IMPAX LABORATORIES INC

FORM 8-K
(Current report filing)

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Address	30831 HUNTWOOD AVENUE HAYWARD, CA 94544
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 30, 2012

Impax Laboratories, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-34263**	**65-0403311**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

30831 Huntwood Avenue, Hayward, CA	**94544**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(510) 240-6000**

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition.

On October 30, 2012, Impax Laboratories, Inc. issued a press release announcing its results for the quarter ended September 30, 2012. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

The information in this report furnished pursuant to Item 2.02, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. It may only be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended, if such subsequent filing specifically references the information furnished pursuant to Item 2.02 of this report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished herewith.

Exhibit No.	Description
99.1	Press release issued October 30, 2012.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: October 30, 2012

IMPAX LABORATORIES, INC .

By: /s/ Larry Hsu, Ph.D.
Name: Larry Hsu, Ph.D.
Title: President and Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued October 30, 2012.

Exhibit 99.1

Company Contact:
Mark Donohue
Sr. Director
Investor Relations and Corporate Communications
(215) 558-4526
www.impaxlabs.com

Impax Laboratories Reports Third Quarter 2012 Results
Adjusted EPS Increased to $0.48; GAAP EPS Increased to $0.29

HAYWARD, Calif. (October 30, 2012) – Impax Laboratories, Inc. (NASDAQ: IPXL) today reported third quarter 2012 financial results.

- Adjusted net income increased $15.3 million to $32.5 million in the third quarter 2012, or $0.48 per diluted share, compared to $17.2 million, or $0.26 per diluted share, in the prior year period. This increase was primarily driven by United States (U.S.) sales of Zomig ® which was licensed from AstraZeneca pursuant to the previously disclosed January 2012 License Agreement. Adjusted results exclude acquisition-related costs, as well as other items noted below.
- GAAP net income increased $2.8 million to $20.0 million in the third quarter 2012, or $0.29 per diluted share, compared to $17.2 million, or $0.26 per diluted share, in the prior year period.
- Total revenues increased 21% to $145.6 million in the third quarter 2012, compared to $119.8 million in the prior year period, primarily due to U.S. sales of Zomig ® . Partially offsetting this increase were lower generic Rx Partner and Research Partner revenues, as well as the completion in June 2012 of a three-year brand product promotional agreement for which there was no revenue recognized in the third quarter 2012 compared to the prior year period.
- Adjusted earnings before interest, taxes, depreciation and amortization (Adjusted EBITDA), increased to $56.6 million in the third quarter 2012, compared to $32.5 million in the prior year period.

Adjusted results exclude amortization and acquisition-related costs related to recent third-party business development transactions, the receipt of reimbursed costs pursuant to the settlement of litigation and expenses associated with the voluntary withdrawal of a generic product from the market. Please refer to “Non-GAAP Financial Measures” below for a reconciliation of GAAP to non-GAAP items.

“Our U.S. promotional efforts of Zomig ® exceeded our expectations in the third quarter and support our brand commercial organization as we continue to prepare for the potential launch of Rytary ™ ,” said Larry Hsu, Ph.D., president and CEO, Impax Laboratories, Inc. “The success of our brand business is an important element to the future growth of the Company.”

“A few weeks ago, the U.S. Food and Drug Administration (FDA) notified us that Rytary’s ™ New Drug Application review date would be extended three months to January 21, 2013. We continue to have dialogue with the FDA on both this application and the resolution of the Hayward warning letter. We expect that upon the resolution of the warning letter, we should begin to see approvals for generic products in backlog and will look to commercialize these opportunities assuming the market dynamics remain attractive. In the meantime, we continue to explore investment opportunities that can deliver growth and progress the Company towards its long term generic and brand division goals,” Dr. Hsu concluded.

Segment Information

The Company has two reportable segments, the Global Pharmaceuticals Division (generic products & services) and the Impax Pharmaceuticals Division (brand products & services) and does not allocate general corporate services to either segment.

Global Pharmaceuticals Division Information

(unaudited, amounts in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	**2011**	**2012**	**2011**
Revenues:				
Global Product sales, net	$ 99,463	$ 97,661	$ 342,105	$ 301,124
Rx Partner	(792)	12,621	4,652	20,169
OTC Partner	763	879	2,237	4,006
Research Partner	996	3,385	7,765	13,154
Total revenues	100,430	114,546	356,759	338,453
Cost of revenues	44,106	54,196	177,690	164,627
Gross profit	56,324	60,350	179,069	173,826
Operating expenses:				
Research and development	12,392	11,487	35,190	34,728
Patent litigation (recovery) expense	(371)	2,114	6,581	6,097
Selling, general and administrative	3,790	3,694	11,482	8,892
Total operating expenses	15,811	17,295	53,253	49,717
Income from operations	$ 40,513	$ 43,055	$ 125,816	$ 124,109

Global Pharmaceuticals Division revenues in the third quarter 2012 were $100.4 million, compared to $114.5 million in the prior year period, primarily due to lower Rx Partner and Research Partner revenues.

For the third quarter 2012, Rx Partner revenues declined $13.4 million, as the Company realized a $7.4 million profit share adjustment in the third quarter 2011 from Teva Pharmaceuticals Industries Limited (“Teva”) for which there was no comparable amount in the third quarter 2012. Also contributing to the decline in the third quarter 2012 Rx revenues were lower sales of our generic products through our Strategic Alliance Agreement with Teva and an estimated $2.0 million charge for the voluntary withdrawal of bupropion XL 300 mg from the market.

Research Partner revenues in the third quarter 2012 declined $2.4 million to $1.0 million, compared to the prior year period of $3.4 million, due to the extension of the revenue recognition period for the Joint Development Agreement with Medicis Pharmaceutical Corporation (the “Medicis Agreement”). During the third quarter 2012, the Company extended the estimated performance period from the previous recognition period ending November 2012 to November 2013 due to changes in the estimated timing of completion of certain research and development activities.

Gross profit in the third quarter 2012 was $56.3 million, compared to $60.4 million in the prior year period. The decline in gross profit was due to the third quarter 2011 receipt of $7.4 million in profit share adjustment from Teva for which there was no comparable amount in the third quarter 2012, as well as the change in the estimated performance period for the Medicis Agreement. Partially offsetting the third quarter 2012 decrease in gross profit was a reduction in the royalty rate paid on sales of our authorized generic Adderall XR ® products as a result of additional generic competition and increased sales of higher margin products. Gross margin in the third quarter 2012 increased to 56%, compared to 53% in the prior year period, due to the reduction in the royalty rate and increased sales of higher margin products as noted above.

Total generic operating expenses in the third quarter 2012 decreased $1.5 million to $15.8 million, compared to the prior year period of $17.3 million, due to lower patent litigation expenses resulting from the receipt of $5.0 million for reimbursement of legal fees received pursuant to the settlement of litigation. The increase in patent litigation expense before the $5.0 million reimbursement was the result of legal activity related to several Abbreviated New Drug Application cases.

Impax Pharmaceuticals Division Information

(unaudited, amounts in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	**2011**	**2012**	**2011**
Revenues:				
Impax Product sales, net	$ 43,327	$ -	$ 71,422	$ -
Rx Partner	1,500	1,438	4,375	4,313
Research Partner	330	330	989	989
Promotional Partner	-	3,535	7,070	10,605
Total revenues	45,157	5,303	83,856	15,907
Cost of revenues	23,454	2,999	44,522	8,840
Gross profit	21,703	2,304	39,334	7,067
Operating expenses:				
Research and development	7,620	7,352	23,507	27,580
Selling, general and administrative	12,498	1,632	22,266	4,116
Total operating expenses	20,118	8,984	45,773	31,696
Income (loss) from operations	$ 1,585	$ (6,680)	$ (6,439)	$ (24,629)

Impax Pharmaceuticals Division revenues in the third quarter 2012 increased $39.9 million to $45.2 million, compared to the prior year period of $5.3 million, due to U.S. sales of Zomig ® pursuant to the AstraZeneca License Agreement for which there was no comparable amount in the prior year period. This increase was partially offset by a $3.5 million decline in Promotional Partner revenues as the Company's detailing for Pfizer's product Lyrica ® pursuant to the Co-Promotion Agreement ended on June 30, 2012.

Gross profit of $21.7 million increased $19.4 million in the third quarter 2012, due to U.S. Zomig ® sales, compared to the prior year period of $2.3 million. Gross margin in the third quarter 2012 increased to 48%, compared to 43% in the prior year period. The third quarter 2012 gross margin was, however, negatively impacted by the inclusion of $21.6 million in cost of revenues for amortization and acquisition-related costs due to the Zomig ® transaction.

Total brand operating expenses in the third quarter 2012 increased $11.1 million to $20.1 million, compared to the prior year period of $9.0 million, due to higher selling, general and administration expenses resulting from Zomig ® marketing costs, the expansion of the Company's neurology focused sales force and pre-launch planning costs for Rytary ™.

Corporate and Other

(unaudited, amounts in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	**2011**	**2012**	**2011**
General and administrative expenses	$ 12,639	$ 10,992	$ 41,282	$ 35,398
Loss from operations	$ (12,639)	$ (10,992)	$ (41,282)	$ (35,398)

General and administrative expenses in the third quarter 2012 increased $1.6 million to $12.6 million, compared to the prior year period of $11.0 million, primarily due to increased consulting and personnel expenses.

Cash and Short-term Investments

Cash and short-term investments were $339.7 million as of September 30, 2012, compared to $346.4 million as of December 31, 2011.

2012 Financial Outlook

The Company updated its 2012 financial outlook as noted below.

Expense guidance:

- UPDATED - Total R&D expenses across the generic and brand divisions to approximate $86.0 million with generic R&D of approximately $48.0 million and brand R&D of approximately $38.0 million.
- UPDATED - Patent litigation expenses of approximately $13.0 million. In the third quarter 2012, the Company received a $5.0 million patent litigation settlement reimbursement.
- SG&A expenses of approximately $113.0 million.

Other outlook items:

- Gross margins as a percent of total revenues of approximately 60%.
- UPDATED - Effective tax rate of approximately 35%.
- Capital expenditures of approximately $78.0 million.

Revenue:

- With the recent additional competition on fenofibrate capsules and generic Adderall XR ®, the Company expects its total revenues for the fourth quarter of 2012 to decline by approximately 15% to 20% from the third quarter of 2012.

Conference Call Information

The Company will host a conference call on October 30, 2012 at 12:00 p.m. EDT to discuss its results. The number to call from within the United States is (877) 356-3814 and (706) 758-0033 internationally. The call can also be accessed via a live Webcast through the Investor Relations section of the Company's Web site, www.impaxlabs.com . A replay of the conference call will be available shortly after the call for a period of seven days. To access the replay, dial (855) 859-2056 (in the U.S.) and (404) 537-3406 (international callers). The access conference code is 39759746.

About Impax Laboratories, Inc.

Impax Laboratories, Inc. (NASDAQ: IPXL) is a technology based specialty pharmaceutical company applying its formulation expertise and drug delivery technology to the development of controlled-release and specialty generics in addition to the development of branded products. Impax markets its generic products through its Global Pharmaceuticals Division and markets branded products through the Impax Pharmaceuticals Division. Additionally, where strategically appropriate, Impax has developed marketing partnerships to fully leverage its technology platform. Impax Laboratories is headquartered in Hayward, California, and has a full range of capabilities in its Hayward, Philadelphia and Taiwan facilities. For more information, please visit the Company's Web site at: www.impaxlabs.com .

" *Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995:*

To the extent any statements made in this news release contain information that is not historical, these statements are forward-looking in nature and express the beliefs and expectations of management. Such statements are based on current expectations and involve a number of known and unknown risks and uncertainties that could cause the Company's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to, the effect of current economic conditions on the Company's industry, business, financial position and results of operations, fluctuations in the Company's revenues and operating income, the Company's ability to successfully develop and commercialize pharmaceutical products, reductions or loss of business with any significant customer, the impact of consolidation of the Company's customer base, the impact of competition, the Company's ability to sustain profitability and positive cash flows, any delays or unanticipated expenses in connection with the operation of the Company's Taiwan facility, the effect of foreign economic, political, legal and other risks on the Company's operations abroad, the uncertainty of patent litigation, increased government scrutiny on the Company's agreements with brand pharmaceutical companies, consumer acceptance and demand for new pharmaceutical products, the difficulty of predicting Food and Drug Administration filings and approvals, the Company's inexperience in conducting clinical trials and submitting new drug applications, the Company's ability to successfully conduct clinical trials, the Company's reliance on third parties to conduct clinical trials and testing, the availability of raw materials and impact of interruptions in the Company's supply chain, the use of controlled substances in the Company's products, disruptions or failures in the Company's information technology systems and network infrastructure, the Company's reliance on alliance and collaboration agreements, the Company's dependence on certain employees, the Company's ability to comply with legal and regulatory requirements governing the healthcare industry, the regulatory environment, the Company's ability to protect the Company's intellectual property, exposure to product liability claims, changes in tax regulations, the Company's ability to manage the Company's growth, including through potential acquisitions, the restrictions imposed by the Company's credit facility, uncertainties involved in the preparation of the Company's financial statements, the Company's ability to maintain an effective system of internal control over financial reporting, any manufacturing difficulties or delays, the effect of terrorist attacks on the Company's business, the location of the Company's manufacturing and research and development facilities near earthquake fault lines and other risks described in the Company's periodic reports filed with the Securities and Exchange Commission. Forward-looking statements speak only as to the date on which they are made, and Impax undertakes no obligation to update publicly or revise any forward-looking statement, regardless of whether new information becomes available, future developments occur or otherwise.

Impax Laboratories, Inc .

Consolidated Statements of Operations

(unaudited, amounts in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	**2011**	**2012**	**2011**
Revenues:				
Global Pharmaceuticals Division	$ 100,430	$ 114,546	$ 356,759	$ 338,453
Impax Pharmaceuticals Division	45,157	5,303	83,856	15,907
Total revenues	145,587	119,849	440,615	354,360
Cost of revenues	67,560	57,195	222,212	173,467
Gross profit	78,027	62,654	218,403	180,893
Operating expenses:				
Research and development	20,012	18,839	58,697	62,308
Patent litigation (recovery) expense	(371)	2,114	6,581	6,097
Selling, general and administrative	28,927	16,318	75,030	48,406
Total operating expenses	48,568	37,271	140,308	116,811
Income from operations	29,459	25,383	78,095	64,082
Other income (expense), net	46	69	(129)	(470)
Interest income	272	268	771	879
Interest expense	(145)	(53)	(607)	(81)
Income before income taxes	29,632	25,667	78,130	64,410
Provision for income taxes	9,635	8,486	27,166	20,844
Net income before noncontrolling interest	19,997	17,181	50,964	43,566
Add back loss attributable to noncontrolling interest	40	39	110	67
Net income	$ 20,037	$ 17,220	$ 51,074	$ 43,633
Net income per share:				
Basic	$ 0.30	$ 0.27	$ 0.78	$ 0.68
Diluted	$ 0.29	$ 0.26	$ 0.75	$ 0.65
Weighted average common shares outstanding:				
Basic	65,797,722	64,387,413	65,451,926	63,937,796
Diluted	68,366,849	66,986,758	68,230,487	67,318,658

Impax Laboratories, Inc .

Condensed Consolidated Balance Sheets

(unaudited, amounts in thousands)

	September 30, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 172,692	$ 104,419
Short-term investments	167,046	241,995
Accounts receivable, net	97,770	153,773
Inventory, net	78,674	54,177
Deferred tax asset	43,170	37,853
Prepaid expenses and other assets	24,040	7,718
Total current assets	583,392	599,935
Property, plant and equipment, net	171,126	118,158
Other assets	64,941	45,942
Intangible assets, net	54,172	2,250
Goodwill	27,574	27,574
Total assets	$ 901,205	$ 793,859
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 121,742	$ 93,071
Accrued profit sharing and royalty expenses	9,159	40,766
Accrued product licensing payments	40,000	-
Deferred revenue	12,328	23,024
Total current liabilities	183,229	156,861
Deferred revenue	15,092	17,131
Other liabilities	21,242	16,861
Total liabilities	219,563	$ 190,853
Total stockholders' equity	681,642	603,006
Total liabilities and stockholders' equity	$ 901,205	$ 793,859

Impax Laboratories, Inc .
Consolidated Statements of Cash Flows
(unaudited, amounts in thousands)

	Nine Months Ended September 30,	
	2012	**2011**
Cash flows from operating activities:		
Net income	$ 51,074	$ 43,633
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	23,273	11,903
Accretion of interest income on short-term investments	(473)	(665)
Recognition of deferred charge – Zomig ® prepaid royalty	24,997	-
In-process research and development charge	1,550	-
Deferred income taxes	(23,437)	4,464
Tax benefit related to the exercise of employee stock options	(3,515)	(6,086)
Deferred revenue	1,738	2,182
Deferred product manufacturing costs	(2,743)	(1,275)
Recognition of deferred revenue	(16,236)	(19,489)
Amortization of deferred product manufacturing costs	2,775	2,494
Accrued profit sharing and royalty expense	67,427	67,210
Payments of profit sharing and royalty expense	(99,034)	(58,759)
Share-based compensation expense	12,146	9,632
Bad debt expense	-	163
Changes in certain assets and liabilities:		
Accounts receivable	56,003	(24,112)
Inventory	(24,497)	(5,577)
Prepaid expenses and other assets	47,446	(9,606)
Accounts payable and accrued expenses	23,019	(6,871)
Other liabilities	5,774	1,213
Net cash provided by operating activities	147,287	10,454
Cash flows from investing activities:		
Purchase of short-term investments	(177,461)	(280,602)
Maturities of short-term investments	252,883	316,277
Purchases of property, plant and equipment	(58,618)	(18,433)
Payment for product licensing rights	(111,000)	-
Net cash (used in) provided by investing activities	(94,196)	17,242
Cash flows from financing activities:		
Tax benefit related to the exercise of employee stock options and restricted stock	3,515	6,086
Proceeds from exercise of stock options and ESPP	11,667	12,632
Net cash provided by financing activities	15,182	18,718
Net increase in cash and cash equivalents	68,273	46,414
Cash and cash equivalents, beginning of period	104,419	91,796
Cash and cash equivalents, end of period	$ 172,692	$ 138,210

Impax Laboratories, Inc .
Non-GAAP Financial Measures

Total adjusted net income, adjusted net income per diluted share and adjusted EBITDA are not measures of financial performance under generally accepted accounting principles (GAAP) and should not be construed as substitutes for, or superior to, GAAP net income, and net income per diluted share as a measure of financial performance. However, management uses both GAAP financial measures and the disclosed non-GAAP financial measures internally to evaluate and manage the Company's operations and to better understand its business. Further, management believes the inclusion of non-GAAP financial measures provides meaningful supplementary information to and facilitates analysis by investors in evaluating the Company's financial performance, results of operations and trends. The Company's calculation of adjusted net income, adjusted net income per diluted share and adjusted EBITDA, may not be comparable to similarly designated measures reported by other companies, since companies and investors may differ as to what type of events warrant adjustment.

The following table reconciles reported net income to adjusted net income.

(Unaudited, amounts in millions, except per share data)	**Three months ended September 30,**		**Nine months ended September 30,**	
	2012	**2011**	**2012**	**2011**
Net income	$ 20.0	$ 17.2	$ 51.1	$ 43.6
Adjusted to add (deduct):				
Amortization and acquisition-related costs [(a)]	22.1	-	36.4	-
Generic product withdrawal costs [(b)]	2.0	-	2.0	-
Patent litigation settlement reimbursement [(c)]	(5.0)	-	(5.0)	-
Gross profit earned on Zomig® Agreement	-	-	46.2	-
Acquisition related in process R&D	-	-	1.6	-
Employee severance	-	-	1.9	0.8
Inventory adjustment	-	-	3.5	-
Lower of cost or market charge	-	-	1.7	-
Income tax effect	(6.6)	-	(30.4)	(0.3)
Adjusted net income	$ 32.5	$ 17.2	$ 109.0	$ 44.1
Net income adjusted per diluted share	$ 0.48	$ 0.26	$ 1.60	$ 0.66
Net income per diluted share	$ 0.29	$ 0.26	$ 0.75	$ 0.65

Impax Laboratories, Inc .
Non-GAAP Financial Measures

The following table reconciles reported net income to adjusted EBITDA.

(Unaudited, amounts in millions)	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Net income	$ 20.0	$ 17.2	$ 51.1	$ 43.6
Adjusted to add (deduct):				
Interest income	(0.3)	(0.3)	(0.8)	(0.9)
Interest expense	0.1	0.1	0.6	0.1
Depreciation and other	4.3	3.5	11.9	11.9
Income taxes	9.6	8.5	27.2	20.8
EBITDA	33.7	29.0	90.0	75.5
Adjusted to add:				
Amortization and acquisition-related costs [(a)]	22.1	-	36.4	-
Generic product withdrawal costs [(b)]	2.0	-	2.0	-
Patent litigation settlement reimbursement [(c)]	(5.0)	-	(5.0)	-
Gross profit earned on Zomig® Agreement	-	-	46.2	-
Acquisition related in process R&D	-	-	1.6	-
Employee severance	-	-	1.9	0.8
Inventory adjustment	-	-	3.5	-
Lower of cost or market charge	-	-	1.7	-
Share-based compensation	3.8	3.5	12.1	9.6
Adjusted EBITDA	$ 56.6	$ 32.5	$ 190.4	$ 85.9

(a) Amortization and acquisition-related costs from the January 2012 Distribution, License, Development and Supply Agreement with AstraZeneca UK Limited and the June 2012 Development, Distribution and Supply Agreement with TOLMAR, Inc.

(b) The Company recorded a charge of $2.0 million related to the voluntary withdrawal from the market of bupropion XL 300 mg, manufactured by Impax and marketed through our Strategic Alliance Agreement with Teva.

(c) The Company received $5.0 million for reimbursement of legal fees pursuant to the settlement of litigation.