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SAMARITAN PHARMACEUTICALS INC Form 10-K

April 14, 2008

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

## Form 10-K

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

#### For the fiscal year ended December 31, 2007 or ( ) TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from

to

Commission file number 0-26775

Samaritan Pharmaceuticals Inc.

(Exact name of registrant as specified in its charter)

88-0431538

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

(State or other jurisdiction of Incorporation or organization)

101 Convention Center Drive, Suite 310, Las Vegas, Nevada 89109

(Address of Principal Executive Offices)

(702) 735-7001

Issuer's telephone number

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

Securities Registered Pursuant to Section 12(g) of the Exchange Act: Common Stock, \$0.001 par value per share (Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes |X| No||

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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 |\_| Accelerated filer |\_| Non-accelerated filer |X| Smaller reporting company |X|

Nevada

(Zip Code)

None

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of Act). Yes |\_| No |X| The aggregate market value of Common Stock held by non-affiliates as of June 30, 2007 was \$20,179,310. All executive officers and directors of the registrant have been deemed, solely for the purpose of the foregoing calculation, to be "affiliates" of the registrant.

The Company had 30,762,672 common shares issued and outstanding as of March 27, 2008.

#### DOCUMENTS INCORPORATED BY REFERENCE:

None.

#### FORWARD LOOKING STATEMENTS

This document and the documents incorporated by reference herein contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Also, our Company management may make forward-looking statements orally or in writing to investors, analysts, the media and others. Forward-looking statements express our expectations or predictions of future events or results. They are not guarantees and are subject to many risks and uncertainties. There are a number of factors that could cause actual events or results to be significantly different from those described in the forward-looking statements. Forward-looking statements might include one or more of the following:

- anticipated results of financing activities;
- anticipated clinical trial timelines or results;
- anticipated research and product development results;
- projected regulatory timelines;
- descriptions of plans or objectives of management for future operations, products or services;
- anticipated agreements with marketing partners;
- forecasts of future economic performance; and
- descriptions or assumptions underlying or relating to any of the above items.

Forward-looking statements can be identified by the fact that they do not relate strictly to historical or current facts or events. They use words such as anticipate , estimate , expect , project , intend , opportunity , plan , potential , believe or words of similar meaning. They may such as will , would , should , could or may.

We obtained the market data and industry information contained in this Annual Report on Form 10-K from internal surveys, estimates, reports and studies, as appropriate, as well as from market research, publicly available information and industry publications. Although we believe our internal surveys, estimates, reports, studies and market research, as well as industry publications are reliable, we have not independently verified such information, and as such, we do not make any representation as to its accuracy.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of such statements. We do not intend to update any of the forward-looking statements after the date of this report to conform such statements to actual results except as required by law. Given these uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date of this report. You should carefully consider that information before you make an investment decision. You should review carefully the risks and uncertainties identified in this report. This annual report will not be updated as a result of new information or future events.



## **Table of Contents**

## Part I

Item 1. Business	4
Item 1A. Risk Factors	16
Item 1B. Unresolved Staff Comments	25
Item 2. Properties	25
Item 3. Legal Proceedings	25
Item 4. Submission of Matters to a Vote of Security Holders	25
Part II	
Item 5. Market For Registrant's Common Equity, Related Stockholder Matters	
and Issuer's Purchases of Equity Securities	25
Item 6. Selected Financial Data	27
Item 7. Management's Discussion and Analysis of Financial Condition and	
Results of Operations	28
Item 7A. Quantitative and Qualitative Disclosures about Market Risk	41
Item 8. Financial Statements and Supplementary Data	41
Item 9. Changes in and Disagreements with Accountants on Accounting and	
Financial Disclosure	41
Item 9A (T). Controls and Procedures	41
Item 9B. Other Information	42
Part III	
Item 10. Directors, Executive Officers and Corporate Governance	43
Item 11. Executive Compensation	47
Item 12. Security Ownership of Certain Beneficial Owners and Management	
and Related Stockholder Matters	55
Item 13. Certain Relationships and Related Transactions, and Director Independence	57
Item 14. Principal Accounting Fees and Services	57
Part IV	
Item 15. Exhibits, Financial Statement Schedules	59
Signatures	

### PART I ITEM 1. BUSINESS

Samaritan Pharmaceuticals, Inc. (including the subsidiaries, referred to as Samaritan, the "Company", "its", "we", and "our"), formed in September 1994, is an entrepreneurial biopharmaceutical company, focused on commercializing innovative therapeutic products to relieve the suffering of patients with Alzheimer's disease; cancer; cardiovascular disease, HIV, and Hepatitis C; as well as, commercializing its acquired marketing and sales rights, to sell fifteen (15) marketed revenue-generating products, in Greece, and/or various Eastern European countries.

Samaritan has partnered its oral entry inhibitor HIV drug SP-01A, a drug that has demonstrated safety and efficacy, in Phase II clinical trials, with Pharmaplaz, Ireland to advance to Phase III clinical trials. In addition, Samaritan aims to commercialize three (3) market drug candidates with late-stage preclinical development programs. Samaritan is evaluating the use of Caprospinol, SP-233 in Alzheimer's disease patients; the use of SP-1000 with acute coronary disease patients; and the use of SP-30 as an "oral treatment" for Hepatitis C patients.

#### Commercialization Business Model

Our commercialization business model is focused dually on, the partnering of our promising innovative products to pharmaceutical companies; and the acquisition of the marketing and sales rights to revenue-generating marketed products for sales in Greece and Eastern Europe. This model allows Samaritan to focus on our core competencies in drug discovery and drug development. Samaritan seeks to bring its promising innovative therapeutics to Phase II proof of concept clinical trials, and partner compelling drugs before costly Phase III clinical trials. Potential revenue streams with this model could include up-front fees, milestone payments, and participation in the marketing success of partnered products through royalties. In addition, Samaritan licenses branded approved specialty drug products, and its sales and marketing force, registers and commercializes specialty drugs in the niche territories of Greece and Eastern Europe to generate revenue with the goal of eventually sustaining the Company. Our business model is entirely focused on achieving growth and maximizing value for the benefit of our investors.

#### Marketed Products

Samaritan has collaborative relationships with other pharmaceutical companies to commercialize branded approved prescription products in selected niche territories, such as, in Greece, Albania, Bosnia, Bulgaria, Croatia, Cyprus, Czech Republic, Egypt, FYROM, Hungary, Montenegro, Poland, Romania, Serbia, Slovakia, Slovenia, Syria and Turkey. We use our expertise to register approved drugs with regulatory agencies in the country we have acquired the rights for; and then, upon regulatory approval, we distribute, market and sell these products. Currently, we have in-licensed the rights to sell fifteen (15) drugs, Amphocil from Three Rivers Pharmaceuticals, Elaprase and Replagal from Shire Pharmaceuticals, Infasurf from Ony, Inc, Erwinase, Kidrolase, and the Rapydan pain patch from EUSA, Mepivamol, Methadone, Morphine Sulphate, Naloxone, Naltrexone, Oramorph and Pethidine from Molteni Farmaceutici and Abioklad from Abiogen Pharma. Our efforts are focused on specialist physicians in private practice or at hospitals and major medical centers in our territories. Below is a description of our in-licensed products.

#### ABIOKLAD(R)

ABIOKLAD(R) (Disodium Clodronate) is a bisphosphonate that binds to calcium and inhibits osteoclastic bone resorption, crystal formation and dissolution, resulting in a reduction of bone turnover. ABIOKLAD(R) is indicated for the control of malignancy-associated hypercalcemia (high levels of calcium in blood), the inhibition of osteolysis (degeneration of bone tissue) resulting malignant tumors and the decrease of bone pain.

ABIOKLAD(R) is an approved FDA prescription product owned by Abiogen Pharmaceuticals, Inc. and marketed by Abiogen Pharmaceuticals, Inc. in the US. Samaritan signed an exclusive distribution deal for Greece and Cyprus with Abiogen Pharmaceuticals on March 14, 2008.

Currently, Samaritan Pharmaceuticals is utilizing the US FDA approved regulatory file in preparing marketing applications for ABIOKLAD(R) with regulatory authorities in Greece and Cyprus to gain country marketing authorization drug approval.



#### AMPHOCIL(R)

AMPHOCIL(R) is a lipid form of amphotericin B indicated for the treatment of invasive aspergillosis, a life threatening systemic fungal infection. AMPHOCIL(R) is indicated for the treatment of severe systemic and/or deep mycoses in cases where toxicity or renal failure precludes the use of conventional amphotericin B in effective doses, and in cases where prior systemic antifungal therapy has failed. Fungal infections successfully treated with AMPHOCIL(R) include disseminated candidiasis and aspergillosis. AMPHOCIL(R) has been used successfully in severely neutropenic patients.

AMPHOCIL(R) is an approved FDA prescription product owned by Three Rivers Pharmaceuticals, Inc. and marketed by Three Rivers Pharmaceuticals, Inc. in the US. Samaritan signed an exclusive distribution deal for Greece and Cyprus with Three Rivers on December 14, 2005. Three Rivers added the territory of Ireland to Samaritan's existing exclusive licensing agreement to market Amphocil in Greece and Cyprus in October 2007.

Currently, Samaritan is marketing AMPHOCIL(R) in Greece.

#### ELAPRASE(R)

ELAPRASE(R) is a human enzyme replacement therapy for the treatment of Hunter syndrome, also known as Mucopolysaccharidosis II (MPS II). Hunter syndrome is a rare, life-threatening genetic condition that results from the absence or insufficient levels of the lysosomal enzyme iduronate-2-sulfatase. Without this enzyme, cellular waste products accumulate in tissues and organs, which then begin to malfunction.

ELAPRASE(R) was granted marketing authorization for the long-term treatment of patients with Hunter's disease by the European Commission in January 2007. ELAPRASE(R) is the first, and only, enzyme replacement therapy for Hunter's disease patients and was launched in the U.S. in July 2006.

On December 19, 2007, the Company received pricing approval for ELAPRASE from the Greek Ministry of Development. On March 1, 2007, Samaritan signed an exclusive licensing agreement with Shire Human Genetic Therapies (SHPGY.O) to market and sell Elaprase in Greece and Cyprus.

Currently, Samaritan is marketing ELAPRASE(R) in Greece.

#### ERWINASE(R)

ERWINASE(R) is indicated for the treatment of Acute Lymphoblastic Leukemia (ALL). Asparagine is an amino acid that is essential for cell growth; it is produced by most cells, but not all blood cells. Mutated (cancer) cells in ALL rely on asparagine circulating in the blood for growth. L-sparaginase is an enzyme that lowers circulating asparagine levels in the blood thereby depriving the mutated blood cells of asparagine and inhibiting their growth.

On March 10, 2008, Samaritan signed an exclusive agreement with EUSA for the marketing and distribution of the product Erwinase(R) in Greece and Cyprus. Erwinase(R) is an approved FDA prescription product and is owned by EUSA Pharma. and marketed by EUSA Pharma, in the U.S.

Currently, Samaritan Pharmaceuticals is utilizing the US FDA approved regulatory file in preparing marketing applications for Erwinase® with regulatory authorities in Greece and Cyprus to gain country marketing authorization drug approval.

#### INFASURF(R)

INFASURF(R) treats and prevents Respiratory Distress Syndrome (RDS). This syndrome occurs when infants lack surfactant, a natural substance normally produced in the body, which is necessary for lungs to function normally. INFASURF(R) is used exclusively in hospitals with a neonatal intensive care unit (NICU) and is administered by neonatologists, neonatal nurses, neonatal nurse practitioners and respiratory therapists.

On January 16, 2007, Samaritan signed an exclusive agreement with Siraeo, Ltd for the marketing and distribution of the product INFASURF(R) in Turkey, Serbia, Bosnia, Macedonia, Albania, Egypt and Syria. INFASURF(R) is an approved FDA prescription product owned by ONY, Inc. and marketed by Forest Laboratories in the U.S.

Currently, Samaritan Pharmaceuticals is utilizing the US FDA approved regulatory file in preparing marketing applications for INFASURF(R) with regulatory authorities in Turkey, Serbia, Bosnia, F.Y.R.O.M., Albania, Egypt and Syria to gain country marketing authorization drug approval.

#### KIDROLASE(R)

KIDROLASE(R) is indicated in the treatment of Acute Lymphoblastic Leukemia. Asparagine is an amino acid that is essential for cell growth; it is produced by most cells, but not all blood cells. Mutated (cancer) cells in ALL rely on asparagine circulating in the blood for growth. L-Asparaginase is an enzyme that lowers circulating asparagine levels in the blood thereby depriving the mutated blood cells of asparagine and inhibiting their growth.

On March 10, 2008, Samaritan signed an exclusive agreement with EUSA for the marketing and distribution of the product Kidrolase(R) in Greece and Cyprus. Kidrolase(R) is an approved FDA prescription product and is owned by EUSA Pharma and marketed by EUSA Pharma, in the U.S.

Currently, Samaritan Pharmaceuticals is utilizing the US FDA approved regulatory file in preparing marketing applications for Kidrolase(R) with regulatory authorities in Greece and Cyprus to gain country marketing authorization drug approval.

#### MEPIVAMOL(R)

MEPIVAMOL(R) (Mepivacaine) is an effective and reliable local anesthetic of intermediate duration and low systemic toxicity. It is widely used for regional anesthetic procedures such as IVRA, infiltration, epidural blockade, plexus and peripheral nerve blockade. MEPIVAMOL(R) is approved by the Italian Ministry of Health (The equivalent to the US FDA) and is owned by Molteni Farmaceutici, Inc. and marketed by Molteni Farmaceutici, Inc. in Italy.

On January 1, 2007, Samaritan entered into an exclusive licensing agreement with Molteni Farmaceutici for the marketing and distribution of MEPIVAMOL(R) in the countries of Greece and Cyprus.

Currently, Samaritan Pharmaceuticals is utilizing the Italian Ministry of Health approved regulatory file in preparing marketing applications for MEPIVAMOL(R) with regulatory authorities in Greece and Cyprus to gain country marketing authorization drug approval.

#### METHADONE HCL(R)

METHADONE HCL(R) is an opiate agonist. METHADONE HCL(R) prevents heroin or morphine from interacting with receptors for natural painkillers called endorphins, blocking the effects of the addictive drugs and reducing the physical cravings. METHADONE HCL(R) is approved by the Italian Ministry of Health (The equivalent to the US FDA) and is owned by Molteni Pharmaceuticals, Inc. and marketed by Molteni Farmaceutici, Inc. in Italy.

On January 1, 2007, Samaritan entered into an exclusive licensing agreement with Molteni Farmaceutici for the marketing and distribution of METHADONE HCL(R) in the countries of Greece and Cyprus.

Currently, METHADONE HCL(R) can only be sold in Greece and Cyprus via a centralized government tender. Samaritan is preparing a tender application for the next request by Greek authorities for applications.

#### MORPHINE SULPHATE(R)

MORPHINE SULPHATE(R) (Injectable Formulation) relieves moderate to severe pain by binding to brain receptors. Morphine Sulphate may be used to control the pain following surgery, child birth, and other procedures. It may also be used to treat the pain associated with cancer, heart attacks, sickle cell disease and other medical conditions.

On January 1, 2007, Samaritan entered into an exclusive licensing agreement with Molteni Farmaceutici for the marketing and distribution of MORPHINE SULPHATE(R) in the countries of Greece and Cyprus.

Currently, MORPHINE SULPHATE(R) can only be sold in Greece and Cyprus via a centralized government tender. Samaritan has prepared a tender application for the next request by Greek authorities for applications. Samaritan has received its first tender purchase order of Morphine Sulfate from the Institute of Pharmaceutical Research and Technology (IFET).

#### NALOXONE MOLTENI(R)

NALOXONE MOLTENI(R) is an opioid antagonist which reverses the effects of opioid overdose, for example heroin and morphine overdose. Specifically, Naloxone is used in opioid overdoses for countering life-threatening depression of the central nervous system and respiratory system.

On January 1, 2007, Samaritan entered into an exclusive licensing agreement with Molteni Farmaceutici for the marketing and distribution of NALOXONE MOLTENI(R) in the countries of Greece and Cyprus.

Currently, NALOXONE(R) will be sold and distributed by Samaritan on a named patient basis until the pricing and the reimbursement of NALOXONE(R) is established in Greece and Cyprus, with the relevant regulatory authorities.

#### NALTREXONE MOLTENI(R)

NALTREXONE MOLTENI(R) is an opioid antagonist which is used to help people who have a narcotic or alcohol addiction stay drug free. NALTREXONE MOLTENI(R) is used after the patient has stopped taking drugs or alcohol. It works by blocking the effects of narcotics or by decreasing the craving for alcohol.

NALTREXONE MOLTENI(R) is approved by the Italian Ministry of Health (The equivalent to the US FDA) and is owned by Molteni Farmaceutici, Inc. and marketed by Molteni Farmaceutici, Inc. in Italy.

On January 1, 2007, Samaritan entered into an exclusive licensing agreement with Molteni Farmaceutici for the marketing and distribution of NALTREXONE MOLTENI(R) in the countries of Greece and Cyprus.

Currently, Samaritan Pharmaceuticals is utilizing the Italian Ministry of Health approved regulatory file in preparing marketing applications for NALTREXONE MOLTENI(R) with regulatory authorities in Greece and Cyprus to gain country marketing authorization drug approval.

#### ORAMORPH(R)

ORAMORPH(R) is morphine sulphate in an oral solution and is used for managing moderate to severe chronic pain for more than a few days. It works by dulling the pain perception center in the brain. ORAMORPH(R) is approved by the Italian Ministry of Health (The equivalent to the US FDA) and is marketed by Molteni in Italy.

ORAMORPH(R) is approved by the Italian Ministry of Health (The equivalent to the US FDA) and is owned by Molteni Farmaceutici, Inc. and marketed by Molteni Farmaceutici, Inc. in Italy.

On January 1, 2007, Samaritan entered into an exclusive licensing agreement with Molteni Farmaceutici for the marketing and distribution of ORAMORPH(R) in the countries of Greece and Cyprus.

Currently, Oramorph has a Greek marketing authorization. Oramorph can only be sold in Greece via a centralized government tender. Samaritan is preparing a tender application for the next request by Greek authorities for applications.

#### PETHIDINE(R)

PETHIDINE(R) is indicated for the treatment of moderate to severe pain, and may be prescribed as a preoperative medication, support of anesthesia, and obstetric analgesia.

Samaritan has received its first tender purchase order of Pethidine from the Institute of Pharmaceutical Research and Technology (IFET). On January 1, 2007, Samaritan entered into an exclusive licensing agreement with Molteni Farmaceutici for the marketing and distribution of PETHIDINE(R) in the countries of Greece and Cyprus.

Currently, Pethidine® can only be sold in Greece and Cyprus via a centralized government tender. Samaritan is preparing a tender application for the next request by Greek authorities for applications.

#### RAPYDAN(R)

RAPYDAN(R) is indicated for local dermal analgesia on intact skin, and consists of a thin, uniform, local anesthetic formulation with an integrated, oxygen-activated heating component that is intended to enhance the delivery of the local anesthetic. The drug formulation is a eutectic mixture of lidocaine 70 mg and tetracaine 70 mg. Rapydan(R) is indicated to provide local dermal analgesia for superficial venous access and superficial dermatological procedures such as excision, electrodessication and shave biopsy of skin lesions.

On August 3, 2007, Samaritan signed an exclusive agreement with EUSA for the marketing and distribution of the product Rapydan(R) in Greece and Cyprus. Rapydan(R) is an approved FDA prescription product under the name SYNERA(R) and is owned by ZARS Pharmaceuticals, Inc. and marketed by Endo Pharmaceuticals, Inc. in the US.

Currently, Samaritan Pharmaceuticals is utilizing the US FDA approved regulatory file in preparing marketing applications for Rapydan® with regulatory authorities in Greece and Cyprus to gain country marketing authorization drug approval.

#### REPLAGAL(R)

REPLAGAL(R) is a long-term enzyme replacement therapy used to treat patients with a confirmed diagnosis of Fabry Disease. Fabry Disease is caused by a deficiency of an enzyme, alpha-galactosidase A (also called ceramidetrihexosidase), involved in the breakdown of fats.

Replagal(R) will be sold and distributed by Samaritan on a named patient basis until the pricing and the reimbursement of Replagal(R) is established in Greece and Cyprus, with the relevant regulatory authorities.

On April 13, 2007, Samaritan signed an exclusive licensing agreement with Shire Pharmaceuticals for the marketing and sale of Replagal(R) in Greece and Cyprus.

#### Sales and Marketing

We in-license products that focus on targeting healthcare providers, managed healthcare organizations, specialty distribution companies, government purchasers, and payers.

#### Product Candidates

A significant portion of our operating expenses are related to the research and development of investigational-stage product candidates. Research and development expenses were \$1,733,194 in 2007, \$4,667,053 in 2006, and \$3,456,301 in 2005.

We currently focus our research and development efforts in the therapeutic areas of Alzheimer's, cancer, cardiovascular and infectious diseases. Any of our programs in these disease areas could become more significant to us in the future, but there can be no assurance that any program in development or investigation will generate viable marketable products. As such, we continually evaluate all product candidates and may, from time to time, discontinue the development of any given program and focus our attention and resources elsewhere. We may choose to address new opportunities for future growth in a number of ways including, but not limited to, internal discovery and development of new products, out licensing and in-licensing of products and technologies, and/or acquisition of companies with products and/or technologies. Any of these activities may require substantial research and development efforts and expenditure of significant amounts of capital. The following summarizes our current product candidate programs with relevant out-licensing deals that the Company has completed.

#### Alzheimer's disease

SP-233

Caprospinol (SP-233) is a novel Alzheimer's drug candidate that Samaritan believes has the potential to clear beta-amyloid plaque from the brain; a problem that most researchers today believe is the cause of Alzheimer's. Samaritan filed an IND application for Caprospinol on October 30, 2006 and was subsequently granted an IND number by the FDA. The Company believes that Caprospinol could be a significant breakthrough in the treatment of Alzheimer's, and plans to provide the information requested by the FDA in order to continue moving our Caprospinol development program forward.

On December 7, 2006, Samaritan announced that the U.S. Food and Drug Administration (FDA) has completed its regulatory review of our IND (Investigational New Drug) application for Caprospinol and has requested that additional information be submitted in support of the safety of Caprospinol, prior to initiating Samaritan's proposed Phase I clinical study. Samaritan is currently performing additional studies to submit and support the IND submitted to the FDA.

#### Cardiovascular

#### SP-1000

SP-1000 is a fast-acting peptide that can be used to clean the blood of excessive cholesterol in acute high cholesterol conditions. SP-1000 plays a role in transformation and binding of LDL cholesterol and raising HDL, the good cholesterol, with immediate results.

To this end, Samaritan's collaborating scientists developed SP-1000 to be a potential hypocholesterolemic agent that acts through a new and novel mechanism of action that is quite distinct to the mechanism of action mediating the effects of statins.

The effectiveness of SP-1000 peptide treatment has been demonstrated in two validated hypercholesterolemia animal models, a genetically engineered mouse model mimicking familial hypercholesterolemia, and in diet-induced hypercholesterolemia guinea pigs.

Based on the study results, Samaritan collaborative scientists believe that the SP-1000 peptide could have the following pharmacological activities:

- o SP-1000 peptide will not interfere with cholesterol metabolism and disposition
- o SP-1000 peptide will increase HDL while decreasing serum free cholesterol and total bile cholesterol

o SP-1000 peptide will be effective in removing atheromas and preventing plaque formation

o SP-1000 peptide will protect against high cholesterol-induced neurological, cardiac and muscular suffering, and gross liver morphology Taken together, these data on classic animal models of familial and dietary hypercholesterolemia show that SP-1000 is an interesting new and novel lipid lowering drug with a strong patent position that represents a competitive advantage over currently available therapeutic options

#### Infectious Diseases

#### SP-01A

SP-01A is an HIV oral entry inhibitor drug. In order for viruses to reproduce, they must infect or hi-jack a cell, and use it to make new viruses. Just as your body is constantly making new skin cells, or new blood cells, each cell often makes new proteins in order to stay alive and to reproduce itself. Viruses hide their own DNA in the DNA of the cell, and then, when the cell tries to make new proteins, it accidentally makes new viruses as well. HIV mostly infects cells in the immune system.

Clinical studies to date suggest that SP-01A prevents HIV from entering cells by inhibiting HIV-1 viral replication through a novel mechanism that is unique to any antiviral drug SP-01A reduces intracellular cholesterol and corticosteroid biosynthesis, which causes the inability of lipid rafts in the cellular membrane to organize, ultimately preventing fusion of an HIV receptor and both the CCR5 and CXCR4 cellular receptors.

On March 28, 2007, Samaritan and Pharmaplaz, a private Irish Healthcare company and a shareholder of Samaritan, signed an agreement (the "Pharmaplaz Agreement") to commercialize SP-01A. Under the terms of the agreement, Pharmaplaz is required to pay Samaritan \$10 million upfront. To date, under the Pharmaplaz Agreement, the amount of funds received from Pharmaplaz is \$2.15 million; \$1.4 million and \$750,000 were received during the first and fourth quarter of 2007 respectively. On May 15, 2007, the CEO of Pharmaplaz, Michael Macken, signed a personal guarantee and on May 21, 2007 a stock pledge agreement for 943,291 (split-adjusted) shares of Samaritan Pharmaceuticals to guarantee the balance of the \$7.85 million. On May 15, 2007, the amount of shares pledged was worth \$1,300,742. On December 31, 2007, the last reported market sale price of our Common Stock was \$0.33 and the value of the stock pledge was \$311,286. As a result of Pharmaplaz's failure to timely pay the remaining balance of 7.85 million, Pharmaplaz is not in compliance with the terms of the Pharmaplaz Agreement. Samaritan is currently working with Pharmaplaz to collect the past due remaining balance.

Pharmaplaz, a shareholder, will pay for and be responsible for future research and development to bring the technology to market. Samaritan has no remaining obligations or performance for future research and development. The \$10,000,000 payment is non-refundable. Upon request, Samaritan might occasionally advise Pharmaplaz regarding SP-01A, in relationship to Principal Investigators with applications for NIH grants, or other grant applications to advance SP-01A, at Pharmaplaz's cost. Samaritan and Pharmaplaz will split 50/50 of all revenues stemming from SP-01A.

#### SP-30

SP-30 has demonstrated promise in preclinical studies as an antiviral therapeutic in the treatment of Hepatitis C (HCV) as well as a therapeutic adjuvant in the treatment of HIV. SP-30 offers several distinctive competitive advantages as a potential oral adjuvant therapeutic in the treatment of HCV infected individuals. SP-30 is uniquely different from other inhibitors of viral replication in that it appears to condition the cell. This unique multiple target mechanism of action provides several advantages.

- 1. In HCV infected individuals, SP-30 uses its unique mechanism to build a fence around the cell and prevent viral entry. Consequently, HCV is unable to replicate or mutate and is eventually eradicated by the immune system.
- 2. Because SP-30's targets belong to the host cell and not to the virus itself, SP-30 may not be susceptible to the development of resistance.
- 3. SP-30 does not appear to be contraindicated with any other currently approved ARV or HCV treatments.

Therefore, based on its favorable in-vitro inhibition data, Samaritan is developing a Phase I clinical study protocol for SP-30 as a potential oral adjuvant therapeutic in the treatment of HCV infected individuals.

#### Endocrinology

#### SP-6300

SP-6300 is a new and novel approach for the treatment of Cushing's syndrome, also known as exogenous hypercortisolism. Cushing's syndrome affects adults 20 to 50 with an estimated 10 to 15 of every million people affected each year. Hypercortisolism occurs when the body's tissues are exposed to excessive levels of cortisol for long periods of time.

Many people suffer the symptoms of exogenous hypercortisolism because they take glucocorticoid hormones such as prednisone, dexamethasone (Decadron) and methylprednisolone (Medrol), for asthma, rheumatoid arthritis, lupus and other inflammatory diseases or for immunosuppression after transplantation. People can also develop exogenous hypercortisolism from injectable corticosteroids for example, repeated injections for joint pain, bursitis and back pain.

On September 18, 2007, Samaritan announced that the U.S. Food and Drug Administration (FDA) has completed its regulatory review of our IND (Investigational New Drug) application for SP-6300.

#### Non Drug Products

#### Alzheimer's Diagnostic Blood Test

Our Alzheimer's diagnostic is a simple blood test which can be used as an alternative or supplement to spinal taps or expensive MRIs currently used by competitors.

#### Breast Cancer Diagnostic

Our non-invasive blood test could be the first diagnostic tool to predict if a breast tumor is cancerous, with the added possibility to detect one single aggressive cancer cell out of a million blood cells. This tool could also be used as a monitoring tool to measure the success of chemotherapy, radiation and other drug treatments for aggressive cancer and ultimately allow patients to avoid the high costs and negative effects of unnecessary chemotherapy.

#### Alzheimer's Rat Model Tool to Test New Drugs

We have developed an animal model that mimics the human phenotype of Alzheimer's disease pathology. We believe this Alzheimer's Rat Model will likely provide pharmaceutical companies the means to rapidly screen and develop therapeutics to control Alzheimer's disease.

#### Collaborations, Alliances, and Investments

The Research Institute of McGill University Health Centre and Samaritan Therapeutics

On July 1, 2007, Samaritan executed research collaboration (the "Research Collaboration") with the Research Institute of McGill University Health Centre and Samaritan Therapeutics over a ten-year period through 2017 to discover and develop new compounds. The budget is for \$1,000,000 paid over four (4) quarterly payments of \$250,000, is unallocated, and covers the general research and development effort. Under the Research Collaboration, the Company receives worldwide exclusive rights, excluding Canada, to any novel therapeutic agents or diagnostic technologies that may result from the Research Collaboration. Samaritan Therapeutics receives exclusive rights to the Canadian market to any novel therapeutic agents or diagnostic technologies that may result from the Research Collaboration.

Under the Research Collaboration, Samaritan receives worldwide exclusive rights to any novel therapeutic agents or diagnostic technologies that may result from the Research Collaboration. Dr. Vassilios Papadopoulos, Dr. Janet Greeson, Dr. Thomas Lang and Dr. Wolfgang Renz lead our team of eight (8) research professionals (including five (5) Ph.D. level research scientists) who have expertise in the fields of endocrinology, pharmacology, cell biology, organic and steroid chemistry, and computer modeling. We are not obligated to pay the Research Collaboration any milestone payments. Our collaborators are entitled to receive royalties based on our revenue from product sales and sublicenses, if any. Samaritan Pharmaceuticals and Samaritan Therapeutics have both assumed responsibility, at their own individual expense, for the process of seeking any regulatory approvals for and conducting clinical trials with respect to any licensed product or application of the licensed technology. Samaritan controls and has the financial responsibility for the prosecution and maintenance in respect to any patent rights related to the licensed technology.

#### Pharmaplaz, LTD

Samaritan and Pharmaplaz, a private Irish Healthcare company and a shareholder of Samaritan, have an agreement (the "Pharmaplaz Agreement") to commercialize SP-01A. Under the terms of the agreement, Pharmaplaz is required to pay Samaritan \$10 million upfront. To date, under the Pharmaplaz Agreement, Samaritan has received \$2.15 million, with a balance of \$7.85 million remaining.

Pharmaplaz will be responsible for clinical development, clinical trial costs and manufacturing. Upon successful commercialization, Samaritan and Pharmaplaz will co-market SP-01A and will share 50-50, in its revenue royalty stream. Samaritan is responsible for all patent expenses, including filing, prosecution, and enforcement expenses.

Pharmaplaz is a fully integrated pharmaceutical company located in Athlone, Ireland. Pharmaplaz develops patented pharmaceutical technologies and products, and has expertise in initial research, process development, clinical trials, regulatory submissions and product manufacturing. Pharmaplaz, in addition, offers facilities for the development of products and processes in life sciences, and can also provide additional support with government grant aid and regulatory affairs.

#### Shire Pharmaceuticals

On March 1, 2007, Samaritan executed a two-year exclusive licensing deal with Shire Pharmaceuticals for the marketing of Elaprase in Greece and Cyprus. The product shall be supplied on a named patient basis until the conclusion of the negotiations relating to the pricing and reimbursement of Elaprase in the territories with the relevant regulatory authorities.

Founded in 1986, Shire is a global specialty pharmaceutical company marketing products to defined customer groups (specialist doctors). Sales and marketing is a core Shire competence, where effective targeting of prescribers allows maximization of sales by a relatively small but high quality sales force.

Shire's strategic goal is to become the leading specialty pharmaceutical company that focuses on meeting the needs of the specialist physician. Shire focuses its business on attention deficit and hyperactivity disorder (ADHD), human genetic therapies (HGT), gastrointestinal (GI) and renal diseases. The structure is sufficiently flexible to allow Shire to target new therapeutic areas to the extent opportunities arise through acquisitions. Shire believes that a carefully selected portfolio of products with a strategically aligned and relatively small-scale sales force will deliver strong results. Shire's in-licensing, merger and acquisition efforts are focused on products in niche markets with strong intellectual property protection either in the US or Europe.

#### Three Rivers Pharmaceuticals(R)

On December 12, 2005, Samaritan signed a ten-year (with five-year automatic renewals) exclusive licensing agreement with Three Rivers Pharmaceuticals, Inc. for the marketing of Amphocil, a prescription drug in Greece; authorization is pending for Cyprus and Ireland.

Established in 2000, Three Rivers Pharmaceuticals(R) devotes its efforts and resources to developing, manufacturing, and marketing pharmaceutical therapies which are indicated for diseases/medical conditions requiring specialized treatment. Currently, Three Rivers Pharmaceuticals markets prescription drugs in both the U.S. and internationally, in the therapeutic categories of antiviral and antifungal agents.

#### Molteni Farmaceutici

On January 1, 2007, Samaritan executed a four-year (with two-year automatic renewals) exclusive licensing agreement with Molteni Farmaceutici for the marketing of Mepivamol, Methadone, Morphine Sulphate, Naloxone, Naltrexone, and Oramorph in Greece and Cyprus.

Molteni is rich in history with over a century of experience beginning with the opening of its manufacturing facility at the Molteni Pharmacy Laboratory located in the historic center of Florence, Italy. The strategic therapeutic areas on which Molteni makes an effort for trading new alliances are concentrated on Analgesia, Anesthesia and Drug Addition Therapy.

#### Siraeo, Ltd.

On December 28, 2006, Samaritan signed a ten-year (with three-year automatic renewals) exclusive licensing agreement with Siraeo, Ltd for the marketing of Infasurf in Turkey, Serbia, Bosnia, Macedonia, Albania, Egypt and Syria. Infasurf is an approved FDA prescription product owned by Ony, Inc. and marketed by Forest Laboratories in the US.

#### EUSA Pharma

On August 3, 2007, Samaritan signed an exclusive agreement with EUSA for the marketing and distribution of the product RAPYDAN(R) in Greece and Cyprus. Rapydan(R) is an approved FDA prescription product under the name SYNERA(R) and is owned by ZARS Pharmaceuticals, Inc. and marketed by Endo Pharmaceuticals, Inc. in the US.

On March 10, 2008, Samaritan signed an exclusive agreement with EUSA for the marketing and distribution of the products ERWINASE(R) and KIDROLASE(R) in Greece and Cyprus. Erwinase(R) and Kidrolase are approved FDA prescription products and are owned by EUSA Pharma and marketed by EUSA Pharma, in the U.S.

EUSA Pharma is a specialty pharma company with a strong and growing portfolio of specialty hospital medicines which has been built through the acquisition of Talisker Pharmaceuticals in July 2006 and OPI in March 2007. Its primary marketed products are Erwinase(R) Rapydan(R), Kidrolase(R), Fomepizole(R) and Xenazine(R). In addition, it has an active development pipeline including candidates in rheumatoid arthritis and Alzheimer s disease, schizophrenia and Lambert Eaton Syndrome.

#### Abiogen Pharma

Abiogen Pharma is a private Italian pharmaceutical company, founded in Pisa in 1997, involved in R&D, manufacturing and marketing. Abiogen has a prestigious R&D pipeline, has demonstrated significant skills in innovative compound development and is now broadening into the biotechnological field. Abiogen s research on the osteo-articular metabolism led to the marketing of four bisphosphonates and established Abiogen Pharma as a unique world-wide company.

#### Patents, Licenses and Proprietary Rights

The products and product candidates currently being developed or considered for development by Samaritan are in the area of biotechnology, an area in which there are extensive patent filings. We rely on patent protection against use of our proprietary products and technologies by competitors. The patent positions of biotechnology firms generally are highly uncertain and involve complex legal and factual questions. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology patents. We currently own or in-license patents related to our products or product candidates and own or in-license additional applications for patents that are currently pending. In general, when we in-license intellectual property from various third parties, we are required to pay royalties to the parties on product sales.

Our marketed products, ABIOKLAD(R), AMPHOCIL(R), ELAPRASE(R), ERWINASE(R), INFASURF(R), KIDROLASE(R), MEPIVAMOL(R), METHADONE(R), MORPHINE SULPHATE(R), NALOXONE(R), NALTREXONE(R), ORAMORPH(R), PETHIDINE(R), RAPYDAN(R) and REPLAGAL(R) are covered by trademark and patents by their respective owners.

Trademark protection continues in some countries for as long as the mark is used and, in other countries, for as long as it is registered. Registrations generally are for fixed, but renewable, terms.

The protection of our unpatented confidential and proprietary information and materials is important to us. To protect our trade secrets, materials and other confidential information, we generally require our employees, consultants, scientific advisors, and parties to collaboration and licensing agreements to execute confidentiality agreements upon the commencement of employment, the consulting relationship, or the collaboration or licensing arrangement with us. However, others could either develop independently the same or similar information or obtain access to our information.

PATENT SUMMARY TABLE				TRADEMARK SUMMARY TABLE			
Item	Issued	Pending	Total	Item	Issued	Pending	Total
US Patents	13	21	34	US Trademarks	3	0	3
Foreign Patents	28	76	94	Foreign Trademarks	1	0	1
Total	41	97	128	Total	4	0	4

Our trademarks for our marketed products are not included in the above list, since they are trademarked by our partners. On March 1, 2007, Samaritan announced that we had completed our acquisition of Metastatin Pharmaceuticals, a biopharmaceutical company engaged in the development of cytostatic and anti-metastatic therapies for the management of cancer. As part of the acquisition of Metastatin, Samaritan acquired several patent rights which have been included in the table above.

#### Manufacturing

The Company has no commercial scale manufacturing facilities for our products. For our products that we are developing, we plan to establish relationships with third-party suppliers to manufacture sufficient quantities of our product candidates to undertake clinical trials and to manufacture sufficient quantities of any products that are approved for commercial sale. If we are unable to contract for large-scale manufacturing with third parties on acceptable terms for our future products and are unable to develop manufacturing capabilities internally, our ability to conduct large-scale clinical trials and to meet customer demand for commercial products would be adversely affected. For our products that we have commercial sales for, we purchase the product from our respective partner.

#### Government Regulation

Our pharmaceutical products are subject to extensive government regulation in the United States. If we distribute our products abroad, these products will also be subject to extensive foreign government regulation. In the United States, the FDA regulates pharmaceutical products. FDA regulations govern the testing, manufacturing, advertising, promotion, labeling, sale and distribution of our products.

In general, the FDA approval process for drugs includes, without limitation:

preclinical studies;

submission of an Investigational New Drug Application, or IND, for clinical trials;

adequate and well-controlled human clinical trials to establish the safety and efficacy of the product;

submission of an NDA to obtain marketing approval;

review of the NDA; and

inspection of the facilities used in the manufacturing of the drug to assess compliance with the FDA s current Good Manufacturing Practice, or cGMP, regulations.

The NDA must include comprehensive and complete descriptions of the preclinical testing, clinical trials, and the chemical, manufacturing and control requirements of a drug that enable the FDA to determine the drug safety and efficacy. An NDA must be submitted by Samaritan, and filed and approved by the FDA before any of our drugs can be marketed commercially in the United States.

The FDA testing and approval process requires substantial time, effort and money. We cannot assure that any approval will ever be granted.

Preclinical studies include laboratory evaluation of the product, as well as animal studies to assess the potential safety and effectiveness of the product. These studies must be performed according to good laboratory practices. The results of the preclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of the IND.

Clinical trials may begin 30 days after the IND is received, unless the FDA raises concerns or questions about the conduct of the clinical trials. If concerns or questions are raised, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed.

We cannot assure that submission of an IND will result in authorization to commence clinical trials. Nor can we assure that if clinical trials are approved, that data will result in marketing approval. Clinical trials involve the administration of the product that is the subject of the trial to volunteers or patients under the supervision of a qualified principal investigator. Each clinical trial must be reviewed and approved by an independent institutional review board at each institution at which the study will be conducted. The institutional review board will consider, among other things, ethical factors, safety of human subjects and the possible liability of the institution. Also, clinical trials must be performed according to good clinical practices. Good clinical practices are enumerated in FDA regulations and guidance documents.

Clinical trials typically are conducted in three sequential phases: Phases I, II and III, with Phase IV studies conducted after approval. Drugs for which Phase IV studies are required include those approved under accelerated approval regulations. The four phases may overlap. In Phase I clinical trials, the drug is usually tested on a small number of healthy volunteers to determine:

- safety;
- any adverse effects;
- proper dosage;
- absorption;
- metabolism;
- distribution;
- excretion; and
- other drug effects.

In Phase II clinical trials, the drug is usually tested on a limited number of subjects (generally up to several hundred subjects) to preliminarily evaluate the efficacy of the drug for specific, targeted indications, determine dosage tolerance and optimal dosage, and identify possible adverse effects and safety risks.

In Phase III clinical trials, the drug is usually tested on a larger number of subjects (up to several thousand), in an expanded patient population and at multiple clinical sites. The FDA may require that we suspend clinical trials at any time on various grounds, including if the FDA makes a finding that the subjects are being exposed to an unacceptable health risk.



In Phase IV clinical trials or other post-approval commitments, additional studies and patient follow-up are conducted to gain experience from the treatment of patients in the intended therapeutic indication. Additional studies and follow-up are also conducted to document a clinical benefit where drugs are approved under accelerated approval regulations and based on surrogate endpoints. In clinical trials, surrogate endpoints are alternative measurements of the symptoms of a disease or condition that are substituted for measurements of observable clinical symptoms. Failure to promptly conduct Phase IV clinical trials and follow-up could result in expedited withdrawal of products approved under accelerated approval regulations.

The facilities, procedures, and operations of our contract manufacturers must be determined to be adequate by the FDA before product approval. Manufacturing facilities are subject to inspections by the FDA for compliance with cGMP, licensing specifications, and other FDA regulations before and after an NDA has been approved. Foreign manufacturing facilities are also subject to periodic FDA inspections or inspections by foreign regulatory authorities. Among other things, the FDA may withhold approval of NDAs or other product applications of a facility if deficiencies are found at the facility. Vendors that supply us finished products or components used to manufacture, package and label products are subject to similar regulation and periodic inspections.

Following such inspections, the FDA may issue notices on Form 483 and Warning Letters that could cause the Company to modify certain activities identified during the inspection. A Form 483 notice is generally issued at the conclusion of an FDA inspection and lists conditions the FDA investigators believe may violate cGMP or other FDA regulations. FDA guidelines specify that a Warning Letter be issued only for violations of regulatory significance for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action.

In addition, the FDA imposes a number of complex regulatory requirements on entities that advertise and promote pharmaceuticals, including, but not limited to, standards and regulations for direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet.

Failure to comply with FDA and other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA s review of NDAs, injunctions and criminal prosecution. Any of these actions could have a material adverse effect on us.

For marketing outside the United States, we also are subject to foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. The requirements governing the conduct of clinical trials, product approval, pricing and reimbursement vary widely from country to country. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained before manufacturing or marketing the product in those countries. The approval process varies from country to country and the time required for such approvals may differ substantially from that required for FDA approval. We cannot assure you that clinical trials conducted in one country will be accepted by other countries or that approval in one country will result in approval in any other country. For clinical trials conducted outside the United States, the clinical stages are generally comparable to the phases of clinical development established by the FDA.

In the United States, physicians, hospitals and other healthcare providers that purchase pharmaceutical products generally rely on third-party payers, principally private health insurance plans, Medicare and, to a lesser extent, Medicaid, to reimburse all or part of the cost of the product and procedure for which the product is being used. Even if a product is approved for marketing by the FDA, there is no assurance that third-party payers will cover the cost of the product and related medical procedures. Although they are not required to do so, private health insurers often follow the Medicare program s lead when determining whether or not to reimburse for a drug. To support our applications for reimbursement coverage with Medicare and other major third-party payers, we intend to use data from clinical trials. The lack of satisfactory reimbursement for our drug products would limit their widespread use and lower potential product revenues.

Reimbursement systems in international markets vary significantly by country and, within some countries, by region. Reimbursement approvals must be obtained on a country-by-country basis. In many foreign markets, including markets in which we anticipate selling our products, the pricing of prescription pharmaceuticals is subject to government pricing control. In these markets, once marketing approval is received, pricing negotiations could take another six to twelve months or longer. As in the United States, the lack of satisfactory reimbursement or inadequate government pricing of our products would limit their widespread use and lower potential product revenues.

Federal, state and local laws of general applicability, such as laws regulating working conditions, also govern us. In addition, we are subject to various federal, state and local environmental protection laws and regulations, including those governing the discharge of material into the environment. We do not expect the costs of complying with such environmental provisions to have a material effect on our earnings, cash requirements or competitive position in the foreseeable future.

#### Competition

The biotechnology and pharmaceutical industries are characterized by rapidly evolving technology and intense competition. Our competitors include pharmaceutical, chemical and biotechnology companies, many of which have financial, technical and marketing resources significantly greater than ours. In addition, many specialized biotechnology companies have formed collaborations with large, established companies to support research, development and commercialization of products that may be competitive with ours. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or through collaboration arrangements.

We expect our products to compete primarily on the basis of product efficacy, safety, patient convenience, reliability and patent position. In addition, the first product to reach the market in a therapeutic or preventive area is often at a significant competitive advantage relative to later entrants to the market. Our competitive position will also depend on our ability to attract and retain qualified scientific and other personnel, develop effective proprietary products, implement product and marketing plans, obtain patent protection and secure adequate capital resources.

#### Employees

As of December 31, 2007, we have twenty (20) employees consistent of sixteen (16) full-time employees and four (4) part time employees. Of our employees, sixteen (16) are engaged in pharmaceutical, research, development or sales activities, two (2) are engaged in administration and finance, and two (2) are Information Technology employees. Additionally, Samaritan has eight (8) research professionals (including five (5) Ph.D. level research scientists) who work under the Research Collaboration with The Research Institute of McGill University Health Centre. Further, we make extensive use of another fifteen (15) consultants including Dr. Papadopoulos, our Key Scientific Consultant.

A significant number of our management and professional employees have had experience with pharmaceutical, biotechnology or medical product companies. While we have been successful in attracting skilled and experienced scientific personnel, there can be no assurance that we will be able to attract or retain the necessary qualified employees and/or consultants in the future. None of our employees are covered by collective bargaining agreements and we consider relations with our employees to be good.

#### Available Information

Our website address is www.samaritanpharma.com. The contents of our website are not part of this annual report. We make available on our website our annual reports on Form 10-K, our quarterly reports on Form 10-Q, any current reports on Form 8-K and any amendments to those reports as soon as reasonably practicable after this material is electronically filed with or furnished to the U.S. Securities and Exchange Commission, or SEC. In addition, we provide paper copies of our filings free of charge upon request.

#### **ITEM 1A. RISK FACTORS**

You should carefully consider the risks described below before purchasing our Common Stock. Our most significant risks and uncertainties are described below; however, they are not the only risks we face. If any of the following risks actually occur, our business, financial condition, or results of operations could be materially adversely affected, the trading of our Common Stock could decline, and you may lose all or part of your investment therein. You should acquire shares of our Common Stock only if you can afford to lose your entire investment.

### RISKS ASSOCIATED WITH OUR BUSINESS

### We Have A Limited Operating History With Significant Losses And Expect Losses To Continue In The Near Future

We have yet to establish any history of profitable operations. We have incurred annual operating losses of \$3,025,998 and \$7,572,746 during the years ended December 31, 2007 and 2006 respectively. As a result, at December 31, 2007, we had an accumulated deficit of \$44,335,140. To date, our revenues have not been sufficient to sustain our operations. Our profitability will require the successful commercialization of one or more drugs for our territories in Eastern Europe as well as the out-licensing of our internal development programs in Alzheimer's, cancer, cardiovascular disease, and infectious diseases. Currently, the Company has in-licensed fifteen (15) products to be marketed and distributed in our Eastern Europe territories. No assurances can be given when this will occur or when we will become profitable.

## We Will Need Additional Capital In The Future, But Our Access To Such Capital Is Uncertain.

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Our current resources are insufficient to fund all of our planned development and commercialization efforts. As of December 31, 2007, we have a working capital deficiency and we had cash, cash equivalents, and marketable securities of approximately \$287,571. On March 28, 2007, Samaritan and Pharmaplaz, a private Irish Healthcare company and a shareholder of Samaritan, signed an agreement (the "Pharmaplaz Agreement") to commercialize SP-01A. Under the terms of the agreement, Pharmaplaz is required to pay Samaritan \$10 million upfront. To date, under the Pharmaplaz Agreement, the amount of funds received from Pharmaplaz is \$2.15 million; \$1.4 million and \$750,000 were received during the first and fourth quarter of 2007 respectively. On May 15, 2007, the CEO of Pharmaplaz, Michael Macken, signed a personal guarantee and on May 21, 2007 a stock pledge agreement for 943,291 (split-adjusted) shares of Samaritan Pharmaceuticals to guarantee the balance of the \$7.85 million. On May 15, 2007, the amount of shares pledged was worth \$1,300,742. On December 31, 2007, the last reported market sale price of our Common Stock was \$0.33 and the value of the stock pledge was \$311,286. As a result of Pharmaplaz's failure to timely pay the remaining balance of 7.85 million, Pharmaplaz is not in compliance with the terms of the Pharmaplaz Agreement. Samaritan is currently working with Pharmaplaz to collect the past due remaining balance.

At our current level of expenditures and profits from our sales in Eastern Europe, we believe that our cash resources are not adequate to meet our requirements into 2009. Our capital needs will depend on many factors, including our research and development activities, the scope and timing of our clinical trial programs, the timing of regulatory approval for our products under development and the successful commercialization of our products. Our needs may also depend on the magnitude and scope of these activities, the progress and the level of success in our clinical trials, the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights, competing technological and market developments, changes in or terminations of collaboration and existing licensing arrangements, the establishment of new collaboration and licensing arrangements and the cost of manufacturing scale-up and development of marketing activities, if undertaken by us. We do not have committed external sources of funding. If adequate funds are not available, we may be required to:

- delay, reduce the scope of, or eliminate one or more of our research and development programs;
- obtain funds through arrangements with collaboration partners or others that may require us to relinquish rights to technologies, product candidates or products that we would otherwise seek to retain in order to develop or commercialize them ourselves;
- license rights to technologies, product candidates or products on terms that are less favorable to us than might otherwise be available; or

We intend to actively seek new financing from time to time to provide financial support for our activities. If we raise additional funds by issuing additional stock, further dilution to our stockholders may result, and new investors could have rights superior to existing stockholders. If funding is insufficient at any time in the future, we may be unable to develop or commercialize our products, take advantage of business opportunities or respond to competitive pressures, which could have a material adverse effect on our business.

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# Our Independent Registered Public Accounting Firm Has Issued An Unqualified Opinion With An Explanatory Paragraph, To The Effect That There Is Substantial Doubt About Our Ability To Continue As A Going Concern.

The Company s independent registered public accounting firm has issued an unqualified opinion with an explanatory paragraph, to the effect that there is substantial doubt about the Company s ability to continue as a going concern. This unqualified opinion with an explanatory paragraph could have a material adverse effect on the business, financial condition, results of operations and cash flows of the Company.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in note 2 to the financial statements, the Company has generated minimal revenues and experienced an accumulated deficit of \$44,335,140 through December 31, 2007. For the year ended December 31, 2007 and 2006, the Company incurred net losses of \$3,025,998 and \$7,572,746, respectively and used cash flows from operations of \$1,347,122 and \$6,248,128, respectively. These matters raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are described in note 2. The accompanying financial statements do not include any adjustments relating to the recoverability and classification of asset carrying amounts or the amount and classification of liabilities that might result should the Company be unable to continue as a going concern.

We have no committed sources of capital and do not know whether additional financing will be available when needed on terms that are acceptable, if at all. Our current lack of resources is exacerbated by our inability to date to collect the remaining balance from Pharmaplaz. The addition of this going concern statement from our independent registered public accounting firm may discourage some investors from purchasing our Common Stock or providing alternative capital financing. The failure to satisfy our capital requirements will adversely affect our business, financial condition, results of operations and prospects.

Unless we raise additional funds, either through the sale of equity securities or one or more collaborative arrangements, we will need to reduce our research and development and significantly reduce our workforce and our operating expenses. If we do not take these actions, we will not have sufficient funds to continue operations. Even if we take these actions, they may be insufficient, particularly if our costs are higher than projected or unforeseen expenses arise. Reducing our research and development or significantly reducing our workforce or operating expenses will adversely affect our business and prospects.

#### If We Do Not Receive And Maintain Regulatory Approvals For Our Products Or Product Candidates, We Will Not Be Able To Commercialize Our Products, Which Would Substantially Impair Our Ability To Generate Revenues And Materially Harm Our Business And Financial Condition.

Approval from the FDA is necessary to manufacture and market pharmaceutical products in the United States. The regulatory approval process is extensive, time-consuming and costly, and the FDA may not approve additional product candidates, or the timing of any such approval may not be appropriate for our product launch schedule and other business priorities, which are subject to change.

Clinical testing of pharmaceutical products is also a long, expensive and uncertain process. Even if initial results of preclinical studies or clinical trial results are positive, we may obtain different results in later stages of drug development, including failure to show desired safety and efficacy. The clinical trials of any of our product candidates could be unsuccessful, which would prevent us from obtaining regulatory approval and commercializing the product.

FDA approval of our products can be delayed, limited or not granted for many reasons, including, among others:

- FDA officials may not find a product candidate safe or effective to merit an approval;
- FDA officials may not find that the data from preclinical testing and clinical trials justifies approval, or they may require additional studies that would make it commercially unattractive to continue pursuit of approval;
- the FDA might not approve the processes or facilities of our contract manufacturers or raw material suppliers or our manufacturing processes or facilities;
- the FDA may change its approval policies or adopt new regulations; and
- the FDA may approve a product candidate for indications that are narrow or under conditions that place our product at a competitive disadvantage, which may limit our sales and marketing activities or otherwise adversely impact the commercial potential of a product.

If the FDA does not approve our product candidates in a timely fashion on commercially viable terms or we terminate development of any of our product candidates due to difficulties or delays encountered in clinical testing and the regulatory approval process, it will have a material adverse impact on our business.

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## If Our Products Do Not Gain Market Acceptance, Our Business Will Suffer Because We Might Not Be Able To Fund Future Operations.

A number of factors may affect the market acceptance of our products or any other products we develop or acquire, including, among others:

- the price of our products relative to other therapies for the same or similar treatments;
- the perception by patients, physicians and other members of the health;
- care community of the safety and effectiveness of our products for their prescribed treatments;
- the availability of satisfactory levels, or at all, of third party reimbursement for our products and related treatments;
- our ability to fund our sales and marketing efforts; and
- the effectiveness of our sales and marketing efforts.

In addition, our ability to market and promote our products is restricted to the labels approved by the FDA. If the approved labels are restrictive, our sales and marketing efforts and market acceptance and the commercial potential of our products may be negatively affected.

If our products do not gain market acceptance, we may not be able to fund future operations, including the development or acquisition of new product candidates and/or our sales and marketing efforts for our approved products, which would cause our business to suffer.

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#### If We Fail To Properly Manage Our Anticipated Growth, Our Business Could Suffer.

Rapid growth of our business is likely to place a significant strain on our managerial, operational and financial resources and systems. To manage our anticipated growth successfully, we must attract and retain qualified personnel and manage and train them effectively. We are dependent on our personnel and third parties to effectively manufacture, market, sell and distribute our products. We will also continue to depend on our personnel and third parties to successfully develop and acquire new products. Further, our anticipated growth will place additional strain on our suppliers and manufacturers, resulting in increased need for us to carefully manage these relationships and monitor for quality assurance. Although we may not grow as we expect, if we fail to manage our growth effectively or to develop and expand a successful commercial infrastructure to support marketing and sales of our products, our business and financial results will be materially harmed. In addition, we have certain raw materials manufactured in foreign countries. We may also elect in the future to market certain of our products, and perhaps have certain of our products or certain additional raw materials manufactured, in foreign countries. Many other countries, including the countries where the Company currently markets products have similar requirements as the United States for the manufacture, marketing, and sale of pharmaceutical products.

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#### The Company's License Agreements May Be Terminated In The Event Of A Breach

The license agreements pursuant to which the Company has licensed its core technologies for its potential drug products permit the licensors to terminate such agreements under certain circumstances, such as the failure by the licensee to use its reasonable best efforts to commercialize the subject drug or the occurrence of any uncured material breach by the licensee. The license agreements also provide that the licensor is primarily responsible for obtaining patent protection for the licensed technology, and the licensee is required to reimburse the licensor for costs it incurs in performing these activities. The license agreements also require the payment of specified royalties. Any inability or failure to observe these terms or pay these costs or royalties may result in the termination of the applicable license agreement in certain cases. The termination of any license agreement could force us to curtail our business operations. As of April 11, 2008, Samaritan Pharmaceuticals and Samaritan Therapeutics' payment to McGill University is in arrears, which may permit our collaborator to terminate the research and development agreement. The termination of any license agreement could force us to curtail our business operations. As of the April 11, 2008, Samaritan Pharmaceuticals and Samaritan Therapeutics' payment to McGill University is in arrears, which may permit our collaborator to terminate the research and development agreement. The termination of any license agreement could force us to curtail our business operations. As of the April 11, 2008, Samaritan Pharmaceuticals and Samaritan Therapeutics' payment to McGill University is in arrears, which may permit our collaborator to terminate the research and development agreement. Currently, all parties are in discussion to bring the balance in arrears current.

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#### Protecting Our Proprietary Rights Is Difficult and Costly

The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. The license agreements also provide that the licensor is primarily responsible for obtaining patent protection for the licensed technology, and the licensee is required to reimburse the licensor for costs it incurs in performing these activities. Accordingly, we cannot predict the breadth of claims allowed in these companies' patents or whether the Company may infringe or be infringing on these claims. Patent disputes are common and could preclude the commercialization of our products. Patent litigation is costly in its own right and could subject us to significant liabilities to third parties. In addition, an adverse decision could force us to either obtain third-party licenses at a material cost or cease using the technology or product in dispute.

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# The Company's Success Will Be Dependent Upon The Licenses And Proprietary Rights It Receives From Other Parties, And On Any Patents It May Obtain

The Company and Samaritan Therapeutics Canada, have signed a Research Collaboration and Licensing Agreement with The Research Institute of McGill University Health Centre (RI-MUHC) in Montreal, Canada, to advance its promising pipeline into clinical trial status and develop new innovative drug candidates. Once drug candidates, derived from the collaborative research, are clinically-validated and deemed to hold promise, Samaritan Therapeutics will continue to develop the drug candidate in Canada, while Samaritan Pharmaceuticals will focus on the drug candidate's process through regulatory agencies and its commercialization throughout the rest of the world.

Our success will depend in large part on the ability of the Company and its licensors to (a) maintain license and patent protection with respect to their drug products, (b) defend patents and licenses once obtained, (c) maintain trade secrets, (d) operate without infringing upon the patents and proprietary rights of others and (e) obtain appropriate licenses to patents or proprietary rights held by third parties if infringement should otherwise occur, both in the United States and in foreign countries. We have obtained licenses to patents and other proprietary rights from Georgetown University and George Washington University.

The patent positions of pharmaceutical companies, including those of the Company, are uncertain and involve complex legal and factual questions. There is no guarantee the Company or its licensors have or will develop or obtain the rights to products or processes that are patentable, that patents will issue from any of the pending applications or that claims allowed will be sufficient to protect the technology licensed to the Company. In addition, we cannot be certain that any patents issued to or licensed by the Company will not be challenged, invalidated, infringed or circumvented, or that the rights granted thereunder will provide competitive advantages to the Company.

Litigation, which could result in substantial cost, may also be necessary to enforce any patents to which the Company has rights, or to determine the scope, validity and unenforceability of other parties' proprietary rights, which may affect the rights of the Company. U.S. patents carry a presumption of validity and generally can be invalidated only through clear and convincing evidence. There can be no assurance that our licensed patents would be held valid by a court or administrative body or an alleged infringer would be found to be infringing. The mere uncertainty resulting from the institution and continuation of any technology-related litigation or interference proceeding could have an adverse material effect on the Company pending resolution of the disputed matters.

We may also rely on unpatented trade secrets and expertise to maintain a competitive position, which we seek to protect, in part, by confidentiality agreements with employees, consultants and others. There can be no assurance these agreements will not be breached or terminated, that we will have adequate remedies for any breach or that trade secrets will not otherwise become known or be independently discovered by competitors.

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#### We Are Faced With Intense Competition And Industry Changes, Which May Make It More Difficult For Us To Achieve Significant Market Penetration.

The pharmaceutical and biotech industry generally is characterized by rapid technological change, changing customer needs, and frequent new product introductions. If our competitors' existing products or new products are more effective than or considered superior to our products, the commercial opportunity for our products will be reduced or eliminated. We face intense competition from companies in our marketplace as well as companies offering other treatment options. Many of our potential competitors are significantly larger than we are and have greater financial, technical, research, marketing, sales, distribution and other resources than we do. We believe there will be intense price competition for products developed in our markets. Our competitors may develop or market technologies and products that are more effective or commercially attractive than any that we are developing or marketing. Our competitors may obtain regulatory approval, and introduce and commercialize products before we do. These developments could force us to curtail or cease our business operations. Even if we are able to compete successfully, we may not be able to do so in a profitable manner.

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#### If We Are Unable To Continue Product Development, Our Business Will Suffer

Our growth depends in part on a continued ability to successfully develop our products. We may experience difficulties that could delay or prevent the successf