GLAXOSMITHKLINE PLC
Form 6-K
February 08, 2018

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION
Washington D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of
the Securities Exchange Act of 1934

For period ending 08 February 2018

GlaxoSmithKline plc
(Name of registrant)

980 Great West Road, Brentford, Middlesex, TW8 9GS
(Address of principal executive offices)

Indicate by check mark whether the registrant files or
will file annual reports under cover Form 20-F or Form 40-F

Form 20-F x Form 40-F

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Indicate by check mark whether the registrant by furnishing the
information contained in this Form is also thereby furnishing the
information to the Commission pursuant to Rule 12g3-2(b) under the
Securities Exchange Act of 1934.

Yes No x

Issued 8 February, 2018, London UK

PRESS RELEASE
ViiV Healthcare launches eighth phase III study in two-drug regimen programme for HIV-1 treatment

TANGO study will investigate dolutegravir (TIVICAY) and lamivudine (EPIVIR) in patients with HIV who have achieved viral suppression on a tenofovir alafenamide fumarate-based regimen

London, UK 8 February 2018 - Today ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, announced the start of a phase III study designed to establish if adults with HIV-1 with current virologic suppression on a tenofovir alafenamide fumarate (TAF)-based regimen of at least three drugs are able to maintain viral suppression upon switching to a two-drug regimen (2DR) of dolutegravir (TIVICAY) and lamivudine (EPIVIR). TANGO will seek to enrol approximately 550 adults with HIV-1, from clinical trial sites in North America, Europe, Australia, and Japan.

HIV care is a long-term prospect for those living with the disease, requiring life-long adherence to treatment. Since the introduction of highly active antiretroviral therapy 20 years ago, HIV treatment regimens have predominantly included three antiretroviral drugs.[1],[2] ViiV Healthcare is looking to the future and exploring how HIV treatment could evolve to reduce the number of drugs to which a patient is exposed, while maintaining the level of efficacy achieved with three-drug regimens.

John C Pottage, Jr, MD, Chief Scientific and Medical Officer, ViiV Healthcare, said: "We are asking a simple question in the TANGO study - can virally suppressed people with HIV reduce the number of medicines in their HIV treatment regimen while maintaining viral suppression? If the data show the answer to be yes, this may allow healthcare providers to address issues of long-term toxicity by reducing exposure to antiviral agents over a lifetime of treatment. We believe that with its high barrier to resistance, dolutegravir has the right clinical profile to be a core part of 2DRs for the treatment of HIV-1 and look forward to seeing the results of TANGO in 2019."

The TANGO trial is designed to demonstrate the non-inferior antiviral activity of switching to dolutegravir and lamivudine compared to continuation of a TAF-based regimen over 48 weeks in virologically suppressed subjects. TANGO will characterise patient satisfaction as well as the long-term antiviral activity, tolerability and safety of a 2DR of dolutegravir and lamivudine through to 96 weeks.

The TANGO study follows the GEMINI studies' investigation of the 2DR of dolutegravir and lamivudine in treatment-naïve patients with HIV-1. Results from those trials are anticipated later this year.

Notes to editors

About TANGO (this study does not yet have an NCT number)
TANGO is a phase III, randomised, open-label, active-controlled, multicentre, parallel-group study to assess the non-inferior antiviral activity and safety of a two-drug regimen of dolutegravir and lamivudine compared to continuation on a TAF-based regimen in HIV-infected adults who are virologically suppressed and stable on a TAF-based regimen. Approximately 550 HIV-1 infected adults who are on a stable TAF-based regimen will be randomised 1:1 to switch to dolutegravir and lamivudine once daily for up to 96 weeks, or to continue their TAF-based regimen for 48 weeks. For patients in the TAF-based arm, if the HIV-1 RNA is <50 c/ml at the Week 48 visit, these study participants will switch to dolutegravir and lamivudine for the remainder of the study.

The primary endpoint for the study is the proportion of participants who meet the Snapshot virologic failure criteria at Week 48 using the Intent-to-Treat Exposed (ITT-E) population.

Other studies in ViiV Healthcare's phase III 2DR programme:

SWORD 1 and 2 (NCT02429791 and NCT02422797) - Two identical studies evaluating the safety and efficacy of switching virologically suppressed patients from a three- or four-drug antiretroviral regimen to a two-drug regimen of dolutegravir and rilpivirine (Janssen Sciences Ireland UC). Results presented at CROI 2017.
GEMINI 1 and 2 (NCT02831673 and NCT02831764) - Two identical studies comparing a two-drug regimen of dolutegravir plus lamivudine with a three-drug regimen of dolutegravir plus the fixed-dose tablet tenofovir/emtricitabine in treatment-naïve adults living with HIV. Results are anticipated in 2018.
ATLAS (NCT02951052) - Study evaluating the efficacy and safety of a two-drug regimen of long-acting, injectable cabotegravir and rilpivirine (Janssen Sciences Ireland UC) administered every 4 weeks compared to continuation of current ART of two nucleoside reverse transcriptase inhibitors (NRTIs) plus an integrase inhibitor (INI), non-nucleoside reverse transcriptase inhibitor (NNRTI) or protease inhibitor (PI). Results are anticipated in 2018.
FLAIR (NCT02938520) - Study evaluating the safety and efficacy of a two-drug regimen of intramuscular, long-acting, injectable cabotegravir and rilpivirine (Janssen Sciences Ireland UC) administered every four weeks in treatment-naïve adults living with HIV. Results are anticipated in 2018.
ATLAS 2M (NCT03299049) - Study evaluating the safety and efficacy of long-acting cabotegravir and long-acting rilpivirine (Janssen Sciences Ireland UC) administered every 8 weeks compared to long-acting cabotegravir and long-acting rilpivirine (Janssen Sciences Ireland UC) administered every 4 weeks. Results are anticipated in 2019.

About EPIVIR
Lamivudine is a nucleoside analogue used in combination with other antiretroviral agents for the treatment of HIV infection. Lamivudine is available in branded (EPIVIR) and generic forms.

About TIVICAY (dolutegravir)
Dolutegravir (TIVICAY) is an integrase strand transfer inhibitor (INSTI) for use in combination with other antiretroviral agents for the treatment of HIV. Integrase inhibitors block HIV replication by preventing the viral DNA from integrating into the genetic material of human immune cells (T-cells). This step is essential in the HIV replication cycle and is also responsible for establishing chronic infection. Tivicay is approved in over 100 countries across North America, Europe, Asia, Australia, Africa and Latin America.

TIVICAY (dolutegravir) tablets
Professional Indication(s) and Important Safety Information
Indications and Usage
TIVICAY is a human immunodeficiency virus type 1 (HIV-1) integrase strand transfer inhibitor (INSTI) indicated in combination with:

- other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 30 kg
- rilpivirine as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies per mL) on a stable antiretroviral regimen for ≥6 months with no history of treatment failure or known substitutions associated with resistance to either antiretroviral agent

Important Safety Information
CONTRAINDICATIONS:

TIVICAY is contraindicated in patients:

with previous hypersensitivity reaction to dolutegravir

receiving dofetilide (antiarrhythmic)

WARNINGS AND PRECAUTIONS:

Hypersensitivity Reactions:

Hypersensitivity reactions have been reported and were characterized by rash, constitutional findings, and sometimes organ dysfunction, including liver injury. The events were reported in <1% of subjects receiving TIVICAY in Phase 3 clinical trials

Discontinue TIVICAY and other suspect agents immediately if signs or symptoms of hypersensitivity reactions develop, as a delay in stopping treatment may result in a life-threatening reaction. Monitor clinical status, including liver aminotransferases, and initiate appropriate therapy if hypersensitivity reaction is suspected

Hepatotoxicity:

Patients with underlying hepatitis B or C may be at increased risk for worsening or development of transaminase elevations with use of TIVICAY. In some cases the elevations in transaminases were consistent with immune reconstitution syndrome or hepatitis B reactivation, particularly in the setting where anti-hepatitis therapy was withdrawn

Cases of hepatic toxicity, including elevated serum liver biochemistries, hepatitis, and acute liver failure, have also been reported in patients receiving a dolutegravir-containing regimen who had no pre-existing hepatic disease or other identifiable risk factors. Drug-induced liver injury leading to liver transplant has been reported with TRIUMEQ (abacavir, dolutegravir, and lamivudine)

Monitoring for hepatotoxicity is recommended

Risk of Adverse Reactions or Loss of Virologic Response Due to Drug Interactions:

The concomitant use of TIVICAY and other drugs may result in known or potentially significant drug interactions (see Contraindications or Drug Interactions).

Immune Reconstitution Syndrome, including the occurrence of autoimmune disorders with variable time to onset, has been reported.

ADVERSE REACTIONS:

The most commonly reported (≥2%) adverse reactions of moderate to severe intensity in treatment-naïve adult subjects in any one trial receiving TIVICAY in a combination regimen were insomnia (3%), fatigue (2%), and headache (2%).

DRUG INTERACTIONS:

Coadministration of TIVICAY with certain inducers of UGT1A and/or CYP3A may reduce plasma concentrations of dolutegravir and require dose adjustments of TIVICAY

Administer TIVICAY 2 hours before or 6 hours after taking polyvalent cation-containing antacids or laxatives, sucralfate, oral supplements containing iron or calcium, or buffered medications. Alternatively, TIVICAY and supplements containing calcium or iron can be taken with food

Consult the full Prescribing Information for TIVICAY for more information on potentially significant drug interactions, including clinical comments

USE IN SPECIFIC POPULATIONS:

Pregnancy:

There are insufficient human data on the use of TIVICAY during pregnancy to inform a drug-associated risk of birth defects and miscarriage. An Antiretroviral Pregnancy Registry has been established.

Lactation:

Breastfeeding is not recommended due to the potential for HIV transmission and developing viral resistance in HIV-positive infants.

Pediatric Use:
Safety and efficacy of TIVICAY have not been established in pediatric patients weighing less than 30 kg or in any pediatric patients who are INSTI-experienced.

EPIVIR (lamivudine) tablets
Important Safety Information (ISI)
The following ISI is based on the Highlights section of the US Prescribing Information for EPIVIR. Please consult the full Prescribing Information for all the labeled safety information for EPIVIR.
HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use EPIVIR safely and effectively. See full prescribing information for EPIVIR.

EPIVIR (lamivudine) tablets for oral use
WARNING: LACTIC ACIDOSIS AND SEVERE HEPATOMEGALY, EXACERBATIONS OF HEPATITIS B, and DIFFERENT FORMULATIONS OF EPIVIR
See full prescribing information for complete boxed warning.

Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues.

Severe acute exacerbations of hepatitis B have been reported in patients who are co-infected with hepatitis B virus (HBV) and human immunodeficiency virus (HIV-1) and have discontinued EPIVIR. Monitor hepatic function closely in these patients and, if appropriate, initiate anti-hepatitis B treatment.

Patients with HIV-1 infection should receive only dosage forms of EPIVIR appropriate for treatment of HIV-1.

INDICATIONS AND USAGE
EPIVIR is a nucleoside analogue reverse transcriptase inhibitor indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection.
Limitations of Use: The dosage of this product is for HIV-1 and not for HBV.

DOSAGE AND ADMINISTRATION

Adults: 300 mg daily, administered as either 150 mg twice daily or 300 mg once daily.

Pediatric Patients Aged 3 Months and Older: Administered either once or twice daily. Dose should be calculated on body weight (kg) and should not exceed 300 mg daily.

Patients with Renal Impairment: Doses of EPIVIR must be adjusted in accordance with renal function.

DOSAGE FORMS AND STRENGTHS

Tablets: 150 mg, scored.

Tablets: 300 mg.

Oral Solution: 10 mg per mL.

CONTRAINDICATIONS

EPIVIR is contraindicated in patients with previous hypersensitivity reaction to lamivudine.

WARNINGS AND PRECAUTIONS

Co-infected HIV-1/HBV Patients: Emergence of lamivudine-resistant HBV variants associated with lamivudine-containing antiretroviral regimens has been reported.

Hepatic decompensation, some fatal, has occurred in HIV-1/HCV co-infected patients receiving interferon and ribavirin-based regimens. Monitor for treatment-associated toxicities. Discontinue EPIVIR as medically appropriate and consider dose reduction or discontinuation of interferon alfa, ribavirin, or both.

Pancreatitis: Use with caution in pediatric patients with a history of pancreatitis or other significant risk factors for pancreatitis. Discontinue treatment as clinically appropriate.

Immune reconstitution syndrome and redistribution/accumulation of body fat have been reported in patients treated with combination antiretroviral therapy.

Lower virologic suppression rates and increased risk of viral resistance were observed in pediatric subjects who received EPIVIR oral solution concomitantly with other antiretroviral oral solutions compared with those who received tablets. An all-tablet regimen should be used when possible.

ADVERSE REACTIONS

The most common reported adverse reactions (incidence greater than or equal to 15%) in adults were headache, nausea, malaise and fatigue, nasal signs and symptoms, diarrhea, and cough.

The most common reported adverse reactions (incidence greater than or equal to 15%) in pediatric subjects were fever and cough.

To report SUSPECTED ADVERSE REACTIONS, contact ViiV Healthcare at 1-888-844-8872 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

Sorbitol: Coadministration of lamivudine and sorbitol may decrease lamivudine concentrations; when possible, avoid chronic coadministration.

USE IN SPECIFIC POPULATIONS

Lactation: Breastfeeding not recommended.

About ViiV Healthcare

ViiV Healthcare is a global specialist HIV company established in November 2009 by GlaxoSmithKline (LSE: GSK) and Pfizer (NYSE: PFE) dedicated to delivering advances in treatment and care for people living with HIV and for people who are at risk of becoming infected with HIV. Shionogi joined in October 2012. The company's aim is to take a deeper and broader interest in HIV/AIDS than any company has done before and take a new approach to deliver effective and innovative medicines for HIV treatment and prevention, as well as support communities affected by HIV.

For more information on the company, its management, portfolio, pipeline, and commitment, please visit www.viivhealthcare.com.

GSK - a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. For further information please visit www.gsk.com

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Cautionary statement regarding forward-looking statements
GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described under Item 3.D 'Principal risks and uncertainties' in the company's Annual Report on Form 20-F for 2016.

[1] Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents; p. F-4. Available at www.aidsinfo.nih.gov/guidelines Last accessed February 2018
[2] Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: Recommendations for a public health approach - Second edition. WHO June 2016; p. 97. Available at http://www.who.int/hiv/pub/arv/arv-2016/en/ Last accessed February 2018

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, thereunto duly authorised.

GlaxoSmithKline plc
(Registrant)

Date: February 08, 2018

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc

			116,071
			161,644
			257,957
Total revenues			
			6,030,858
			5,579,943
			12,346,859
			10,585,783
Costs and expenses:			
Costs of procedures and maintenance fees			
			2,611,460
			2,677,076
			5,038,409
			5,510,106
Cost of equipment sales			

		1,194,027	
		671,539	
		2,668,936	
		1,021,827	
Research and development			
		313,971	
		299,147	
		574,910	
		560,104	
Selling			
		794,030	
		713,029	
		1,606,245	
		1,243,651	
General and administrative			
		833,731	
		648,276	
		1,651,221	
		1,312,305	

Total costs and operating expenses	5,747,219	5,009,067	11,539,721	9,647,993
Operating income	283,639	570,876	807,138	937,790
Other expense (income):				
Gain on sale of investments				

	(69,497)	
	(427,605)	
Other expense		
	4,153	
	19,033	
	2,266	
	52,376	
Total other expenses (income)		
	4,153	
	(50,464)	
	2,266	
	(375,229)	

Minority interests:			
Minority interest in subsidiaries income			
	160,511		
	179,564		
	330,530		
	334,959		
Equity in income from unconsolidated subsidiary			
	(7,656)		
	30,359		
	(37,165)		

Total minority interest	160,511	171,908	
	360,889	297,794	
Income before provision for income taxes	118,975	449,432	
	443,983	1,015,225	
Provision for income taxes	37,700	219,651	
	195,500		

			434,651
Net income	$ 81,275	$ 229,781	$ 248,483	$ 580,574
Earnings per share:				
Basic	$ .02	$ .05		

			$ .06
			$ .14

Diluted			
			$ .02
			$ .05
			$ .06
			$ .14

Number of shares used in the computation of earnings per share:

Basic			
	3,923,753		
	4,198,220		
	3,939,154		
	4,235,720		
Diluted			
	3,927,685		
	4,198,609		
	3,940,437		
	4,240,728		

See accompanying notes.

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MEDSTONE INTERNATIONAL, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

	Common Stock		Additional paid-in capital	Accumulated earnings	Accumulated Other Comprehensive income (loss)	Treasury Stock	Total
	Number of shares	Amount					
Balance at December 31, 2001	4,111,220	$ 22,971	$ 19,646,388	$ 16,050,251	$ 32,756	$ (11,162,849)	$ 24,589,517
Net income				248,483			248,483
Other comprehensive income:							
Unrealized loss on foreign currency translation, net					(45,390)		(45,390)
Total comprehensive income							203,093
Treasury stock repurchased	(191,200)					(870,052)	(870,052)
Balance at June 30, 2002 (Unaudited)	3,920,020	$ 22,971	$ 19,646,388	$ 16,298,734	$ (12,634)	$ (12,032,901)	$ 23,922,558

See accompanying notes.

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MEDSTONE INTERNATIONAL, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

Six months ended June 30, 2002 and 2001
(Unaudited)

	2002	2001
Cash flows from operating activities:		
Net income	$ 248,483	$ 580,574
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	890,172	1,080,129
Provision for doubtful accounts	120,000	110,000
Provision for inventory obsolescence	84,000	84,000
Gain on sale of long-term investments		(427,605)
Minority interest in partnerships	330,530	334,959
Minority equity in consolidated subsidiary	30,359	(37,165)
Changes in assets and liabilities:		
Accounts receivable	103,212	(194,971)
Inventories	240,112	(110,672)
Prepaid expenses and other current assets	28,163	8,078
Accounts payable and accrued expenses	72,871	(137,826)
Accrued payroll expenses	82,042	(76,642)
Accrued income taxes		72,028
Deferred revenue	(106,420)	(119,859)
Customer deposits	(257,868)	308,367
Other, net	(26,248)	(15,308)
Net cash provided by operating activities	1,839,408	1,458,087
Cash flows from investing activities:		
Purchase of short-term investments	(2,328,167)	(5,602,921)
Proceeds from sales of short-term investments	2,275,420	6,340,681
Investment in sales type lease	(7,860)	
Proceeds from sale of long-term investments		427,605
Distribution of minority interest	(424,000)	(348,000)
Purchase of property and equipment, net	(778,811)	(830,138)
Net cash provided by (used in) investing activities	(1,263,418)	(12,773)
Cash flows from financing activities:		
Purchase of treasury stock	(870,052)	(650,506)
Deferral of rent payments	1,700	5,409
Loan payments	(4,584)	(8,631)
Net cash used in financing activities	(872,936)	(653,728)
Net increase in cash and equivalents	(296,946)	791,586
Cash and equivalents at beginning of period	1,928,731	945,610
Cash and equivalents at end of period	$ 1,631,785	$ 1,737,196

Supplemental cash flow disclosures:
Cash paid during the period for:

Income taxes	$ 37,528	$ 396,452

See accompanying notes.

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MEDSTONE INTERNATIONAL, INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2002

A. Basis of presentation

The accompanying condensed consolidated financial statements include the accounts of Medstone International, Inc. and its subsidiaries (the Company). All significant intercompany transactions and accounts have been eliminated.

In the opinion of the Company s management, the accompanying unaudited condensed consolidated financial statements include all adjustments (which consist only of normal recurring adjustments) necessary for a fair presentation of its consolidated financial position at June 30, 2002 and consolidated results of operations and cash flows for the periods presented. Although the Company believes that the disclosures in these financial statements are adequate to make the information presented not misleading, certain information and disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted. These financial statements should be read in conjunction with the Company s audited financial statements included in the Company s 2001 Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 1, 2002. Results of operations for the three and six months ended June 30, 2002 are not necessarily indicative of results to be expected for the full year.

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

B. Accumulated Other Comprehensive Loss

The components of other comprehensive loss are as follows:

	Currency Translation Adjustment
Balance at December 31, 2001	$ 32,756
Foreign currency translation adjustments	(45,390)
Balance at June 30, 2002	$ (12,634)

The functional currency of the investment in foreign subsidiary is considered to be the United States dollar.

The earnings associated with the Company s investment in its foreign subsidiary are

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considered to be permanently invested and no provision for U.S. federal and state income taxes on those earnings or translation adjustments has been provided.

For the three months ended June 30, 2002 and 2001, total comprehensive income was $65,602 and $220,482, respectively, For the six months ended June 30, 2002 and 2001, total comprehensive income was $203,093 and $566,752, respectively.

C. Business Segments

The Company operates in two business segments, equipment sales and fees for procedures, maintenance and management.

	Three months ended		Six months ended	
	June 30, 2002	June 30, 2001	June 30, 2002	June 30, 2001
Revenue:				
Equipment sales	$ 1,639,249	$ 744,678	$ 3,535,692	$ 1,097,859
Fees for procedures, maintenance and management	4,312,088	4,719,194	8,649,523	9,229,967
	$ 5,951,337	$ 5,463,872	$ 12,185,215	$ 10,327,826
Operating income (loss):				
Equipment sales	$ 109,059	$ (35,918)	$ (30,885)	$ (123,691)
Fees for procedures, maintenance and management	174,580	606,794	838,023	1,061,481
	$ 283,639	$ 570,876	$ 807,138	$ 937,790

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D. Per share information

Basic net income per share is computed by dividing income available to common stockholders by the weighted average number of common shares outstanding. Diluted net income per share includes the effect of the potential shares outstanding, including dilutive stock options and warrants using the treasury stock method.

The following table sets forth the computation of earnings per share:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2002	2001	2002	2001
Numerator: Net income	$ 81,275	$ 229,781	$ 248,483	$ 580,574
Denominator for weighted average shares outstanding	3,923,753	4,198,220	3,939,154	4,235,720
Basic earnings per share	$ .02	$ .05	$ .06	$ .14
Effect of dilutive securities:				
Weighted average shares outstanding	3,923,753	4,198,220	3,939,154	4,235,720
Stock options	3,932	389	1,283	5,008
Denominator for diluted earnings per share	3,927,685	4,198,609	3,940,437	4,240,728
Diluted earnings per share	$ .02	$ .05	$ .06	$ .14

Common equivalent shares result from the assumed exercise of outstanding dilutive securities when applying the treasury stock method. Fully diluted per share information is not presented for periods in which the effect is antidilutive.

E. Inventories

At June 30, 2002 and December 31, 2001, inventories consisted of the following:

	June 31, 2002	December 31, 2001
Raw materials	$ 4,382,952	$ 4,567,799
Work in process	313,930	363,768
Finished goods	1,115,335	1,364,502
	$ 5,812,217	$ 6,296,069

F. Contingencies

From time to time, the Company is subject to legal actions and claims for personal injuries or property damage related to patients who use its products. The Company has obtained a liability insurance policy providing coverage for product liability and other claims. Management does not believe that the resolution of any current proceedings will have a material financial impact on the Company or the condensed consolidated financial statements.

G. Stock Repurchase Plan

In the second quarter of 2002 the Company purchased a total of 11,200 shares at an

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aggregate cost of $50,302, under the Company s latest Stock Repurchase Plan. Under all of the Company s stock repurchase plans a total of 1,822,650 shares have been repurchased at a total cost of $12,032,901.

H. Subsequent Events

Through August 7, 2002, the Company purchased 110,000 shares of its Common Stock for a cost of $501,600 under its current Stock Repurchase Program.

I. Goodwill

As required by Financial Accounting Standards Board pronouncement No. 142, Goodwill and Other Intangible Assets , the Company has performed the first of the required impairment tests for goodwill. Based on the results of that test, the Company has determined that goodwill was not impaired at January 1, 2002.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with the Company s audited financial statements and Management s Discussion and Analysis of Financial Condition and Results of Operations included in the Company s 2001 Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 1, 2002.

In the ordinary course of business, the company has made a number of estimates and assumptions relating to the reporting of results of operations and financial condition in the preparation of its financial statements in conformity with accounting principles generally accepted in the United States of America. Actual results could differ significantly from those estimates under different assumptions and conditions. The Company believes that the following discussion addresses the Company s most critical accounting policies, which are those that are most important to the portrayal of the Company s financial condition and results. The Company constantly re-evaluates these significant factors and makes adjustments where facts and circumstances dictate. Historically, actual results have not significantly deviated from those determined using the necessary estimates inherent in the preparation of financial statements. Estimates and assumptions include, but are not limited to, customer receivables, inventories, equity investments, fixed asset lives, contingencies and litigation. The Company has also chosen certain accounting policies when options were available, including:

The first-in, first-out (FIFO) method to value a majority of our inventories; and

The intrinsic value method, or APB Opinion No. 25, to account for our common stock incentive awards; and

We record an allowance for credit losses based on estimates of customers ability to pay. If the financial condition of our customers were to deteriorate, additional allowances may be required.

These accounting policies are applied consistently for all years presented. Our operating results would be affected if other alternatives were used. Information about the impact on our operating results is included in the footnotes to our consolidated financial statements.

Results of Consolidated Operations

General

Medstone manufactures, markets and maintains lithotripters, and continues to expand its Fee-for-Service Program to supply lithotripsy equipment to providers on a per procedure basis. The lithotripters manufactured by Medstone are approved to treat both kidney stones and gallstones. The Company is also marketing a urology imaging and treatment table, used for various urological functions, mobile urology and patient handling tables to serve the mobile treatment market and various radiology room equipment, capitalizing on the relationships that the Company has with radiology equipment manufacturers. To date, the Company s consolidated revenues have come primarily from Medstone s lithotripsy business.

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As a manufacturer of medical devices, the Company is vertically integrated by offering its medical devices directly to providers. It currently offers lithotripsy procedures using 14 mobile systems, one fixed site and 26 transmobile lithotripters located throughout the United States on a per procedure basis. With the ability to offer quality equipment at reasonable prices, Medstone intends to continue the growth of this manufacturer direct business.

Results of Operations

Three Months ended June 30, 2002 Compared to Three Months Ended June 30, 2001

The Company recognized total revenue of $6.0 million in the second quarter of 2002 compared to $5.6 million in the second quarter of 2001, or an 8% increase. Revenues from procedures, maintenance and management fees decreased from $4.7 million in the three months ended June 30, 2001 to $4.3 million in the three months ended June 30, 2002 due to both lower average per patient charges on the Company s fee-for-service equipment and lower patient count. Also decreasing were spares revenues as there were lower shipments for both domestic and foreign customers in the current year when compared to the same period of the prior year. Partially offsetting these decreases were the revenues from maintenance contracts as the number of contracts increased due to additional equipment sales and customer selecting factory maintenance contracts. Equipment revenues increased to $1.64 million in the quarter ending June 30, 2002 from $.74 million in the comparable quarter of the prior year, or a 120% increase. The Company shipped three lithotripsy systems, one urology table and 26 various patient handling tables in the 3 months ended June 30, 2002 compared to one lithotripsy system and 30 various patient handling tables shipped in the same period of 2001.

Interest income decreased by 31% in the second quarter of 2002 when compared to the same period of the prior year due to a significant decline in investment yields and a slight decline in the average invested balance.

Recurring revenue cost of sales increased to 61% of sales in the quarter ended June 30, 2002 compared to 57% in the same quarter of the prior year. This is due to slightly lower depreciation and equipment rental expense in the fee-for-service revenue stream offset by a significant decline in the revenue per patient. Cost of sales on equipment sales decreased to 73% of sales in the three months ended June 30, 2002 compared to 90% of sales in the same period of 2001. This decrease is due to lower costs associated with an increase in volume of system shipments. Overall cost of sales, as a percentage of revenue (excluding interest), increased to 64% in the second quarter of 2002 compared to 61% in the second quarter of 2001.

Research and development costs increased to $314,000 in the second quarter of 2002 compared to $299,000 in the second quarter of 2001 or an increase of 5% due to additional consulting expenses for development of new applications for our existing equipment.

Selling costs increased to $794,000 in the second quarter of 2002 compared to $713,000 in the same period of the prior year, a change of $81,000 or 11% due to higher payroll expenses for added radiology sales staff and increased commission expense on higher sales revenue.

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General and administrative expenses increased by $185,000 or 29% in the three months ended June 30, 2002 compared to the same period in the prior year due to higher consulting and legal expenses.

Gain on sale of investments decreased to $0 in the quarter ending June 30, 2002 compared to $69,000 in the three months ended June 30, 2001. The Company did not sell any investments in the current year, whereas the Company sold 28,000 shares of Cardiac Science in the same period of 2001.

Total minority interest expense decreased to $161,000 in the three months ended June 30, 2002 compared to $172,000 in the same period of the prior year due to lower profits in the Northern Nevada and Southern Idaho operations.

Provision for income taxes for the second quarter of 2002 decreased by $182,000 as a result of lower taxable income in the current year when compared to the same period of 2001.

Six Months Ended June 30, 2002 Compared to Six Months Ended June 30, 2001

The Company recorded total revenue of $12.3 million in the first six months of 2002 or a 17% increase compared to $10.6 million in the corresponding period of 2001. Revenues from procedures, maintenance and management fees decreased by $580,000, or 6%, due to lower average reimbursement per patient even as total patient count increased by 6% in the current year, to over 14,650 patients. Spares revenue also decreased in the current year compared to the same period in the prior year. Equipment revenue increased by $2,437,000, or 222%, as unit shipments increased significantly in the six months ended June 30, 2002 compared to the same period of 2001. Six lithotripsy systems were shipped in the current year compared to one unit in the prior year. Four urology systems were shipped in the six months ended June 30, 2002 with no comparable revenue in the prior year. Offsetting some of the increase in unit shipments is a slight decline in the Company s imaging tables, as the Company has shipped 42 various types of tables in 2002 compared to 47 units sold in the corresponding period of 2001.

Interest income decreased by 37% for the first six months of 2002 when compared to the same period of the prior year as significantly lower interest yields were earned on a slightly lower average invested balance.

Procedure, maintenance and management fee cost of sales decreased to 58% in the six months ended June 30, 2002 compared to 60% in the same period of the prior year as costs decreased in the fee-for-service program due to lower depreciation and equipment rental costs. Cost of sales on equipment sales decreased to 75% of revenue in the first six months of 2002 compared to 93% of revenue in the first six months of 2001 due to a higher number of lithotripsy units sold, which have higher profit margins compared to imaging tables. Overall cost of sales, as a percentage of revenue (excluding interest), remained constant at 63% in both the first six months of 2002 and the same period of 2001.

Research and development costs increased by $15,000, or 3% in the first six months of 2002 when compared to the same period of 2001 as the Company is developing new project applications.

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Selling costs increased by 29%, or $363,000, in the first six months of 2002 compared to the same period of 2001 due to higher payroll for expanded imaging sales efforts, increased commission expense on higher revenues and services related to the biliary marketing efforts.

General and administrative expenses increased by 26%, or $339,000, in the six months ended June 30, 2002 compared to the first six months of 2001 due to higher consulting and legal expenses.

Gain on sale of investments was $428,000 in the six months ended June 30,2001 with no comparable amount in the six months ended June 30, 2002. The Company did not sell any investments in the current year, whereas the Company sold 101,000 shares of Cardiac Science in the same period of the prior year.

Minority interest increased by 21% in the six months ended June 30, 2002 when compared to the same period of the prior year due to recognition of the Company s portion of the losses of Arcoma AB in the current year compared to recognition of equity earnings from Medicredit.com, Inc. in the six months ended June 30, 2001.

Provision for income taxes decreased to $196,000 in the first six months of 2002 compared to $435,000 for the same period of 2001 as a result of lower taxable income in the current year.

Liquidity and Capital Resources

At June 30, 2002, the Company had cash and short-term investments of approximately $6.3 million. These funds were generated from continuing operating activities and from the Company s initial public offering in June 1988.

The Company s long-term capital expenditure requirements will depend on numerous factors, including the progress of the Company s research and development programs, the time required to obtain regulatory approvals, the resources that the Company devotes to the development of self-funded products, proprietary manufacturing methods and advanced technologies, the costs of acquisitions and/or new revenue opportunities, the ability of the Company to obtain additional licensing arrangements and to manufacture products under those arrangements, and the demand for its products if and when approved and possible acquisitions of products, technologies and companies.

The Company believes that its existing working capital and funds anticipated to be generated from operations will be sufficient to meet the cash needs for continuation of its present operations during 2002.

Safe Harbor Statement Under the Private Securities Litigation Reform Act of 1995

Forward-looking statements in this report, including without limitation, statements relating to the Company s plans, strategies, objectives, expectations, intentions and adequacy of resources, are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that such forward-looking statements involve risks and uncertainties including without limitation the following: (i) the Company s plans, strategies, objections,

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expectations and intentions are subject to change at any time at the discretion of the Company, (ii) the Company s plans and results of operations will be affected by the Company s ability to manage its growth; (iii) the Company s businesses are highly competitive and the entrance of new competitors into or the expansion of the operations by existing competitors in the Company s markets and other changes could adversely affect the Company s plans and results of operations; and (iv) other risks and uncertainties indicated from time to time in the Company s filings with the Securities and Exchange Commission.

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MEDSTONE INTERNATIONAL, INC.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Previously reported.

Item 2. Changes in Securities

None

Item 3. Defaults upon Senior Securities

None

Item 4. Submission of Matters to a Vote of Security Holders

(a) The annual meeting of stockholders of the Company was held on June 28, 2002.

(b) The election of five board of directors of the Company was held. The number of shares cast for each of the individuals listed below to serve until the next Annual Meeting of stockholders and until their successors are elected and have qualified was as follows:

Name	For	Withheld
David V. Radlinski	2,291,968	761,359
Frank R. Pope	2,304,768	748,559
Jack Olshansky	2,297,437	755,890
Michael C. Tibbitts	2,306,622	746,359
David A. Reed	2,306,968	746,705

The ratification of the appointment of Moss Adams LLP as independent accountants of the Company for the year ending December 31, 2002.

For	2,454,726
Against	259,409
Abstain	339,192

Item 5. Other Information

None

Item 6. Exhibits and Reports on Form 8-K

(a) The following exhibits are included herein:

99.1 Certification of the Chairman and Chief Executive Officer of the Company pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

99.2 Certification of the Chief Financial Officer of the Company pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(b) Reports on Form 8-K.

None

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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.

MEDSTONE INTERNATIONAL, INC.
A Delaware corporation

Date: August 13, 2002 By: /s/ MARK SELAWSKI

Mark Selawski
Chief Financial Officer
(Principal financial and accounting officer)

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INDEX TO EXHIBITS

Exhibit No.	Document Description
99.1	Certification of Chairman and Chief Executive Officer
99.2	Certification of Chief Financial Officer