ALLERGAN INC Form 10-Q November 08, 2006

## UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

#### **FORM 10-Q**

(Mark One)

# **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 29, 2006

OR

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

# COMMISSION FILE NUMBER 1-10269 **ALLERGAN, INC.**

(Exact name of Registrant as Specified in its Charter)

**DELAWARE** 

95-1622442

(State or Other Jurisdiction of Incorporation or Organization)

(I.R.S. Employer Identification No.)

#### 2525 DUPONT DRIVE, IRVINE, CALIFORNIA

(Address of Principal Executive Offices)

92612

(Zip Code)

(714) 246-4500

(Registrant s Telephone Number,

Including Area Code)

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

Yes b No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one)

Large accelerated filer b

Accelerated filer o

Non-accelerated filer o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes o No b

As of November 2, 2006, there were 153,755,944 shares of common stock outstanding (including 2,234,900 shares held in treasury).

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

Allergan, Inc.

Unaudited Condensed Consolidated Statements of Operations

(in millions, except per share amounts)

	Three months ended		Nine months ended	
	September	September	September	September
	29,	30,	29,	30,
	2006	2005	2006	2005
Revenues				
Product net sales	\$791.7	\$ 606.1	\$2,193.9	\$1,724.3
Other revenues	15.1	5.4	40.3	11.9
Total revenues	806.8	611.5	2,234.2	1,736.2
Operating costs and expenses				
Cost of sales (excludes amortization of				
acquired intangible assets)	167.7	94.2	433.2	294.3
Selling, general and administrative	364.0	243.0	975.4	701.1
Research and development	120.4	109.5	930.1	281.5
Amortization of acquired intangible assets	24.9	5.1	54.8	12.3
Restructuring charges (reversal)	8.6	(0.1)	17.1	37.6
Operating income (loss)	121.2	159.8	(176.4)	409.4
Non operating income (expense)				
Non-operating income (expense) Interest income	12.8	11.4	34.3	23.0
Interest expense	(11.9)	1.6	(40.2)	(7.5)
Unrealized gain (loss) on derivative	(11.9)	1.0	(40.2)	(7.5)
instruments, net	0.2	(0.2)	(1.0)	1.0
Gain on investments	0.1	0.8	0.3	0.8
Other, net	(1.7)	(0.8)	(7.1)	3.0
Other, net	(1.7)	(0.8)	(7.1)	5.0
	(0.5)	12.8	(13.7)	20.3
Earnings (loss) before income taxes and	120.7	172.6	(100.1)	400.7
minority interest	120.7	172.6	(190.1)	429.7
Provision for income taxes	14.3	19.9	74.0	163.2
Minority interest expense		2.2	0.1	2.7
Net earnings (loss)	\$106.4	\$ 150.5	\$ (264.2)	\$ 263.8
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Earnings (loss) per share:

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Basic \$ 0.71 \$ 1.15 \$ (1.82) \$ 2.02

Diluted \$ 0.70 \$ 1.12 \$ (1.82) \$ 1.98

See accompanying notes to unaudited condensed consolidated financial statements.

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## Allergan, Inc. Unaudited Condensed Consolidated Balance Sheets (in millions, except share data)

	September 29, 2006	December 31, 2005
ASSETS		
Current assets:		
Cash and equivalents	\$1,061.6	\$1,296.3
Trade receivables, net	394.0	246.1
Inventories	164.7	90.1
Other current assets	207.4	193.1
Total current assets	1,827.7	1,825.6
Investments and other assets	274.2	258.9
Deferred tax assets		123.2
Property, plant and equipment, net	576.3	494.0
Goodwill	1,802.3	9.0
Intangibles, net	1,067.8	139.8
Total assets	\$5,548.3	\$2,850.5
LIABILITIES AND STOCKHOLDERS	EQUITY	
Current liabilities:		
Notes payable	\$ 30.0	\$ 169.6
Convertible notes, net of discount		520.0
Accounts payable	130.4	92.3
Accrued compensation	102.5	84.8
Other accrued expenses	259.4	177.3
Total current liabilities	522.3	1,044.0
Long-term debt	856.1	57.5
Long-term convertible notes	750.0	
Deferred tax liabilities	161.3	
Other liabilities	232.6	181.0
Commitments and contingencies		
Minority interest	1.2	1.1
Stockholders equity:		
Preferred stock, \$.01 par value; authorized 5,000,000 shares; none issued		
Common stock, \$.01 par value; authorized 500,000,000 shares; issued		
153,756,000 shares as of September 29, 2006 and 134,255,000 shares as of	1.5	1.2
December 31, 2005	1.5	1.3 417.7
Additional paid-in capital	2,334.5	
Accumulated other comprehensive loss	(30.5)	(50.6)
Retained earnings	961.0	1,305.1

L	3,266.5	1,673.5
Less treasury stock, at cost (2,297,000 shares as of September 29, 2006 and 1,431,000 shares as of December 31, 2005, respectively)	(241.7)	(106.6)
	2.024.0	1.566.0
Total stockholders equity	3,024.8	1,566.9
Total liabilities and stockholders equity	\$5,548.3	\$2,850.5
See accompanying notes to unaudited condensed consolidated financial statements.		
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Allergan, Inc. Unaudited Condensed Consolidated Statements of Cash Flows (in millions)

	Nine months ended	
	September 29, 2006	September 30, 2005
CASH FLOWS FROM OPERATING ACTIVITIES:	2000	2003
Net (loss) earnings	\$ (264.2)	\$ 263.8
Non-cash items included in earnings:	+ (=+··-)	+
In-process research and development charge	579.3	
Depreciation and amortization	108.6	58.1
Amortization of original issue discount and debt issuance costs	8.7	7.4
Amortization of net realized gain on interest rate swap	(0.6)	
Deferred income taxes	(7.0)	(8.7)
Loss (gain) on investments and disposal of fixed assets	3.1	(6.1)
Unrealized loss (gain) on derivative instruments	1.0	(1.0)
Expense of share-based compensation plans	48.0	10.0
Minority interest expense	0.1	2.7
Restructuring charge	17.1	37.6
Changes in assets and liabilities:		
Trade receivables	(70.3)	(14.9)
Inventories	35.6	1.3
Other current assets	19.9	(26.4)
Other non-current assets	1.3	(38.4)
Accounts payable	6.3	17.7
Accrued expenses	18.5	(22.1)
Income taxes	(17.2)	14.3
Other liabilities	22.5	9.4
Net cash provided by operating activities	510.7	304.7
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of Inamed, net of cash acquired	(1,328.6)	
Additions to property, plant and equipment	(73.4)	(36.2)
Additions to capitalized software	(13.1)	(10.8)
Additions to intangible assets	(11.0)	(99.3)
Proceeds from sale of investments	0.6	1.3
Proceeds from sale of property, plant and equipment	3.3	5.5
Other, net	3.3	0.2
Net cash used in investing activities	(1,422.2)	(139.3)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Dividends to stockholders	(43.3)	(39.1)
Proceeds from issuance of senior notes	797.7	(37.1)
1 1000000 110HI ISSUANCE OF SCHOOL HOUS	171.1	

Proceeds from issuance of convertible senior notes	750.0	
Debt issuance costs	(19.7)	
Bridge credit facility borrowings	825.0	
Bridge credit facility repayments	(825.0)	
Repayments of convertible borrowings	(521.9)	
Net (repayments) borrowings of notes payable	(139.5)	113.3
Sale of stock to employees	118.1	70.5
Payments to acquire treasury stock	(307.8)	(94.3)
Net proceeds from settlement of interest rate swap	13.0	
Excess tax benefits from share-based compensation	27.9	
Net cash provided by financing activities	674.5	50.4
Effect of exchange rate changes on cash and equivalents	2.3	
Net (decrease) increase in cash and equivalents	(234.7)	215.8
Cash and equivalents at beginning of period	1,296.3	894.8
Cash and equivalents at end of period	\$ 1,061.6	\$1,110.6
Supplemental disclosure of cash flow information Cash paid for:		
Interest (net of capitalization)	\$ 6.0	\$ 12.9
Income taxes, net of refunds	\$ 115.5	\$ 152.1

On March 23, 2006, the Company completed the acquisition of Inamed Corporation. In exchange for the common stock of Inamed Corporation, the Company issued common stock with a fair value of \$1,859.3 million and paid \$1,328.6 million in cash, net of cash acquired. In connection with the Inamed acquisition, the Company acquired assets with a fair value of \$3,768.2 million and assumed liabilities of \$477.6 million. See accompanying notes to unaudited condensed consolidated financial statements.

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Notes to Unaudited Condensed Consolidated Financial Statements

#### 1. Basis of Presentation

In the opinion of management, the accompanying unaudited condensed consolidated financial statements contain all adjustments necessary (consisting only of normal recurring accruals) to present fairly the financial information contained therein. These statements do not include all disclosures required by accounting principles generally accepted in the United States of America (GAAP) for annual periods and should be read in conjunction with the Company s audited consolidated financial statements and related notes for the year ended December 31, 2005. The Company prepared the condensed consolidated financial statements following the requirements of the Securities and Exchange Commission for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP can be condensed or omitted. The results of operations for the three and nine month periods ended September 29, 2006 are not necessarily indicative of the results to be expected for the year ending December 31, 2006 or any other period(s).

## Reclassifications

Certain reclassifications of prior year amounts have been made to conform with the current year presentation. Beginning with the second fiscal quarter of 2006, the Company reports amortization of acquired intangible assets on a separate line in its statements of operations, which includes the amortization of the intangible assets acquired in connection with the Inamed acquisition, as well as the amortization of other intangible assets previously reported in cost of sales, selling, general and administrative expenses, and research and development expenses. For the three month period ended September 30, 2005, a total of \$5.1 million of intangible asset amortization was reclassified, consisting of \$4.3 million previously classified in cost of sales, \$0.1 million previously classified in selling, general and administrative expenses, and \$0.7 million previously classified in research and development expenses. For the nine month period ended September 30, 2005, a total of \$12.3 million of intangible asset amortization was reclassified, consisting of \$10.0 million previously classified in cost of sales, \$0.3 million previously classified in selling, general and administrative expenses, and \$2.0 million previously classified in research and development expenses. Intangible asset amortization for the nine month period ended September 29, 2006 includes a total reclassification of \$5.1 million, representing the reclassification of \$4.3 million, \$0.1 million and \$0.7 million from cost of sales, selling, general and administrative expenses, and research and development expenses, respectively, previously reported for the three month period ended March 31, 2006.

### Share-Based Payments

On January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised), *Share-Based Payment* (SFAS No. 123R), which requires measurement and recognition of compensation expense for all share-based payment awards made to employees and directors. Under SFAS No. 123R, the fair value of share-based payment awards is estimated at grant date using an option pricing model, and the portion that is ultimately expected to vest is recognized as compensation cost over the requisite service period. Prior to the adoption of SFAS No. 123R, the Company accounted for share-based awards using the intrinsic value method prescribed by Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB No. 25), as allowed under Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (SFAS No. 123). Under the intrinsic value method, no share-based compensation cost was recognized for awards to employees or directors if the exercise price of the award was equal to the fair market value of the underlying stock on the date of grant.

The Company adopted SFAS No. 123R using the modified prospective application method. Under the modified prospective application method, prior periods are not revised for comparative purposes. The valuation provisions of SFAS No. 123R apply to new awards and awards that were outstanding on the adoption effective date that are subsequently modified or cancelled. Estimated compensation expense for awards outstanding and unvested on the adoption effective date is recognized over the remaining service period using the compensation cost calculated for *pro forma* disclosure purposes under SFAS No. 123.

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

Pre-tax share-based compensation expense recognized under SFAS No. 123R for the three month period ended September 29, 2006 was \$16.1 million, which consisted of compensation related to employee and director stock options of \$11.1 million, employee and director restricted share awards of \$2.4 million, and \$2.6 million related to stock contributed to employee benefit plans. Pre-tax share-based compensation expense recognized under SFAS No. 123R for the nine month period ended September 29, 2006 was \$48.0 million, which consisted of compensation related to employee and director stock options of \$32.5 million, employee and director restricted share awards of \$7.2 million, and \$8.3 million related to stock contributed to employee benefit plans. Pre-tax share-based compensation expense recognized under APB No. 25 for the three month period ended September 30, 2005 was \$2.9 million, which consisted of compensation related to employee and director restricted share awards of \$0.8 million and \$2.1 million related to stock contributed to employee benefit plans. Pre-tax share-based compensation expense recognized under APB No. 25 for the nine month period ended September 30, 2005 was \$9.9 million, which consisted of compensation related to employee and director restricted share awards of \$3.0 million and \$6.9 million related to stock contributed to employee benefit plans. There was no share-based compensation expense recognized during the three and nine month periods ended September 30, 2005 related to employee or director stock options. The income tax benefit related to recognized share-based compensation was \$5.7 million and \$17.2 million for the three and nine month periods ended September 29, 2006, respectively. The income tax benefit related to recognized share-based compensation was \$1.1 million and \$3.6 million for the three and nine month periods ended September 30, 2005, respectively.

The Company uses the Black-Scholes option-pricing model to estimate the fair value of share-based awards. The determination of fair value using the Black-Scholes model is affected by the Company s stock price as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, the Company s expected stock price volatility over the term of the awards and projected employee stock option exercise behaviors. Prior to the adoption of SFAS No. 123R, the Company used an estimated stock price volatility based on the Company s five year historical average. Upon adoption of SFAS No. 123R, the Company changed its estimated volatility calculation to an equal weighting of the Company s ten year historical average and the average implied volatility of at-the-money options traded in the open market. The Company believes this method provides a more accurate estimate of stock price volatility over the expected life of the share-based awards. Employee stock option exercise behavior is estimated based on actual historical exercise activity and assumptions regarding future exercise activity of unexercised, outstanding options.

The Company recognizes share-based compensation cost over the requisite service period using the straight-line single option method. Since share-based compensation under SFAS No. 123R is recognized only for those awards that are ultimately expected to vest, an estimated forfeiture rate has been applied to unvested awards for the purpose of calculating compensation cost. SFAS No. 123R requires these estimates to be revised, if necessary, in future periods if actual forfeitures differ from the estimates. Changes in forfeiture estimates impact compensation cost in the period in which the change in estimate occurs. In the Company s *pro forma* information required under SFAS No. 123 prior to January 1, 2006, the Company accounted for forfeitures as they occurred.

On November 10, 2005, the Financial Accounting Standards Board (FASB) issued FASB Staff Position No. FAS 123(R)-3, *Transitional Election Related to Accounting for Tax Effects of Share-Based Payment Awards*. The Company has elected to adopt the alternative transition method provided in this FASB Staff Position for calculating the tax effects of share-based compensation pursuant to SFAS No. 123R. The alternative transition method includes a simplified method to establish the beginning balance additional paid-in capital pool (APIC Pool) related to tax effects of employee share-based compensation, which is available to absorb tax deficiencies recognized subsequent to the adoption of SFAS No. 123R.

### Recently Adopted Accounting Standards

In May 2005, the FASB issued Statement of Financial Accounting Standards No. 154, *Accounting Changes and Error Corrections* (SFAS No. 154). SFAS No. 154 requires retrospective application to prior-period financial statements of changes in accounting principles, unless a new accounting pronouncement provides specific transition provisions to the contrary or it is impracticable to determine either the period-specific effects or the cumulative effect

of the change. SFAS No. 154 also redefines restatement as the revising of previously issued financial statements to reflect the correction of an error. The Company adopted the provision of SFAS No. 154 in its first fiscal quarter of 2006. The adoption did not have a material effect on the Company s consolidated financial statements.

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

## New Accounting Standards Not Yet Adopted

In February 2006, the FASB issued Statement of Financial Accounting Standards No. 155, Accounting for Certain Hybrid Financial Instruments an amendment of FASB Statements No. 133 and 140 (SFAS No. 155). SFAS No. 155 permits an entity to measure at fair value any financial instrument that contains an embedded derivative that otherwise would require bifurcation. This statement is effective for all financial instruments acquired, issued, or subject to a remeasurement event occurring after the beginning of an entity s first fiscal year that begins after September 15, 2006, which is the Company s fiscal year 2007. The Company does not expect the adoption of SFAS No. 155 to have a material impact on its consolidated financial statements.

In June 2006, the FASB issued FASB Interpretation No. (FIN) 48, *Accounting for Uncertainty in Income Taxes An Interpretation of FASB Statement No. 109* (FIN48), which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 will be effective for fiscal years beginning after December 15, 2006, which is the Company s fiscal year 2007. The Company is currently in the process of evaluating the potential impact of adopting FIN 48 on its consolidated financial statements.

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (SFAS No. 157), which defines fair value, establishes a framework for measuring fair value under GAAP, and expands disclosures about fair value measurements. SFAS No. 157 will be effective for fiscal years beginning after November 15, 2007, which is the Company s fiscal year 2008. The Company has not yet evaluated the potential impact of adopting SFAS No. 157 on its consolidated financial statements.

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 158, Employers Accounting for Pensions and Other Postretirement Benefits (SFAS No. 158). SFAS No. 158 requires employers to recognize on their balance sheet an asset or liability equal to the over- or under-funded benefit obligation of each defined benefit pension and other postretirement plan and to recognize as a component of other comprehensive income, net of tax, the gains or losses and prior service costs or credits that arise during the period but are not recognized as components of net periodic benefit cost. Amounts recognized in accumulated other comprehensive income, including the gains or losses, prior service costs or credits, and the transition asset or obligation remaining from the initial application of (i) FASB Statement No. 87, Employers Accounting for Pensions and (ii) FASB Statement No. 106, Employers Accounting for Postretirement Benefits Other Than Pensions, are adjusted as they are subsequently recognized as components of net periodic benefit cost pursuant to the recognition and amortization provisions of those statements. This change in balance sheet reporting is effective for fiscal years ending after December 15, 2006 for public companies, which is the Company s fiscal year 2006. SFAS No. 158 also eliminates the ability to use an early measurement date, commencing with fiscal years ending after December 15, 2008, which is the Company s fiscal year 2008. The Company will adopt the balance sheet reporting provisions of SFAS No. 158 during the Company's fourth fiscal quarter 2006. The Company is currently in the process of evaluating the potential impact of adopting SFAS No. 158 on its consolidated financial statements.

## 2. Inamed Acquisition

On March 23, 2006, the Company completed the acquisition of Inamed Corporation (Inamed), a global healthcare company that develops, manufactures, and markets a diverse line of products, including breast implants, a range of dermal products to correct facial wrinkles and products for the treatment of obesity.

The Inamed acquisition was completed pursuant to an agreement and plan of merger, dated as of December 20, 2005, and subsequently amended as of March 11, 2006, by and among the Company, its wholly-owned subsidiary Banner Acquisition, Inc., and Inamed, and an exchange offer made by Banner Acquisition to acquire Inamed shares for either \$84.00 in cash or 0.8498 of a share of the Company s common stock, subject to proration so that 45% of the aggregate Inamed shares tendered were exchanged for cash and 55% of the aggregate Inamed shares tendered were exchanged for shares of the Company s common stock. In the exchange offer, the Company paid approximately \$1.31 billion in cash and issued 16,194,051 shares of common stock through Banner Acquisition, acquiring approximately 93.86% of Inamed s outstanding common stock. Following the exchange offer, the remaining

outstanding shares of Inamed common stock were acquired for approximately \$81.7 million in cash and

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

1,010,576 shares of Allergan common stock through the merger of Banner Acquisition with and into Inamed in a merger in which Inamed survived as Allergan s wholly-owned subsidiary. As a final step in the plan of reorganization, the Company merged Inamed into Inamed, LLC, a wholly-owned subsidiary of the Company. The consideration paid in the merger does not include shares of the Company s common stock and cash that were paid to former Inamed option holders for outstanding options to purchase shares of Inamed common stock, which were cancelled in the merger and converted into the right to receive an amount of cash equal to 45% of the in the money value of the option and a number of shares of the Company s common stock with a value equal to 55% of the in the money value of the option. Subsequent to the merger, the Company issued 237,066 shares of common stock and paid \$17.9 million in cash to satisfy its obligation to the option holders. The fair value of these shares of Company common stock and cash paid to option holders of Inamed common stock were included in the calculation of the purchase price detailed below.

The following table summarizes the components of the Inamed purchase price:

	(in millions)
Fair value of Allergan shares issued	\$1,859.3
Cash consideration	1,409.3
Transaction costs	22.0
	\$3,290.6

The value of the shares of Company common stock used in determining the purchase price was \$106.60 per share, based on the closing price of the Company s common stock on December 20, 2005, the effective date of the merger agreement.

#### **Purchase Price Allocation**

The Inamed purchase price was allocated to tangible and intangible assets acquired and liabilities assumed based on their estimated fair values at the acquisition date (March 23, 2006). The excess of the purchase price over the fair value of net assets acquired was allocated to goodwill. The Company expects that all such goodwill will not be deductible for tax purposes.

The Company believes the fair values assigned to the assets acquired and liabilities assumed were based on reasonable assumptions. The following table summarizes the estimated fair values of net assets acquired:

	(in millions)
Current assets	\$ 313.3
Property, plant & equipment	64.7
Identifiable intangible assets	971.9
In-process research and development	579.3
Goodwill	1,793.1
Other non-current assets, primarily deferred tax assets	45.9
Accounts payable and accrued liabilities (a)	(112.9)
Deferred tax liabilities current and non-current	(335.6)
Other non-current liabilities	(29.1)

\$3,290.6

(a) Accounts payable and accrued liabilities include approximately \$9.4 million of recognized liabilities related to the involuntary termination and relocation of certain Inamed employees in accordance with the Emerging Issues Task Force (EITF) in EITF Issue No. 95-3, *Recognition of Liabilities in Connection with a Purchase Business Combination* (EITF 95-3).

The Company s fair value estimates for the purchase price allocation may change during the allocation period, which is up to one year from the acquisition date, if additional information becomes available.

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

## In-process Research and Development

In conjunction with the Inamed acquisition, the Company recorded a charge to in-process research and development expense of \$579.3 million for acquired in-process research and development assets that the Company determined were not yet complete and had no alternative future uses in their current state.

These in-process research and development assets are composed of Inamed s silicone breast implant technology for use in the United States, Inamed s *Juvéderm* dermal filler technology for use in the United States, and Inamed s BioEnterics Intragastric Balloon (BIB®) technology for use in the United States, which were valued at \$405.8 million, \$41.2 million and \$132.3 million, respectively. All of these assets had not received approval by the United States Food and Drug Administration (FDA) as of the Inamed acquisition date of March 23, 2006. Because the in-process research and development assets had no alternative future use, they were charged to expense on the Inamed acquisition date.

As of the Inamed acquisition date, the silicone breast implants, Model 410 and Round Responsive implants, were expected to be approved by the FDA in mid-2006 for the Round Responsive model and approximately six to twelve months thereafter for the Model 410. The Company s management estimated that the projects were approximately 90 percent complete as the patient data had been collected and submitted to the FDA, with remaining efforts focused on responding to FDA questions and compiling additional data regarding clinical trials and other information necessary to answer any additional FDA requests. Subject to final negotiations between the Compan