Protalix BioTherapeutics, Inc.
Form S-3
July 24, 2007
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As filed with the Securities and Exchange Commission on July 24, 2007

Registration No. 333-

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

FORM S-3
REGISTRATION STATEMENT Under THE SECURITIES ACT OF 1933

Protalix BioTherapeutics, Inc.

(Exact name of registrant as specified in its Charter)

Florida	65-0643773
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

2 Snunit Street
Science Park
POB 455
Carmiel, Israel
972-4-988-9488

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

CT Corporation System
111 Eighth Avenue
New York, NY 10011
Tel: (212) 894-8400

(Name, address, including zip code, and telephone number, including area code, of agent for service)

With a Copy to:

James R. Tanenbaum, Esq.
Morrison & Foerster LLP
1290 Avenue of the Americas
New York, New York 10104
(212) 468-8000

Approximate date of commencement of proposed sale to the public:
From time to time after the effective date of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered	Proposed maximum aggregate offering price per share	Proposed maximum aggregate offering price	Amount of registration fee[1]
Common stock, par value $0.001 per share	[2]	[3]	$200,000,000	$6,140

(1) Calculated pursuant to Rule 457(o) of the Securities Act of 1933, as amended, based on the maximum aggregate offering price.

(2) There are being registered hereunder such indeterminate number of shares of common stock as shall have an aggregate initial offering price not to exceed $200,000,000. In addition, pursuant to Rule 416 under the Securities Act of 1933, as amended, the shares being registered hereunder include such indeterminate number of shares of common stock as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transactions.

(3) The proposed maximum aggregate offering price per share of common stock will be determined from time to time by the registrant in connection with the issuance by the registrant of the common stock registered hereunder.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment that specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this Registration Statement shall become effective on such date as the Commission, acting pursuant to said

Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. Neither we nor any securityholder may sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated July 24, 2007

PROSPECTUS

$200,000,000

PROTALIX BIOTHERAPEUTICS, INC.

Common Stock

We or selling securityholders may, from time to time, offer to sell common stock. Each time we or a selling securityholder sells securities pursuant to this prospectus, we will provide a supplement to this prospectus that contains specific information about the offering and the specific terms of the securities offered. You should read this prospectus and the applicable prospectus supplement carefully before you invest in our securities.

We or selling securityholders may, from time to time, offer to sell the common stock through public or private transactions, directly or through underwriters, agents or dealers, on or off the American Stock Exchange, or the AMEX, at prevailing market prices or at privately negotiated prices. If any underwriters, agents or dealers are involved in the sale of any of these securities, the applicable prospectus supplement will set forth the names of the underwriter, agent or dealer and any applicable fees, commissions or discounts.

To the extent that any selling securityholder resells any securities, the selling securityholder may be required to provide you with this prospectus and a prospectus supplement identifying and containing specific information about the selling securityholder and the terms of the securities being offered.

Our common stock is traded on the AMEX under the symbol ‘‘PLX.’’

Our securities may not be sold without delivery of the applicable prospectus supplement describing the method and terms of the offering of such offered securities.

Investing in our common stock involves a high degree of risk. You should read and consider carefully the risk factors beginning on page 3 of this prospectus, in the applicable prospectus supplement and in the documents incorporated by reference into this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of

these securities, or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this Prospectus is , 2007.

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FORWARD-LOOKING STATEMENTS

The statements set forth and incorporated by reference in this prospectus, which are not historical, constitute ‘‘forward looking statements’’ within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding the expectations, beliefs, intentions or strategies for the future. When used in this prospectus, the terms ‘‘anticipate,’’ ‘‘believe,’’ ‘‘estimate,’’ ‘‘expect’’ and ‘‘inter words or phrases of similar import, as they relate to us, our subsidiary or our management, are intended to identify forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the Statement is made or to reflect the occurrence of unanticipated events, except as may be required under applicable law. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

Examples of the risks and uncertainties include, but are not limited to, the following:

- the inherent risks and uncertainties in developing drug platforms and products of the type we are developing;
- delays in our preparation and filing of applications for regulatory approval;
- delays in the approval or potential rejection of any applications we file with the FDA, or other regulatory authorities;
- any lack of progress of our research and development (including the results of clinical trials being conducted by us);
- obtaining on a timely basis sufficient patient enrollment in our clinical trials;
- the impact of development of competing therapies and/or technologies by other companies;
- our ability to obtain additional financing required to fund our research programs;
- the risk that we will not be able to develop a successful sales and marketing organization in a timely manner, if at all;
- our ability to establish and maintain strategic license, collaboration and distribution arrangements and to manage our relationships with collaborators, distributors and partners;
- potential product liability risks and risks of securing adequate levels of product liability and clinical trial insurance coverage;
- the availability of reimbursement to patients from health care payors for procedures in which our products are used;
- the possibility of infringing a third party's patents or other intellectual property rights;
- the uncertainty of obtaining patents covering our products and processes and in successfully enforcing them against third parties; and
- the possible disruption of our operations due to terrorist activities and armed conflict, including as a result of the disruption of the operations of regulatory authorities, our subsidiary, our manufacturing facilities and our customers, suppliers, distributors, collaborative partners, licensees and clinical trial sites.

In addition, companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. These and other risks and uncertainties are detailed under the heading ''Risk Factors'' herein and in our filings with the Securities and Exchange Commission incorporated by reference in this prospectus. We undertake no obligation to update, and we do not have a policy of updating or revising, these forward-looking statements.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, the Commission, using a ''shelf'' registration, or continuous offering process.

Each time that we or our securityholders sell any securities under this prospectus, we will provide a prospectus supplement that will contain specific information about the terms of that offering and certain other offering-specific information. The prospectus supplement also may add, update or change information contained in this prospectus. Any statement that we make in this prospectus will be modified or superseded by any inconsistent statement made by us in a prospectus supplement.

The registration statement we filed with the Commission includes exhibits that provide more detail on descriptions of the matters discussed in this prospectus. You should carefully read this prospectus, the related exhibits filed with the Commission and the applicable prospectus supplement together with the additional information described under the heading ‘‘Where You Can Find More Information’’ in this prospectus. You should not assume that the information in this prospectus, the prospectus supplement or any documents incorporated by reference is accurate as of any date other than the date of the applicable document.

You should rely only on the information incorporated by reference or provided in this prospectus and any prospectus supplement. We have not authorized anyone to provide you with different information.

This prospectus, and any prospectus supplement issued in relation to it, contain our trademarks and trademarks of our affiliates, and may contain trademarks, tradenames and service marks of other parties. Unless we indicate otherwise, references in this prospectus to ‘‘our company,’’ ‘‘we,’’ ‘‘our,’’ and ‘‘us’’ refer to Protalix BioTherapeutics, Inc. and our whol owned subsidiary, Protalix Ltd., an Israeli corporation.

ProCellEx™ is our trademark. Each of the other trademarks appearing in this prospectus belongs to its respective holder.

Our principal business address is 2 Snunit Street, Science Park, POB 455, Carmiel, Israel 20100, where we maintain our principal operations, including our research and development activities and our manufacturing facility. Our phone number is +972-4-988-9488. Our wholly-owned subsidiary and sole operating unit, Protalix Ltd., is an Israeli corporation. On December 31, 2006, we acquired, through a merger with our wholly-owned subsidiary, Protalix Acquisition Co. Ltd., all of the outstanding shares of Protalix Ltd., in exchange for shares of our common stock, par value $0.001 per share. As a result, Protalix Ltd. is now our wholly-owned subsidiary, with the former shareholders of Protalix Ltd. acquiring in excess of 99% of our outstanding shares of common stock. In connection with the merger, we effected a one-for-ten reverse stock split and on February 26, 2007, we changed our name to Protalix BioTherapeutics, Inc. Unless otherwise indicated, all share numbers in this prospectus give effect to such reverse stock split. On March 12, 2007, our shares of common stock were listed on the American Stock Exchange.

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Summary of Business

We are a clinical stage biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins based on our proprietary ProCellEx™ protein expression system. Using our ProCellEx system, we are developing a pipeline of proprietary recombinant therapeutic proteins based on our plant cell-based expression technology that target large, established pharmaceutical markets and that rely upon known biological mechanisms of action. Our initial commercial focus has been on complex therapeutic proteins, including proteins for the treatment of genetic disorders, such as Gaucher disease and Fabry disease, and female infertility disorders. We believe our ProCellEx protein expression system will enable us to develop proprietary recombinant proteins that are therapeutically equivalent or superior to existing recombinant proteins currently marketed for the same indications. Because we are targeting biologically equivalent versions of highly active, well-tolerated and commercially successful therapeutic proteins, we believe our development process is associated with relatively less risk compared to other biopharmaceutical development processes for novel therapeutic proteins.

Our lead product development candidate is prGCD for the treatment of Gaucher disease, which we are developing using our ProCellEx protein expression system. We have received approval from the United States Food and Drug Administration, the FDA, in April 2007 to commence a phase III clinical trial of prGCD. In July 2007, we reached an agreement with the FDA on the final design of our pivotal phase III clinical trial for prGCD through the FDA’s special

protocol assessment process. We expect to initiate enrollment of patients in our phase III clinical trials in the third quarter of 2007. prGCD is our proprietary recombinant form of Glucocerebrosidase (GCD), an enzyme naturally found in human cells that is mutated or deficient in patients with Gaucher disease. The current standard of care for Gaucher disease is enzyme replacement therapy, a medical treatment in which GCD is replaced for patients in whom the enzyme is lacking or dysfunctional. Although Gaucher is a relatively rare disease, it represents a large commercial market due to the severity of the symptoms and the chronic nature of the disease. The annual worldwide sales of Cerezyme®, an enzyme replacement therapy produced by Genzyme Corporation and currently the only approved enzyme replacement therapy for Gaucher disease, were approximately $1 billion in 2006, according to public reports by Genzyme. prGCD is a plant cell expressed version of the GCD enzyme, developed through our ProCellEx protein expression system. prGCD has an amino acid, glycan and three-dimensional structure that is very similar to its naturally-produced counterpart as well as to Cerezyme, the mammalian cell expressed version of the same protein. We believe prGCD may prove more cost-effective than the currently marketed alternative due to the cost benefits of expression through our ProCellEx system. In addition, based on our laboratory testing, preclinical and clinical results, we believe that prGCD may have the potential for increased potency and efficacy as compared to the existing enzyme replacement therapy for Gaucher disease which may translate into lower dosages and/or less frequent treatments.

In addition to prGCD, we are developing an innovative product pipeline using our ProCellEx protein expression system, including therapeutic protein candidates for the treatment of Fabry disease and female infertility disorders. We plan to file an investigational new drug application (IND) with the FDA with respect to at least one additional product during 2008. Because these product candidates are based on well-understood proteins with known biological mechanisms of action, we believe we may be able to reduce the development risks and time to market for such product candidates. We hold the worldwide commercialization rights to our proprietary development candidates and we intend to establish an internal, commercial infrastructure and targeted sales force to market prGCD and our other products, if approved, in North America, the European Union and in other significant markets, including Israel.

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RISK FACTORS

Investment in our securities involves a high degree of risk. Our business, financial condition or results of operations could be adversely affected by any of these risks. If any of these risks occur, the value our common stock and our other securities may decline. You should carefully consider the risk factors discussed in this section, as well as the discussion set forth under the caption ‘‘Risk Factors’’ in our Annual Report on Form 10-K for the fiscal year ended December 31, 2006, as amended, in any other filing we make with the Commission subsequent to the date of this prospectus, each of which are incorporated herein by reference, and in any supplement to this prospectus, before making your investment decision.

Risks Related to this Offering

If we effect an underwritten offering of our common stock, we may offer the shares of our common stock at a significant discount to the market price which could cause a decline in our stock price.

We effected a reverse merger on December 31, 2006. Therefore, all quoted sales prices of our common stock through December 31, 2006 did not fully reflect the value attributable to our current operations of Protalix Ltd. Further, the trading volume for the common stock throughout 2006 was very small and trades were infrequent. This is common for a shell company that has no business operations. Under such circumstances, a small sales volume can have a

disproportionate impact on sales price, a strong indication that the share price did not reflect true market valuation. Trading volume and trade frequency since December 31, 2006 also does not provide a guide to determining fair value of our common stock because, to date, more than 99% of the shares of our common stock are not registered with the Commission and are not available for sale in the public market, the number of trades in the public market have been infrequent and the average daily volume continues to be very low. In the event that we elect to pursue an underwritten offering of our common stock, the common stock may be offered at a price that reflects a substantial discount to the market price of the common stock at the time of sale. The offer or sale of shares of common stock at a discount to the reported market price may cause a decline in the market price of our common stock, which may have a material adverse effect on the trading market for our common stock.

We will have broad discretion in how we use the proceeds of any offering we conduct under this prospectus and we may not apply the proceeds to uses that will benefit stockholders.

We will retain broad discretion over the use of the net proceeds of any securities offered by us hereby, and you will be relying on the judgment of our Board of Directors and management regarding the application of these proceeds. Although we expect to use the net proceeds from this offering for research and development expenses, clinical trials, establishing an internal sales force and general corporate and administrative purposes, we have not allocated these net proceeds for specific purposes other than to pay for certain expenses related to the construction and furnishing of a new manufacturing facility. It is possible that a substantial portion of the net proceeds will be invested in a way that does not yield a favorable, or any, return for us.

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USE OF PROCEEDS

We will retain broad discretion over the use of the net proceeds of the securities offered by us hereby. Unless the applicable prospectus supplement states otherwise, the net proceeds from the securities sold by us will be added to our general corporate funds and may be used for research and development expenses, clinical trials, establishing an internal sales force and general corporate and administrative purposes. We expect to use a portion of the proceeds of any offering by us in connection with the construction and furnishing of a new manufacturing facility. Until the net proceeds have been used, they will be invested in short-term marketable securities. If we elect at the time of the issuance of the securities to make different or more specific use of proceeds other than as described in this prospectus, the change in use of proceeds will be described in the applicable prospectus supplement.

We will not receive any proceeds from the sale of securities by any selling securityholder.

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PLAN OF DISTRIBUTION

We, or any selling securityholders, may sell the securities offered under this prospectus:

- through underwriters, which may include, but not be limited to, UBS Securities LLC, Citigroup Global Markets Inc. and CIBC World Markets Corp.;
- through dealers;
- through agents; or
- directly to purchasers.

Each prospectus supplement relating to an offering of securities will state the terms of the offering, including:

- the names of any underwriters, dealers, or agents;
- the public offering or purchase price of the offered securities and the net proceeds that we will receive from the sale;
- any underwriting discounts and commissions or other items constituting underwriters' compensation;
- any discounts, commissions, or fees allowed or paid to dealers or agents; and
- any securities exchange on which the offered securities may be listed.

Distribution Through Underwriters

We, or any selling securityholders, may offer and sell securities from time to time to one or more underwriters who would purchase the securities as principal for resale to the public, either on a firm commitment or best efforts basis. If we, or the selling securityholders, sell securities to underwriters, we, and/or the selling securityholders, as applicable, will execute an underwriting agreement with the underwriters at the time of the sale and will name them in the applicable prospectus supplement. In connection with these sales, the underwriters may be deemed to have received compensation from us, and/or the selling securityholders, as applicable, in the form of underwriting discounts and commissions. The underwriters also may receive commissions from purchasers of securities for whom they may act as agent. Unless we, or the selling securityholders, specify otherwise in the applicable prospectus supplement, the underwriters will not be obligated to purchase the securities unless the conditions set forth in the underwriting agreement are satisfied, and if the underwriters purchase any of the securities, they will be required to purchase all of the offered securities. The underwriters may acquire the securities for their own account and may resell the securities from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or varying prices determined at the time of sale. The underwriters may sell the offered securities to or through dealers, and those dealers may receive discounts, concessions, or commissions from the underwriters as well as from the purchasers for whom they may act as agent. Any initial public offering price and any discounts or concessions allowed or reallowed or paid to dealers may be changed from time to time.

Distribution Through Dealers

We, or any selling securityholders, may offer and sell securities from time to time to one or more dealers who would purchase the securities as principal. The dealers then may resell the offered securities to the public at fixed or varying prices to be determined by those dealers at the time of resale. We, or the selling securityholders, will set forth the names of the dealers and the terms of the transaction in the applicable prospectus supplement.

Distribution Through Agents

We, or any selling securityholders, may offer and sell securities on a continuous basis through agents that become parties to an underwriting or distribution agreement. We, or the selling securityholders, will name any agent involved in the offer and sale and describe any commissions

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payable by us in the applicable prospectus supplement. Unless we specify otherwise in the applicable prospectus supplement, the agent will be acting on a best efforts basis during the appointment period.

Direct Sales

We, or any selling securityholders, may sell directly to, and solicit offers from, institutional investors or others who may be deemed to be underwriters, as defined in the Securities Act of 1933, as amended (the ‘‘Securities Act’’), for any resale of the securities. We, or the selling securityholders, will describe the terms of any sales of this kind in the applicable prospectus supplement.

General Information

Underwriters, dealers, or agents participating in an offering of securities may be deemed to be underwriters, and any discounts and commissions received by them and any profit realized by them on resale of the offered securities for whom they act as agent, may be deemed to be underwriting discounts and commissions under the Securities Act.

We, or any selling securityholders, may offer to sell securities either at a fixed price or at prices that may vary, at market prices prevailing at the time of sale, at prices related to prevailing market prices, or at negotiated prices. Securities may be sold in connection with a remarketing after their purchase by one or more firms including our affiliates, acting as principal for their own accounts or as our agent.

In connection with an underwritten offering of securities, the underwriters may engage in over-allotment, stabilizing transactions, and syndicate covering transactions in accordance with Regulation M under the Exchange Act. Over-allotment involves sales in excess of the offering size, which creates a short position for the underwriters. The underwriters may enter bids for, and purchase, securities in the open market in order to stabilize the price of the securities. Syndicate covering transactions involve purchases of the securities in the open market after the distribution has been completed in order to cover short positions. In addition, the underwriting syndicate may reclaim selling concessions allowed to an underwriter or a dealer for distributing the securities in the offering if the syndicate repurchases previously distributed securities in transactions to cover syndicate short positions, in stabilization transactions, or otherwise. These activities may cause the price of the securities to be higher than it would otherwise be. Those activities, if commenced, may be discontinued at any time.

Ordinarily, each issue of securities will be a new issue, and there will be no established trading market for any security other than our common stock prior to its original issue date. We may not list any particular series of securities on a securities exchange or quotation system. Any underwriters to whom or agents through whom the offered securities are sold for offering and sale may make a market in the offered securities. However, any underwriters or agents that make a market will not be obligated to do so and may stop doing so at any time without notice. We cannot assure you that there will be a liquid trading market for the offered securities.

Under agreements entered into with us, underwriters and agents may be entitled to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, or to contribution for payments the underwriters or agents may be required to make.

In compliance with the guidelines of the National Association of Securities Dealers, Inc., or the NASD, the maximum commission or discount to be received by any NASD member or independent broker-dealer may not exceed 8% of the initial gross proceeds from the sale of any security being sold.