitis is characterized by the following symptoms: facial pain or pressure, headaches, nasal congestion, post nasal drip, and nasal discharge. The gold standard for a definitive diagnosis of sinusitis is a full CT scan, although a limited CT scan is 70% to 90% effective. A plain x-ray is only 20% to 50% effective. In the United States, limited CT scans are only about 50% more expensive than plain x-rays. Mucosal thickening of greater than 6 millimeters, 3 millimeters for children, or complete opacity of a maxillary sinus, indicates sinusitis. Prolonged sinusitis also could lead to infection of the ear (otitis media) as bacteria migrate through the eustachian tubes.

Figure 24
Xomed Surgical Products, Inc.
Sinus Physiology



Source: William Blair & Company, L.L.C.

Once diagnosed, sinusitis is treated for at least two weeks with antibiotic therapy, again amoxicillin being the drug of choice. If symptoms persist for upwards of 4 to 12 weeks, the disease is deemed chronic. After chronic sinusitis is diagnosed, more powerful antibiotics may be prescribed involving a four-week regimen and sometimes six to eight weeks. The regimen must be long as penetration of antibiotics into the sinuses is typically very poor. If the disease remains refractive, surgery may be suggested. The goal of surgical intervention is to remove the obstruction, allowing proper ventilation of the sinus cavities and thus letting the infection clear. Functional endoscopic sinus surgery (FESS) is a minimally invasive surgical technique being employed by ENT specialists and has an *86%-98% success*

rate in relieving sinusitis. FESS replaces various procedures such as the Caldwell-Luc, which has been found to be very traumatic and ineffective. Using an endoscope and various tools, doctors remove inflamed tissue from the sinus cavities, clearing the obstruction and restoring airflow. Usually, patients are out of work for one to two weeks and take about six weeks essentially to heal. However, it may take 6 to 12 months to heal completely. The advent of powered surgical shavers for use in this procedure allows for rapid and precise tissue removal, minimizing blood loss and recovery time. The procedure using hand tools alone takes approximately 4 hours, while use of powered instruments reduces the surgery time to 45 minutes. More than 300,000 FESS procedures were performed in 1998, and this number is expected to increase as more surgeons learn the technique, new product innovations make the surgery easier and more patient friendly, and as more patients become aware of FESS's benefits. IGS also should help to accelerate FESS use further, because this type of surgery can lead to dangerous complications, because the surrounding anatomy is sensitive and there is a loss of depth perception caused by the monocular view from an endoscope. Intracranial (brain) or intraorbital (eye) injury can occur if the surgeon violates the anatomic boundaries. Furthermore, hemorrhaging by injuring various blood vessels, including the carotid, which passes through the sphenoid sinus. IGS allows for preoperative planning of the route and procedure, as well as correlation during surgery of the instruments to the critical anatomy. Surgery does not necessarily avert future sinusitis, and persistent or recurrent cases, along with possible stenosis or scarring, leads to *reoperation in 5% to 10% of patients*.

Table 11
Xomed Surgical Products, Inc.
Sinusitis Symptoms

Symptom	Chronic Sinusitis	Acute Sinsusitis	Cold	Allergy
Facial pressure	++	++	+	+
Nasal congestion	++	++	++	+
Cough	++	+	++	+
Hoarseness	++	--	+	--
Sore throat	+	++	+	--
Post-nasal drip	+	++	++	+
Headache	+	++	+	+
Ears plugged	+	+	+	+
Bad breath	+	+	--	--
Fever	--	+	+	--
Sneezing	--	--	++	+
Nasal discharge	Thick, yellow - green	Thick, yellow · green	Thick, whitish or thin	Clear, thin, watery

Source: AAO - HNS; *Archives of Otolaryngology - Head & Neck Surgery*; Medscape; William Blair & Company, L.L.C. estimates

Tonsillitis/Tonsillectomy

The tonsils are a collection of lymphatic tissues located on either side of the back wall of the oral cavity, shown in figure 23. Tonsillitis is the infection of the tonsils by bacteria or viruses resulting in inflammation, sore throat, fever, and bad breath or halitosis. Treatment for acute tonsillitis is antibiotic therapy, with dicloxacillin being the most prescribed. If the infection is recurrent, three cases per year for two years, surgical intervention, tonsillectomy, is suggested. Tonsillectomy is a procedure used to treat various malignancies and obstructive sleep apnea and may be combined with an adenoidectomy for other indications as well. Tonsillectomies no longer are recommended for otitis media, although adenoidectomies still are.

Tonsillectomies involve the simple removal of the tonsils using a curette, or more recently powered surgical shavers, or dissection and removal of the tissue. Control of bleeding during the surgery is a major concern since reactionary hemorrhaging often requires a return trip to the operating room to regain control. The abundance of nerves in this region makes this operation a painful one, especially when compared to adenoidectomies.

Deviated Septum/Septoplasty or Rhinoplasty

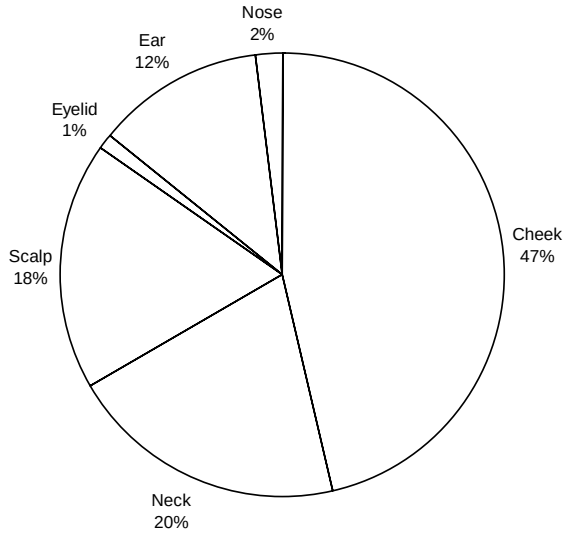
The nasal septum consists of the bone and cartilage that separate the nasal cavities. The septum often is deflected slightly in individuals, causing little or no problems. In cases of severe deviation, caused by birth defects or trauma, one nasal passage may be obstructed, resulting in troubled breathing. Surgery often is used to correct the deflection by removing the tissue in a procedure called submucosal resection, or by mobilizing and repositioning the cartilage, a procedure called septoplasty. Perforation of the septum also may occur due to infection, exposure to pollutants or use of inhaled, illicit drugs. Correction also would require septoplasty. Rhinoplasty is simply the plastic surgery procedure that allows for the cosmetic alteration of the nose. For reimbursement purposes, rhinoplasty may be incorrectly classified as septoplasty.

Head and Neck Procedures

Treatments for disorders of the thyroid, parathyroid and associated cancers make up the majority of cases to which head and neck physicians must tend. The thyroid region is shown in figure 23. Hyperthyroidism, Graves' disease and hyperparathyroidism result in over production of hormones that lead to metabolic disorders. Cancer of the thyroid, with 15,000 new cases arising annually, accounts for more than 1% of cancers. Often treated with radio-ablation using radioactive iodine, surgical removal of the hyperactive or cancerous tissue by thyroidectomy and parathyroidectomy has been found to be a more effective and quicker acting modality for dealing with these diseases, while sparing patients the risks involved with radioiodine treatment and antithyroid drugs.

Malignant melanomas are another form of cancer that may be treated by ENT surgeons. Ten to twenty-five percent of all melanomas arise in the head and neck area, with a breakdown shown in figure 25. ENT surgeons often are involved in their removal; to help avoid damage to various facial nerves and blood vessels located in the head and neck area.

Figure 25
Xomed Surgical Products, Inc.
Malignant Melanoma Distribution in the Head and Neck Region



Source: Clinical Challenges in Otolarygology, William Blair & Company, L.L.C.

Laryngeal (Vocal Chord) Polyps

Laryngeal (Vocal Chord) Polyps or neoplasms may be benign or cancerous in form. The most common malignant cancer in the area is squamous cell carcinoma, which is aggravated by cigarette smoke, alcohol, and pollutants. The course of treatment for these cancers depends on the extent and aggressiveness of the cancer. If mild and diagnosed early, endoscopic removal of the polyp is used to preserve the voice of the patient. If severe and aggressive, radical surgical excision may be required, resulting in the loss of the patient's voice.

Laryngeal papillomatosis is the most prevalent form of potentially benign polyp growth seen on the vocal chords. It is caused by the Human Papilloma Virus (HPV), which is thought to be transmitted by inhalation. Polyps of this sort may be removed using a laser, or endoscopically, thus avoiding the *risk of airway fires associated with lasers*. Strains of HPV have been implicated in some forms of cancer. Tissue from polyps removed endoscopically, even with the use of powered surgical equipment, may be examined by a pathologist to determine if cancer is present. Use of lasers does not easily allow for this type of examination.

Lateral Skull Base Procedures

The increase in collaborations between neurosurgeons and ENT surgeons has increased the knowledge and breadth of diseases that can be treated pertaining to the skull. The majority of conditions treated involve cancers around the skull—lesions of the Petrous Apex, Glomus tumors of the middle-ear space are just two examples. Because tumors often are located either deep in the skull or are adjacent to or associated with critical vascular or nerve structures, surgery historically was avoided in deference to radiation therapy. Advances in the past decade made in imaging, instrumentation, and IGS, as well as collaborations between neurosurgeons and ENT surgeons, have made surgery the treatment choice now in many situations.

Skull base tumors largely are classed as *benign, slow-growing,* or *fast-growing* malignancies. As a general rule, use of surgery increases as the class of tumor becomes less malignant and the use of radiation therapy increases for higher malignancy classes. It is important to note that *benign* tumors still may cause significant problems due to the pressure or "crowding out" effects they may exert in vascular or nerve structures. Table 12, on the following page, illustrates potential effects of skull-based tumors, benign or malignant. The gold standard for a *benign* tumor is the complete surgical removal, depending on its location and involvement of other anatomical structures, with symptoms often resolving fairly quickly. For *slow-growing malignancies*, surgical removal or debulking often is recommended, especially because some tumors are resistant to radiation. Radiation usually is combined with surgery due to the malignancy. For *fast-growing* or highly malignant tumors, radiation most often is used, due to the malignancy, as well as the reality that because these tumors are fast growing, they often are entwined already with critical structures. Thus, surgical approaches often are done to remove as many pieces of the tumor as possible.

Skull-based surgery uses a variety of instruments to gain access to the underlying structures, as well as navigate the delicate anatomical terrain. Fore example, malignant otitis externa and the resulting osteomyelitis (bone destruction due to infection of the ear) often require access via mastoidectomy, which predominantly is accomplished using powered surgical drills. Additionally, brain tumors that must be accessed through the mastoid bone, depicted in figure 23, require careful navigation to avoid unnecessary trauma to the brain. Increasingly, this is undertaken IGS systems that can be used for both preoperative planning and real-time navigation and orientation of surgical instruments during the actual surgery.

Table 12
Xomed Surgical Products, Inc.
Effects of Skull-based Tumors

Portion of the skull base	Examples of affected anatomical structures	Potential symptoms
Anterior	Frontal lobe	Changes in personality
	Olfactory nerve	Nasal discharge or sense of smell
	Orbit	Vision changes
Middle	Cranial nerves (3 - 6)	Facial pain
	Hypothalamus	Diabetes or other hormonal changes
	Optic nerve	Vision changes
Posterior	Cranial nerves (3 - 12)	Atrophy of the hand
		Sensorimotor weakness
		Tinnitus (ringing in the ear)

Source: AAO - HNS; *Archives of Otolaryngology - Head & Neck Surgery*; Medscape; William Blair & Company, L.L.C. estimates

Middle-ear Reconstruction

Trauma and diseases that affect the ear may cause such extensive damage that reconstruction of the middle ear's structure may be required. The tympanic membrane may be perforated by a foreign body, infection (as is the case in otitis media), or dramatic changes in air pressure. Such damage would require a tympanoplasty, repair of the tympanic membrane, or a myringoplasty, the replacement of the tympanic membrane to restore lost hearing. Various cancers may ravage the middle ear, as may otosclerosis, a disease on the middle ear's bony labyrinth, may cause the destruction of the bones in the middle ear. Affected boned can be replaced with prosthesis, restoring hearing.

Sleep Apnea/UPPP (Uvulopalatopharyngoplasty)

Obstructive sleep apnea (OSA) is the interrupted breathing (for at least 10 seconds) during sleep caused by the collapse of the pharynx, thus obstructing airflow. OSA is as prevalent as asthma, affecting 4% of the males and 2% of females in the United States. The collapse of the airway may be attributed to obesity, edema, or large tonsils, and may be further aggravated by other obstructions such as those found in the sinuses. Symptoms include snoring, violent breathing during sleep, and excessive sleepiness. OSA is a serious disease that has been associated with conditions such as cardiovascular disease. Diagnosis is performed by an overnight polysomnography. Treatment may involve weight loss, use of nasal continuous positive airway pressure (CPAP) and in severe cases, surgery. Surgical procedures such as UPPP and laser-assisted uvulopalatoplasty (LAUP) reduce the size of the soft tissue of the palate, thus decreasing the airway obstruction and restoring airflow.

Appendix B: Regulatory Processes

Medical devices such as surgical systems are subject to government regulations in most countries. Therefore, Xomed's success in part hinges on its ability to achieve the necessary approvals and the time and expense of attaining those approvals.

Food and Drug Administration (FDA)
The U.S. FDA regulates medical devices, as well as medicines, cosmetics, food, the feed and drugs for farm animals and pets, and even radiation-emitting products like microwave ovens. To put this in perspective, the FDA regulates more than $1 trillion in products, or about a quarter of each dollar spent each year by consumers in the United States

Federal Food, Drug, and Cosmetics Act
The FDA first was granted limited authority over medical devices in 1938 through the Federal Food, Drug, and Cosmetics Act. The original intention of the Act was to grant the FDA the authority to seize misbranded or adulterated devices that were part of interstate trade. However, the FDA expanded its stated authority in certain circumstances by declaring a device a drug, thus requiring premarket approval. This self-expanded authority was upheld by the Supreme Court.

Medical Device Amendments
In 1976, Congress enacted the Medical Device Amendments, specifically subjecting medical devices to federal regulation. The amendments required good manufacturing practices (GMP) and created three levels of devices based on risk—Classes I through III. In addition, two types of potential premarket authorization were defined—the premarket notification, or 510(k), and premarket approval (PMA).

Three Classes of Medical Devices
Products are classified based on risk, with riskier devices subject to greater controls. Of the approximately 1,700 classified medical devices, 45% are Class I, 47% are Class II, and 8% are Class III.

Class I devices pose minimal potential for harm and are subject to general controls.

- Register establishments with the FDA (strictly applies on U.S. establishments, but foreign establishments are also encouraged).
- List devices to be marketed with the FDA.
- Use good manufacturing processes to make the devices (some Class I devices are exempt from parts of GMP).
- Label devices according to the proper labeling regulation.
- Submit 510(k) (premarket notification) before marketing a device (almost 75% of Class I devices are exempt from this).
- Examination gloves and elastic bandages are examples of Class I devices.

Class II devices are those for which special controls are needed in addition to the general controls described above. These controls might be postmarket surveillance or special labeling requirements. These devices are never exempt from premarket notification or GMP. Infusion pumps and powered wheelchairs are examples of Class II devices.

Class III devices are most strictly controlled, because they sustain life, present a potentially unreasonable risk of injury, or are crucial to prevent impairment of health. A PMA is required before the device can be marketed. This is a scientific review process requiring clinical trials to prove the safety and effectiveness of the product. Replacement heart valves and silicone gel-filled breast implants are examples of Class III devices that used the PMA process.

Some Class III devices may not require a PMA and might be able to obtain 510(k) clearance. These are devices that can show substantial equivalence to a device marketed before May 28, 1976, and for which there has been no published regulation specifically requiring a PMA for that device. Endosseous implants and pulse generators for pacemakers are examples of Class III devices that currently require only a 510(k).

510(k)

To use the 510(k) process, a new device must be shown to be substantially equivalent to a predicate device marketed prior to 1976—that is, it has the same intended use and technological characteristics. Most devices—more than 90%—use the 510(k) process. The original act allowed a company to start marketing 90 days after submission if it had not received notification. However, this was amended through the Safe Medical Devices Act to require the company to wait to receive a notice of substantial equivalence from the FDA.

PMA

A PMA requires a thorough review of human clinical trials, as well as other tests of the device. To begin the clinical trials for the PMA, a company must receive an investigational device exemption (IDE) after describing the trial risks and protocols for the FDA. However, before any human trials, a company must obtain approval from the institutional review board (IRB) of the institution where it will conduct the trial. The IRB is an expert panel that assesses the risks involved in the trial. If the IRB determines that the device represents an insignificant risk, this approval alone is sufficient to begin the trial. The trial results then are reviewed by the FDA regarding both safety and efficacy. After a PMA is granted, supplements must be submitted if there are any design, labeling, or manufacturing changes that might affect the safety or efficacy of the device.

PLA

A product license approval, or PLA, is another form of product approval. Issued by the FDA's Center for Biologics Evaluation and Research, PLAs follow a similar process as PMAs, yet pertain to devices that use biologicals such as antibodies and other blood-derived products.

Clinical Laboratory Improvement Amendments (CLIA) of 1988

This amendment requires all labs conducting clinical testing to meet specified standards in personnel qualification, administration, and proficiency testing, patient test management, quality control, and quality assurance. Three levels of regulatory control (waived, moderate, and high complexity) have been instituted that dictate the certifications required of labs conducting these tests.

Safe Medical Devices Act (SMDA) of 1990

This act strengthened the enforcement authority of the FDA to monitor products that are marketed. For example, the SMDA gave the FDA authority to impose substantial civil monetary penalties for particular violations. In addition, it required summary of safety and effectiveness data for 510(k) filings, postmarket surveillance for certain devices, and reporting of death or injuries attributed to a device.

Medical Devices Amendments of 1992

These amendments helped clear up (and clean up) some of the regulations under the SMDA. For example, it created a single definition for which injuries must be reported. Also, it gave the FDA more leeway in issuing repair, replace, or refund orders for devices presenting unreasonable risks. Lastly, it gave the FDA more time to finalize device-tracking regulations.

Food and Drug Modernization Act of 1997

At the end of 1997, the U.S. Congress enacted legislation that was intended to make the FDA review process less arbitrary and more competitive with world standards without compromising the safety and efficacy of products marketed. The sections of the new law that apply to medical devices are highlighted below.

Investigational device exemptions (Section 201). When an applicant intends to perform a human clinical trial of any implantable or all Class III devices, the applicant has the opportunity to submit the plan in writing, and the FDA must meet with the applicant within 30 days. An official, binding record will be made of any agreement that is reached with the FDA.

Recognizing international device standards (Section 204). The FDA may officially recognize all or part of an international (or national) standard. Subsequently, an applicant may reference the standard in a Declaration of Conformity, which can be used to satisfy the requirement for a 510(k) or PMA. The FDA still may reject the Declaration if the information supplied does not prove compliance with the standard or the standard does not apply.

Data requirements for devices (Section 205). Changes to the law affect 510(k)s, PMAs, and manufacturing under PMAs.

- *Labeling claims for 510 (k)s.* If the Director of the Office of Device Evaluation (ODE) determines that there is a reasonable likelihood that a device will be used in an unintended way and that this use could cause harm, the ODE can require that a specific statement be placed in the labeling specifying the limitations for using the device. The device still would be found substantially equivalent.

- *Collaborative determination of PMA data requirements*. An applicant can request a meeting with the FDA to determine in advance what data will be necessary to support the safety and effectiveness of its device. The FDA must meet with the applicant and provide within 30 days of the meeting a binding, written document specifying what data is required to provide reasonable assurance. This chosen method also must be the least burdensome to satisfy the needs of the applicant.

- *Manufacturing under a PMA*. Changes to the manufacturing process that could affect the safety or efficacy of a product require only a written notice to the FDA, not a PMA supplement.

Exemptions from 510 (k), including specific Class II devices (Section 206). If a Class I device is not intended for use that presents an unreasonable risk or injury, or is not of substantial importance in preventing impairment of health, then it will not require a 510(k). In addition, the FDA will specify certain Class II devices that do not require 510(k)s. Examples of Class II devices that it has specified to date are clinical mercury thermometers, wheeled stretchers, blood-storage refrigerators, hematocrit measuring devices, and AC-powered adjustable hospital beds.

Risk-based classification of post-amendment Class III devices (Section 207). If an applicant receives a Not Substantially Equivalent (NSE) determination—placing the device into a Class III category—the applicant can request, within 30 days in writing, a reclassification of the product into Class I or II. The FDA has 60 days from the date of this request to

classify the product in writing. If the device is classified Class I or II, then the applicant has received clearance and the device may be used by other applicants as a predicate device for 510(k)s.

Review time frames (Section 209). Changes were made to the law to further expedite the review processes for both 510(k)s and PMAs. Now, the law clearly states that the FDA must make 510(k) determinations no later than 90 days after receiving a submission. In addition, the FDA must meet with PMA applicants within 100 days of submission and prior to this meeting inform the applicant in writing of any deficiencies and what data would be needed to correct them.

Device tracking and postmarket surveillance (Sections 211 and 212). Manufacturers no longer automatically will be required to track devices or conduct postmarket surveillance. However, the FDA can specifically require that certain Class II or III devices be tracked or that postmarket surveillance be performed if the device satisfies one of the following conditions:

- Failure of the device would be reasonably likely to have serious adverse health consequences.
- The device is intended to be implanted for more than one year.
- The device is intended to sustain life outside a user facility.

The FDA may only order postmarket surveillance for up to three years without consent of the applicant.

Dispute resolution of scientific controversies (Section 404). The FDA is required to set up a process, which an applicant can invoke, to review scientific controversies when no other process is available. It will include an appropriate advisory committee or scientific panel.

Reengineering the Center for Devices and Radiological Health (CDRH)

Modular review process for PMAs. In the future, the FDA will review the needed scientific data for a PMA in modules as it becomes available. For example, all the data on animal testing would be reviewed, and if accepted, it would not be reexamined unless absolutely necessary. In addition to the other PMA modernization approaches discussed earlier, this allows companies to ensure that the proper scientific and regulatory foundation is developed and accepted as the clinical trials proceed, rather than being told at the end that there were problems with early data.

New multi-type 510(k) approach. For Class I and II products that still require 510(k)s, the CDRH will establish a system of three types of 510(k)—traditional, special, and abbreviated. The special 510(k) is for devices that have been modified, but the intended use has not changed, nor has the fundamental science of the technology. A company need only file a declaration of conformity to design controls and a short summary of the changes, and the FDA will process the application within 30 days. For a new device, if a manufacturer uses special controls or conforms to a standard, it may submit a summary of the special controls or a declaration of conformity to the standard to get an abbreviated 510(k).

Appendix C: Glossary

510(k). A 510(k) is a premarketing notification submitted to the FDA to demonstrate that a medical device is as safe and effective and substantially equivalent to a legally marketed device that was on the United States market before 1976. The Food and Drug Modernization Act of 1997 allows the FDA to reclassify new devices on the basis of their risk.

Adenoidectomy. An operation for the removal of adenoid (defined below) growths in the nasopharynx.

Adenoids (pharyngeal tonsils). A normal collection of encapsulated tissue that is particularly rich in white blood cells that fight infection and disease (lymphocytes).

CT image. CAT scan digital image.

Endoscopy. Examination of the interior of a canal or hollow and multilayered organ by means of a special instrument, such as an endoscope.

Esophagus. A portion of the digestive canal between the pharynx (defined below) and the stomach.

Ethmoid bone. An irregularly shaped bone lying between the orbital plates of the bone forming the forehead and anterior to the bone at the base of the skull.

Ethmoidectomy. Removal of all or part of the mucosal lining and bony partitions between the sinuses to the left and right of the bridge of the nose (ethmoid sinuses).

Laryngology. The branch of medical science concerned with the larynx, the organ of voice production in the respiratory tract.

Lymph nodes. Small, bean-shaped organs that trap bacteria located throughout the lymphatic system (defined below).

Lymphatic system. The tissues and organs (including the bone marrow, spleen, thymus, and lymph nodes) that produce and store cells that fight infection.

Mastoidectomy. Hollowing out of the mastoid process (nipple-like projection) off the base of the skull.

Maxilla. Upper jaw bone.

Myringoplasty. Operative repair of a damaged tympanic membrane (eardrum).

Myringotomy. Tympanotomy. Removal of the tympanic membrane (eardrum).

Nasal cavity. The respiratory passages on either side of the wall (nasal septum) dividing the nose in half.

Neuroma. General term for any abnormal tissue derived from cells of the nervous system that grows by cellular proliferation more rapidly than normal and continues to grow after the stimuli that initiated the new growth ceases.

Otalgia. Ear ache.

Otitis media. Inflammation of the middle ear.

Otolaryngology. Branch of medical science concerned with diagnosis and treatment of disorders and diseases of the ear and larynx (organ of voice production in the respiratory tract).

Otology. Branch of medical science concerned with the study, diagnosis, and treatment of diseases of the ear.

Otorrhea. A discharge from the ear.

Otoscopy. Inspection of the ear.

Pharynx. The upper, expanded portion of the digestive tube, between the esophagus below and the mouth and nasal cavities above.

PMA. Premarket approval, the process of scientific and regulatory review to ensure the safely and effectiveness of all Class III (high-risk) and some Class II (moderate-risk) devices. An approved PMA application is, in effect, a license granted to the applicant for marketing a particular medical device, based on clinical trials proving both safety and efficacy.

Purulent. Containing, consisting of, or forming pus (defined below).

Pus. A fluid product of inflammation comprising white blood cells, bacteria, and cellular debris.

Rhinology. Branch of medical science concerned with the nose and its disease.

Rhinoplasty. Repair of a defect of the nose with tissue taken from elsewhere or plastic surgery to change the shape or size of the nose.

Salivary glands. Any of the saliva-secreting organs of the oral cavity.

Septoplasty. Operation to correct defects or deformities of the nasal septum.

Septum. A thin wall dividing two cavities or masses of softer tissue.

Sinus. A cavity or hollow space in bone or other tissue.

Sinusitis. Inflammation of the lining membrane of any of the hollow areas (sinuses) of the bone of the skull around the nose, which are directly connected to the nasal cavities.

Sphenoids (sphenoid bone). An irregularly shaped bone in front of the bone at the back of the head in the base of the skull

Stapedectomy. Operation to remove, in whole or in part, the smallest of the three bones in the ear (stapes) with replacement by metal or plastic prosthesis.

Thyroid gland. A butterfly-shaped, ductless gland lying in front or to the side of the upper part of the trachea in the neck, which secretes a hormone (thyroxine) that controls the rate of metabolism.

Thyroidectomy. Removal of the thyroid gland (defined above).

Tonsillectomy. Removal of the entire tonsil (defined below).

Tonsils (palatine tonsils). Two almond-shaped masses of lymphoid tissue embedded in the lateral wall of the oral pharynx (defined above).

Tracheostomy. Tracheotomy; the operation of opening the trachea (windpipe).

Trephination. Removal of a circular piece of cranium (skull bone) by a special cylindrical saw (trephine).

Turbinectomy. Surgical removal of the scrolled-shaped bony or cartilaginous plates that support the shape of the nose.

Tympanoplasty. Operative correction of a damaged middle ear.

Tympanotomy (myringoplasty). Removal of the tympanic membrane (eardrum).

Uvulopalatopharyngoplasty (UPPP, or palatopharyngoplasty). Surgical resection of unnecessary palatal tissue and tissue in the section of the pharynx that lies posterior to the mouth (oropharyngeal) in cases of snoring, with or without sleep apnea (absence of breathing during sleep).

Zygomatic. Of or pertaining to the region of the cheekbone.