

ORAMED PHARMACEUTICALS INC.  
Form 10QSB  
January 22, 2007  
UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

**FORM 10-QSB**

QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the quarterly period ended November 30, 2006

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-50298

**Oramed Pharmaceuticals Inc.**  
(Exact name of small business issuer as specified in its charter)

**Nevada**  
(State or other jurisdiction of incorporation or organization)

**98-0376008**  
(I.R.S. Employer Identification No.)

**2 Elza Street, Jerusalem, Israel 93706**  
(Address of principal executive offices)

**011 972-54-7909058**  
(Issuer's telephone number)

**N/A**  
(Former name, former address and former fiscal year, if changed since last report)

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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  No

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

**APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY**

**PROCEEDINGS DURING THE PRECEDING FIVE YEARS**

Check whether the registrant filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Exchange Act after the distribution of securities under a plan confirmed by a court. Yes  No

**APPLICABLE ONLY TO CORPORATE ISSUERS**

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date:

**41,581,779 common shares issued and outstanding as at January 18, 2007**

Transitional Small Business Disclosure Format (Check one): Yes  No

**PART I**

**Item 1. Financial Statements**

Our financial statements are stated in United States Dollars (US\$) and are prepared in accordance with United States Generally Accepted Accounting Principles.

**ORAMED PHARMACEUTICALS, INC.***(A Development Stage Company)***BALANCE SHEETS**

(unaudited)

	<b>30-Nov-06</b>	<b>31-Aug-06</b>
<b>ASSETS</b>		
Cash	\$ 72,300	\$ 176,190
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities		
Accounts payable and accrued expenses	\$ 12,412	\$ 53,652
Due to shareholder	47,252	47,252
Stock payable	508,005	508,005
Total current liabilities	567,669	608,909
Stockholders' deficit		
Common stock:		
Authorized: 200,000,000 with \$0.001 par value		
41,456,779 issued and outstanding	41,456	41,456
Additional paid-in capital	783,093	768,749
Accumulated comprehensive loss: foreign currency	(16)	(16)
Deficit accumulated during the development stage	(1,319,902)	(1,242,908)
Total stockholders' deficit	(495,369)	(432,719)
Total liabilities and stockholders' deficit	\$ 72,300	\$ 176,190

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**ORAMED PHARMACEUTICALS, INC.***(A Development Stage Company)***STATEMENTS OF EXPENSES**

Three months ended November 30, 2006 and 2005, and the period from April 12, 2002 (Inception) through November 30, 2006  
(unaudited)

	<b>Three Months Ended</b>		<b>Inception</b>
	<b>2006</b>	<b>2005</b>	<b>Through</b>
			<b>2006</b>
General and administrative	\$ 47,990	\$ 4,987	\$ 655,608
Research and development	28,062	-	225,810
Loss on impairment	-	-	434,876
Interest income	-	-	(1,991)
Interest	942	675	5,599
Net loss	(76,994)	(5,662)	(1,319,902)
Other comprehensive loss	-	-	(16)
Total comprehensive loss	\$ (76,994)	\$ (5,662)	\$ (1,319,918)
Basic and diluted loss per common share	\$ (0.00)	\$ (0.00)	
Basic and diluted weighted average shares outstanding	41,456,779	18,475,551	

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**ORAMED PHARMACEUTICALS, INC.**

(A Development Stage Company)

**STATEMENTS OF CASH FLOWS**

Three months ended November 30, 2006 and 2005, and the period from April 12, 2002 (Inception) through November 30, 2006

(unaudited)

	2006	2005	Inception through 2006
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
Net loss	\$ (76,994)	\$ (5,662)	\$ (1,319,902)
Adjustments to reconcile net loss to net cash used in operating activities:			
Loss on impairment from investment	-	-	434,876
Stock based compensation	13,402	-	13,402
Imputed interest	942	675	5,599
Changes in operating assets and liabilities:			
Prepaid expenses	-	1,260	-
Accounts payable and accrued expenses	(41,240)	(1,635)	12,412
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(103,890)</b>	<b>(5,362)</b>	<b>(853,613)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Proceeds from sales of common stock	-	-	859,686
Proceeds from short term loan	-	-	100,000
Repayment of short term loan	-	-	(100,000)
Due to/ from shareholder	-	5,362	66,243
<b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>	<b>-</b>	<b>5,362</b>	<b>925,929</b>
Effect of exchange rate on cash			(16)
<b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>	<b>(103,890)</b>	<b>-</b>	<b>72,300</b>
<b>CASH AT BEGINNING OF PERIOD</b>	<b>176,190</b>	<b>-</b>	<b>-</b>
<b>CASH AT END OF PERIOD</b>	<b>\$ 72,300</b>	<b>\$ -</b>	<b>\$ 72,300</b>
Non-cash transactions: forgiveness of debt	\$ -	\$ -	\$ 18,991

**ORAMED PHARMACEUTICALS, Inc.**

**(formerly Integrated Securities Technologies, Inc.)**

**(A development stage company)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**November 30, 2006**

**(UNAUDITED)**

**1. BASIS OF PRESENTATION**

The accompanying unaudited interim consolidated financial statements of Oramed Pharmaceuticals, Inc. have been prepared in accordance with accounting principles generally accepted in the United States of America and the rules of the Securities and Exchange Commission, and should be read in conjunction with the audited consolidated financial statements and notes thereto contained in Oramed's Annual Report filed with the SEC on Form 10-KSB. In the opinion of management, all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of financial position and the results of operations for the interim periods presented have been reflected herein. The results of operations for the interim periods are not necessarily indicative of the results to be expected for the full year. Notes to the financial statements which would substantially duplicate the disclosure contained in the audited consolidated financial statements for fiscal 2006 as reported in the 10-KSB have been omitted.

**2. STOCK OPTIONS**

In November 2006, Oramed granted 750,000 options to two directors valued at \$321,647 exercisable at \$0.76 with a term of 3 years. The options vest monthly until November 2007. The options were valued using a Black-Scholes model with an expected term of 1.77 years, expected volatility of 115% and a risk free rate of 4.74%. \$13,402 was expensed during the three months ended November 30, 2006 related to these options.

**3. SUBSEQUENT EVENT**

In December 2006, Oramed borrowed \$20,000 from a third party at 0% interest, due in one year and unsecured.

In December 2006, Oramed issued 125,000 shares of common stock valued at \$97,500 for services.



**Item 2. Management's Discussion and Analysis and Plan of Operation.**

**FORWARD-LOOKING STATEMENTS**

This quarterly report contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as *may*, *should*, *expects*, *plans*, *anticipates*, *believes*, *estimates*, *predicts*, *potential* or *continue* or the negative or other comparable terminology. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks in the section entitled *Risk Factors*, that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements.

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. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to actual results.

Our financial statements are stated in United States Dollars (US\$) and are prepared in accordance with United States Generally Accepted Accounting Principles. In this quarterly report, unless otherwise specified, all dollar amounts are expressed in United States dollars. All references to *CDN\$* refer to Canadian dollars and all references to *common shares* refer to the common shares in our capital stock.

As used in this quarterly report, the terms *we*, *us*, *our*, and *Oramed* means Oramed Pharmaceuticals Inc., unless otherwise indicated.

**General**

***Corporate Overview***

We were incorporated on April 12, 2002, under the laws of the State of Nevada. From incorporation until March 3, 2006, we were an exploration stage company engaged in the acquisition and exploration of mineral properties. We were unsuccessful in that endeavour and have now become a pharmaceutical research and development company.

Effective April 10, 2006, we changed our name from *Integrated Security Technologies, Inc.* to *Oramed Pharmaceuticals Inc.* when we merged with our newly formed subsidiary, *Oramed Pharmaceuticals Inc.* The board of directors also adopted the Bylaws of the subsidiary, *Oramed Pharmaceuticals Inc.*

***Our Current Business***

On February 17, 2006, we entered into an agreement with Hadasit Medical Services and Development Ltd. to acquire the provisional patent application No. 60/718716 and engage in the research and development of a method to administer insulin orally. On March 8, 2006 we completed the purchase of this provisional patent application No. 60/718716, including related intellectual property from Hadasit. The provisional patent application No. 60/718716 relates to a method of preparing insulin so that it may be taken orally for use in the treatment of people with diabetes. Pursuant to the agreement, we are entitled to ask Hadasit to provide us with consulting services so that clinical trials, including a full report, on our potential oral insulin product may be conducted. We have agreed to provide \$200,000 for the conduct of those consulting services. We will pay the \$200,000 to Hadasit if we choose to obtain such services from Hadasit.

We have also agreed to secure proper conditions for the future development of the potential oral insulin product. To obtain the money to do so, we promise to raise at least \$1,000,000 in a private place of units of our securities. The patent application No. 60/718716 was a provisional application. On August 31, 2006, we filed a patent application under the Patent Cooperation Treaty at the Israel Patent Office for *Methods and Compositions for Oral Administration of Proteins*. Priority was claimed from the provisional patent application No. 60/718716. All



countries were designated and the United States Patent and Trademark Office was designated as the Search and Examination Authority.

We plan to conduct clinical trials of our oral insulin products very shortly and commission a clinical trial report. If the clinical trial report concludes that our clinical trials are not successful, we agree to return the intellectual property covered by provisional patent application No. 60/718716 to Hadasit without any representations or warranties. If the clinical trial report concludes that our clinical trials are successful but if we do not complete our private placement of \$1,000,000 within 120 days from the date the clinical trial report is delivered to us, we also agree to return the intellectual property covered by provisional patent application No. 60/718716 to Hadasit without any representations or warranties.

By acquiring the provisional patent application No. 60/718716, we became a pharmaceutical research and development company engaged in the development of a form of insulin that can be administered orally. Our first project will be to conduct research and development on the method described in the provisional patent application. A form of insulin that is effective when taken orally in pill form is not currently available on the market.

On August 31, 2006, we filed a patent application under the Patent Cooperation Treaty at the Israel Patent Office for *Methods and Compositions for Oral Administration of Proteins*. Priority was claimed from the provisional patent application No. 60/718716. We intend to conduct clinical trials of our potential oral insulin product for the next six months. To date, we have not begun our planned trials of the product and we have not generated sales of any products.

On October 26, 2006, we entered into an agreement whereby Swiss Caps Ag has agreed to manufacture oral gel capsules for clinical testing of our oral insulin project.

#### ***Business Operations***

For the next twelve months, we plan to conduct further research and development on the technology covered by the patent application *Methods and Composition for Oral Administration of Proteins*, which we acquired from Hadasit. Through our research and development efforts, we intend to develop a pill that will not break down in the stomach or intestines and will be effective in delivering insulin to the bloodstream for the treatment of diabetes. The enzymes and compounds that are added to the insulin to make the pill must not change the composition of the insulin once it is absorbed into the bloodstream and the pill must be safe to ingest.

#### ***Governmental Approval and Effect of Regulations***

Our operations and the product that we have under development are subject to extensive regulation by the Food and Drug Administration (hereinafter referred to as the FDA), other governmental authorities in the United States and governmental authorities in other countries.

The duration of the governmental approval process for marketing new pharmaceutical substances, from the commencement of preclinical testing to the receipt of governmental approval for marketing a new product, varies with the nature of the product and with the country in which such approval is sought. For new chemical entities, the approval process could take eight to ten years or more. For reformulations of existing drugs, as management believes our potential product should be considered, typically the process is shorter. In either case, the procedures required to obtain governmental approval to market new drug products will be costly and time-consuming for us, requiring rigorous testing of the new drug product. Even after such time and effort, regulatory approval may not be obtained for our products.

Before we can market or even transport a new human pharmaceutical product commercially in the United States, regulations require that we file an Investigational New Drug Application (for the balance of this quarterly report on Form 10-QSB, we will refer to Investigational New Drug Application as INDA to be concise), conduct clinical trials and file an INDA with the FDA.

In order to conduct the clinical investigations necessary to obtain regulatory approval in the U.S., we must file an INDA with the FDA to permit the shipment and use of the drug for investigational purposes. The INDA will state, in

part, the results of preclinical (laboratory and animal) toxicology testing that we have conducted and our initial Phase I plans for clinical (human) testing. Unless notified that testing may not begin, the clinical testing may commence 30 days after filing an INDA.

Under FDA regulations, the clinical testing program required for marketing approval of a new drug typically involves three clinical phases. In Phase I, safety studies are generally conducted on normal, healthy human volunteers to determine the maximum dosages and side effects associated with increasing doses of the substance being tested. In Phase II, studies are conducted on small groups of patients, in our case those who have diabetes or blood sugar problems, to gain preliminary evidence of efficacy and to determine the common short-term side effects and risks associated with the new product. Phase III involves large-scale trials conducted on disease-afflicted patients to provide statistical evidence of efficacy and safety and to provide an adequate basis for product labeling. Frequent reports are required in each phase and, if unwarranted hazards to patients are found, the FDA may request modification or discontinuance of clinical testing until further studies have been conducted. Phase IV testing is sometimes conducted, either to meet FDA requirements for additional information as a condition of approval, or to gain post-approval market acceptance of the pharmaceutical product. Our potential oral insulin product will be subjected to each step of this lengthy process from conception to market.

Once clinical testing has been completed pursuant to an INDA, we will be required to file an INDA with the FDA seeking approval for marketing the drug product. The FDA will review the INDA to determine whether the drug is safe and effective, and adequately labeled, and whether the applicant can demonstrate proper and consistent manufacture of the drug. The time required for FDA action on an INDA varies considerably, depending on the characteristics of the drug, whether the FDA needs more information than is originally provided in the INDA and whether the FDA has concerns with the evidence submitted.

The facilities of each company involved in the commercial manufacturing, processing, testing, control and labeling of pharmaceutical products must be registered with and approved by the FDA. Continued registration requires compliance with Good Manufacturing Practices regulations and the FDA conducts periodic establishment inspections to confirm continued compliance with its regulations. We are subject to various federal, state and local laws, regulations and recommendations relating to such matters as laboratory and manufacturing practices and the use, handling and disposal of hazardous or potentially hazardous substances used in connection with our research and development work. We do not produce and drugs at this time and are not subject to these commercial manufacturing regulations at this time. However, it is important for the company to be aware of these standards in case a need for compliance develops in the future.

#### ***Research and Development***

We plan to conduct further research and development on the technology to administer insulin orally as covered by the provisional patent application No. 60/718716 we acquired from Hadasit for the next twelve months.

#### ***Marketing, Advertising and Promotion***

We will not conduct any marketing, advertising or promotion activities for our potential products in the next twelve months as the potential products are still only in research and development stage.

#### ***Description of Property***

We own, through our subsidiary, a 100% interest in the Saucy and Salsa mineral claims, which provides us with the right to explore for and extract minerals. We do not own any real property rights in the Saucy or Salsa mineral claims or in any other property. We do not plan to renew our mineral rights in the mineral claims when they expire.

#### ***Employees***

Currently we have two employees, including our Chief Executive Officer, Nadav Kidron and our Chief Financial Officer, George Drazenovic. Dr. Miriam Kidron has been providing consulting services to us. We are considering engaging Dr. Miriam Kidron as our Chief Scientist and depending on the results of those trials and other factors relating to the operations of the company, we may hire additional employees.



**Competition**

Many companies are developing methods that allow for the administration of insulin through other means such as inhalers, into the lungs and then into the bloodstream, and also oral administration of insulin. Studies indicate that inhalable insulin could be effective for many people with diabetes. These studies also show that inhaled insulin is less effective than injected insulin in terms of delivery of the insulin into the bloodstream. Therefore, inhalable solutions require more insulin and will likely be more expensive to produce.

On January 27, 2006, the FDA approved Pfizer, Inc.'s dry powder insulin inhaler product called Exubera. As reported in the Washington Post on January 28, 2006, inhaled insulin causes minor declines in how much air the lungs can hold. The article states that scientists believe that long-term use of inhaled insulin could pose risks, although they do not yet know what those risks are or how serious they will be. The FDA, while it has approved Exubera, recommends that smokers and people with some types of lung disease, including asthma, avoid using the product. Exubera is approved only for people aged 18 or older.

Other companies are also in the process of trying to bring such a product to the market but no other company has been successful as yet. Eli Lilly & Co., Alkermes and Mannkind Corp. are developing dry powder insulin products. Novo Nordisk and Aradigm Corp. are developing inhalable liquid insulin.

**Intellectual Property**

We have a patent application filed on August 31, 2006 under the Patent Cooperation Treaty at the Israel Patent Office for Methods and Compositions for Oral Administration of Proteins and the technology covered by this patent application. Priority was claimed from the provisional patent application No. 60/713716. All countries were designated and the United States Patent and Trademark Office was designated as the Search and Examination Authority.

**Purchase or Sale of Equipment**

We do not intend to purchase any significant equipment over the twelve months ending November 30, 2007.

**Plan of Operations**

Our primary objectives over the 12 months ending November 30, 2007, will be to conduct further research and development on the technology covered by the provisional patent application No. 60/718716 we acquired from Hadasit and to begin Phase I of the clinical trials for our drug product candidate to administer insulin orally.

**Capital Resource Requirements**

For the next 12 months ending November 30, 2007, we will be required to cover a total of approximately \$1.345 million for our proposed research and development and business activities. This budget includes the salaries of the research team, office costs, cost of trials and materials, among others, all of them necessary to execute our plan of operations. The following table provides a cost-breakdown of the first year of operations.

Estimated Funding Required During the Next Twelve Months	
Salaries	\$185,000
Operations	
Legal Fees	\$50,000
Office Expenses	\$60,000
Research and Development	
Insulin, Carrier and Antiproteases	\$200,000
Kits for Insulin and Glucose	\$50,000
Animal Studies	\$200,000
Clinical Trials (Healthy and Type II Diabetes)	\$300,000



Pharmaceutical Technology Services	\$200,000
Pharmacist Consultation	\$100,000
<b>Total</b>	<b>\$1,345,000</b>

**Financial Condition, Liquidity and Capital Resources**

At November 30, 2006, we had a working capital deficit of \$495,369.

At November 30, 2006, our company had \$72,300 in cash and cash equivalents. At November 30, 2006, our company's total liabilities were \$567,669.

We did not generate any revenue in the three months ended November 30, 2006 and we have not generated any revenue since inception to November 30, 2006. We have incurred a loss of \$76,994 in the three months ended November 30, 2006. We do not expect to purchase or sell any significant equipment. We do not expect any significant changes in the number of our employees.

There are no assurances that we will be able to obtain the amount required for our continued operations. In such event that we do not raise sufficient additional funds by secondary offering or private placement, we will consider alternative financing options, if any, or be forced to scale down or perhaps even cease our operations.

***Going Concern***

The continuation of our business is dependent upon us raising additional financial support. The issuance of additional equity securities by us could result in a significant dilution in the equity interests of our current stockholders. Obtaining commercial or other loans, assuming those loans would be available, will increase our liabilities and future cash commitments.

We have historically incurred losses, and through November 30, 2006 have incurred losses of \$1,319,918 from our inception. Because of these historical losses, we will require additional working capital to develop our business operations.

There are no assurances that we will be able to either (1) achieve a level of revenues adequate to generate sufficient cash flow for operations; or (2) obtain additional financing through either private placements, public offerings and/or bank financing necessary to support our working capital requirements. To the extent that funds generated from operations are insufficient to meet our ongoing capital requirements, we will have to raise additional working capital by means of private placements, public offerings and/or bank financing. No assurance can be given that additional financing will be available, or if available, will be on terms acceptable to us. If adequate working capital is not available we may not increase our operations and if we are unable to raise additional funds we may cease operations.

These conditions raise substantial doubt about our ability to continue as a going concern. The 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 be necessary should we be unable to continue as a going concern.

Our independent auditor's report on our audited financial statements, in our Form 10-KSB for the fiscal year ended August 31, 2006, contained a going concern qualifier. The qualifier explanatory paragraph contained in their audit report should be read in connection with our management's discussion of our financial condition, liquidity and capital resources.

**APPLICATION OF CRITICAL ACCOUNTING POLICIES**

Our unaudited financial statements and accompanying notes have been prepared in conformity with generally accepted accounting principles in the United States of America for interim financial statements. Preparing financial statements requires management to make estimates and assumptions that affect the reported amounts of assets,



liabilities, revenue, and expenses. These estimates and assumptions are affected by management's application of accounting policies. We believe that understanding the basis and nature of the estimates and assumptions involved with the following aspects of our financial statements is critical to an understanding of our financials.

## **RISK FACTORS**

Much of the information included in this quarterly report includes or is based upon estimates, projections or other forward-looking statements. Such forward-looking statements include any projections or estimates made by us and our management in connection with our business operations. While these forward-looking statements, and any assumptions upon which they are based, are made in good faith and reflect our current judgment regarding the direction of our business, actual results will almost always vary, sometimes materially, from any estimates, predictions, projections, assumptions, or other future performance suggested herein. We undertake no obligation to update forward-looking statements to reflect events or circumstances occurring after the date of such statements.

Such estimates, projections or other forward-looking statements involve various risks and uncertainties as outlined below. We caution readers of this quarterly report that important factors in some cases have affected and, in the future, could materially affect actual results and cause actual results to differ materially from the results expressed in any such estimates, projections or other forward-looking statements. In evaluating us, our business and any investment in our business, readers should carefully consider the following factors.

### **Risks Relating to Our Business**

#### ***We are dependent on the clinical success of our oral insulin product.***

We have only completed our acquisition of the provisional patent application No. 60/718716 and its related intellectual property. As we have decided to abandon our previous business plan to conduct exploration on our mineral claims, the research and development of our potential oral insulin product is currently our only project. We are obligated to return the intellectual property covered by patent application No. 60/718716 related to our potential insulin product to Hadasit if our initial clinical trials are not successful. Even if our initial clinical trials are successful, we will still be obligated to return the intellectual property related to our potential insulin product to Hadasit if we cannot complete our private placement of \$1,000,000 within 120 days of our receipt of the clinical trial report.

Furthermore, if we fail to develop our potential insulin product to completion or obtain regulatory approval for it, either on our own or in collaboration with other pharmaceutical companies, our ability to fund future operations from either revenue or the issuance of additional equity is likely to be adversely affected. We are dependent on the successful culmination of clinical trials and regulatory approval of our potential oral insulin product and failure to develop and market this product will have a significant and negative effect on our ability to continue operations.

#### ***Our potential oral insulin product is still in the development stage and we cannot be certain that it will be suitable for commercial purposes.***

To be profitable, we must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our oral insulin product that is currently in the development stage. The time necessary to achieve these goals for any individual product is long and uncertain. Before we can sell any of our potential oral insulin products, we will be required to demonstrate through clinical trials that such product is safe and effective for human use in the treatment of people with diabetes. We have never successfully commercialized a drug product and we cannot be certain that we will be able to begin, or continue, planned clinical trials for our potential product, or if we are able, that the potential product will prove to be safe and will produce the intended effects.

Even if safe and effective, the size of the solid dosage form, taste and frequency of dosage may impede the acceptance of our product by patients.

A number of companies in the drug delivery, biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after showing promising results in earlier studies or trials. We cannot assure you that favorable results in any clinical trial will mean that favorable results will ultimately be obtained in future clinical



trials. Nor can we assure you that results of limited animal and human studies are indicative of results that would be achieved in future animal studies or human clinical studies, all or some of which will be required in order to have our potential product obtain regulatory approval. Similarly, we cannot assure you that our potential product will be approved by the FDA.

***Our future business success depends heavily upon regulatory approvals, which can be difficult to obtain for a variety of reasons, including cost.***

Our clinical trials, as well as the manufacturing and marketing of our potential product, are subject to extensive, costly and rigorous regulation by various governmental authorities in the United States and other countries. The process of obtaining required approvals from the FDA and other regulatory authorities often takes many years, is expensive and can vary significantly based on the type, complexity and novelty of the potential product. We cannot assure you that we will meet the applicable regulatory criteria in order to receive the required approvals for manufacturing and marketing. Delays in obtaining United States or foreign approvals for our potential product could result in substantial additional costs to us, and, therefore, could adversely affect our ability to continue operations. Even if regulatory approval of our potential product is obtained, that approval may place limitations on the intended uses of the product, and may restrict the way in which we are allowed to market the product.

The regulatory approval process presents several risks to us:

In general, clinical trials can take more than a year, and require the expenditure of substantial resources, and the data obtained from these tests and trials can be susceptible to varying interpretation that could delay, limit or prevent regulatory approval.

Delays or rejections may be encountered during any stage of the regulatory process based upon the failure of the clinical or other data to demonstrate compliance with, or upon the failure of the product to meet, a regulatory agency's requirements for safety, efficacy and quality or, in the case of a product seeking an orphan drug indication, because another designee received approval first.

Requirements for approval may become more stringent due to changes in regulatory agency policy, or the adoption of new regulations or legislation.

The scope of any regulatory approval, when obtained, may significantly limit the indicated uses for which a product may be marketed and may impose significant limitations in the nature of warnings, precautions and contraindications that could materially affect the profitability of the drug.

Approved drugs, as well as their manufacturers, are subject to continuing and on-going review, and discovery of previously unknown problems with these products or the failure to adhere to manufacturing or quality control requirements may result in restrictions on their manufacture, sale or use or in their withdrawal from the market.

Regulatory authorities and agencies may promulgate additional regulations restricting the sale of our existing and proposed products.

Once a product receives marketing approval, the FDA may not permit us to market that product for broader or different applications, or may not grant us clearance with respect to separate product applications that represent extensions of our basic technology. In addition, the FDA may withdraw or modify existing clearances in a significant manner or promulgate additional regulations restricting the sale of our present or proposed products.

Additionally, we face the risk that our competitors may gain FDA approval for a product before us. Having a competitor reach the market before us would impede the future commercial success for our competing product because we believe that the FDA uses heightened standards of approval for products once approval has been granted to a competing product in a particular product area. We believe that this standard generally limits new approvals to only those products that meet or exceed the standards set by the previously approved product.

***Our business will suffer if we cannot adequately protect our patent and proprietary rights.***

Although we have submitted a patent application covering the intellectual property for our potential oral insulin product, we cannot assure you that our patent will be granted and, if it is granted, whether it will be held to be valid and enforceable and provide us with meaningful protection from competition. Furthermore, we may not possess the financial resources necessary to enforce our patent even if our patent application is successful. Also, we cannot be certain that any products that we or a prospective licensee develop will not infringe upon any patent or other intellectual property right of a third party.

We will also rely upon trade secrets, know-how and continuing technological advances to develop and maintain our competitive position. We plan to maintain a policy of requiring employees, scientific advisors, consultants and collaborators to execute confidentiality and invention assignment agreements upon commencement of a relationship with us. We cannot assure you that these agreements will provide meaningful protection for our trade secrets in the event of unauthorized use or disclosure of such information.

***We may be at risk of having to obtain a license from third parties making proprietary improvements to our technology.***

There is a possibility that third parties may make improvements or innovations to our potential oral insulin product in a more expeditious manner than we do. Although we are not aware of any such circumstance related to our product portfolio, should such circumstances arise, we may need to obtain a license from such third party to obtain the benefit of the improvement or innovation. Royalties payable under such a license would reduce our share of total revenue. Such a license may not be available to us at all or on commercially reasonable terms. Although we currently do not know of any circumstances related to potential oral insulin product that would lead us to believe that a third party has developed any improvements or innovation with respect to it, we cannot assure you that such circumstances will not arise in the future. We cannot reasonably determine the cost to us of the effect of being unable to obtain any such license.

***We are dependent on third parties to manufacture and, in some cases, test our products.***

We have no manufacturing facilities for production of our potential oral insulin product. We have no facilities for clinical testing. The success of our program will be dependent upon securing manufacturing capabilities and contracting with clinical service providers.

The availability of manufacturers is limited by both the capacity of such manufacturers and their regulatory compliance. Among the conditions for New Drug Application approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures continually conform with the FDA's current Good Manufacturing Practice. For the balance of this quarterly report on Form 10-QSB, we will refer to Good Manufacturing Practices as GMP's to be concise. GMP's are regulations established by the FDA that govern the manufacture, processing, packing, storage and testing of drugs intended for human use. In complying with GMP's, manufacturers must devote extensive time, money and effort in the area of production and quality control and quality assurance to maintain full technical compliance.

Manufacturing facilities and company records are subject to periodic inspections by the FDA to ensure compliance. If a manufacturing facility is not in substantial compliance with these requirements, regulatory enforcement action may be taken by the FDA, which may include seeking an injunction against shipment of products from the facility and recall of products previously shipped from the facility. Such actions could severely delay our ability to obtain product from that particular source.

The success of our clinical trials is dependent on our future partner's capacity and ability to adequately manufacture drug products to meet the proposed demand of each respective market. Any significant delay in obtaining a supply source could harm our potential for success. Additionally, if a future manufacturer were to lose its ability to meet our supply demands during a clinical trial, the trial may be delayed or may even need to be abandoned.

***We may face product liability claims related to participation in clinical trials or future products.***

The testing, manufacture and marketing of products for humans utilizing our potential oral insulin product may expose us to product liability and other claims. These may be claims directly by consumers or by pharmaceutical companies or others selling our product in the future. We seek to structure development programs with pharmaceutical companies that would complete the development, manufacturing and marketing of the finished product in a manner that would protect us from such liability, but the indemnity undertakings for product liability claims that we secure from the pharmaceutical companies may prove to be insufficient. We do not yet have product liability insurance.

***We face rapid technological change and intense competition.***

Our success depends, in part, upon maintaining a competitive position in the development of our potential product. Developments in insulin products are expected to continue at a rapid pace because many pharmaceutical companies are in the process of developing new insulin products. If we are able to develop our potential oral insulin product to the point where we can sell it on the market, we will compete with other drug delivery, biotechnology and pharmaceutical companies, research organizations, individual scientists and non-profit organizations engaged in the development of insulin products, especially those who are developing insulin products that can be taken orally. Many of our competitors will have greater research and development capabilities, experience, and marketing, financial and managerial resources than we have, and, therefore, will represent significant competition.

Our products, when developed and marketed, may compete with existing insulin products, some of which are well established in the marketplace and manufactured by our competitors. Our potential oral insulin product, if successful, would compete with insulin that is taken by injection and the new Exubera insulin inhaler from Pfizer, Inc. These products are marketed throughout the world by leading pharmaceutical companies such as Eli Lilly and Company and Pfizer, Inc.

Our competitors may succeed in developing competing technologies or obtaining government approval for products before we do. For example, on January 27, 2006 the FDA approved Pfizer, Inc.'s dry powder insulin inhaler product called Exubera. Developments by others may render our potential products non-competitive or obsolete. We cannot assure you that, if our products are marketed, they will be preferred to existing drugs or that they will be preferred to or available before other products in development.

**Risks Related to our Company**

***We have incurred substantial losses since inception and as we expect to continue to incur research and development costs to further develop our potential oral insulin product, we are likely going to require additional capital and if additional capital is not raised, we may have to cease business operations and investors will lose their entire investment.***

Since our inception in April 12, 2002, we have generated significant losses from operations. Now that we have abandoned our former business acquiring and exploring mineral properties and have become engaged in the pharmaceutical research and development business, we anticipate that we will continue to generate significant losses from operations for the foreseeable future. As at August 31, 2006, our accumulated deficit was approximately \$1,242,908. Our net loss was \$414,576 and \$45,781 for the years ended August 31, 2006 and 2005 respectively. As at August 31, 2006, we had cash or cash equivalents of \$176,190 (including \$125,000 held in trust). We have limited capital resources and no revenue from operations to date have been funded with the proceeds from equity financings. These conditions raise substantial doubt about our ability to continue as a going concern. The audit report prepared by our independent registered public accounting firm relating to our consolidated financial statements for the year ended includes an explanatory paragraph expressing the substantial doubt about our ability to continue as a going concern.

Our existing capital resources will not enable us to continue operations without implementing cost reductions or raising additional capital. These circumstances may adversely affect our ability to raise additional capital. If we fail to raise additional capital, we will be forced to cease operations. If additional capital is raised through the sale of

equity or convertible debt securities, the issuance of such securities would result in dilution to our existing stockholders.

***If we are unable to raise additional capital, we will be required to curtail our research and development efforts, which could have a material adverse effect on our ability to bring our potential oral insulin product to the market.***

If we fail to raise additional capital, we will not be able to conduct the research and development work that we intend to carry out. Our inability to conduct our planned research and development work would have a material adverse effect on our ability to ever achieve profitable operations through sales of our product and to continue as a going concern.

We are also obligated under the purchase and sale agreement for the provisional patent application No. 60/718716 to raise \$1,000,000 through a private placement of units of our securities. If our clinical trial report is successful and we do not raise the \$1,000,000 within 120 days of our receipt of the clinical trial report, we will be required to return the intellectual property covered by provisional patent application No. 60/718716 to Hadassit without any consideration.

***We are dependent on our key personnel and if we cannot recruit and retain qualified individuals to perform our research, development, manufacturing and commercial functions, our business will likely not be successful.***

We are highly dependent on our executive officers, especially on the consulting services to be provided by one of our directors, Dr. Miriam Kidron. Dr. Kidron is a pharmacist with a Ph. D. in biochemistry and is the inventor of the method and composition of insulin that can be administered orally, which was covered by the provisional patent application No. 60/718716. From 1990 to the present time, she has been an investigator in the Diabetes Unit at Hadassah University Hospital in Jerusalem, Israel. We would be significantly disadvantaged if Dr. Kidron were to leave our company. The loss of other officers could have an adverse effect as well, given their specific knowledge related to our proprietary technology. If we are not able to retain our executive officers, our business may suffer. None of our key officers have announced any intention to leave us. We do not have any employment contracts with our executive officers but we do have a consulting agreement for the services of Dr. Kidron. We do not maintain key-person life insurance policies for any of our executive officers.

There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to attract and retain the qualified personnel necessary for developing our business. Additionally, because of the knowledge and experience of our scientific personnel and their specific knowledge with respect to our potential oral insulin product, the continued development of our potential product could be adversely affected by the loss of any one of our executive officers or qualified personnel that we may engage.

***Because some of our officers and directors are located in non-U.S. jurisdictions, our shareholders may have no effective recourse against the management for misconduct and may not be able to enforce judgment and civil liabilities against our officers, directors, experts and agents.***

All of our directors and officers are nationals and/or residents of countries other than the United States, and all or a substantial portion of their assets are located outside the United States. As a result, it may be difficult for investors to enforce within the United States any judgments obtained against our officers or directors, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any U.S. state.

***Our principal research and development facilities will be located in Israel and the unstable military and political conditions in Israel may cause interruption or suspension of our business operations without warning.***

Our principal research and development facilities will initially be located in Israel. As a result, we are directly influenced by the political, economic and military conditions affecting Israel. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors and, since September 2000, involving the Palestinian population, and a state of hostility, varying in degree and intensity, has led to security and economic problems for Israel and companies based in Israel. Acts of random terrorism periodically occur which could affect our operations or personnel.



In addition, Israeli-based companies and companies doing business with Israel have been the subject of an economic boycott by members of the Arab League and certain other predominantly Muslim countries since Israel's establishment. Although Israel has entered into various agreements with certain Arab countries and the Palestinian Authority, and various declarations have been signed in connection with efforts to resolve some of the economic and political problems in the Middle East, we cannot predict whether or in what manner these problems will be resolved. Also, since the end of September 2000, there has been a marked increase in the level of terrorism in Israel, which has significantly damaged both the Israeli economy and levels of foreign and local investment.

Furthermore, certain of our officers and employees may be obligated to perform annual reserve duty in the Israel Defense Forces and are subject to being called up for active military duty at any time. All Israeli male citizens who have served in the army are subject to an obligation to perform reserve duty until they are between 45 and 54 years old, depending upon the nature of their military service.

### **Risks Related to Our Common Stock**

#### ***Our stock price will likely be volatile.***

The trading price for our common stock is likely to be highly volatile. The market prices for securities of drug delivery, biotechnology and pharmaceutical companies have historically been highly volatile. Factors that could adversely affect our stock price include:

fluctuations in our operating results; announcements of partnerships or technological collaborations,

innovations or new products by us or our competitors;

changes in government regulations;

developments in patent or other proprietary rights;

public concern as to the safety of drugs developed by us or others;

the results of clinical studies or trials by us, any partners we may have or our competitors;

litigation;

general stock market and economic conditions;

number of shares available for trading (float);

inclusion in or dropping from stock indexes.

***Future sales of common stock or warrants, or the prospect of future sales, may depress our stock price.***

Sales of a substantial number of shares of our common stock or warrants, or the perception that sales could occur, could adversely affect the market price of our common stock.

***We do not intend to pay dividends and there will be less ways in which you can make a gain on any investment in our company.***

We have never paid any cash dividends and currently do not intend to pay any dividends for the foreseeable future. Because we do not intend to declare dividends, any gain on an investment in our company will need to come through appreciation of the price of our common stock. There can be no assurance that the price of our common stock will increase.



***Trading of our stock may be restricted by the SEC's penny stock regulations, which may limit a stockholder's ability to buy and sell our stock.***

The Securities and Exchange Commission has adopted regulations which generally define penny stock to be any equity security that has a market price (as defined) less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to certain exceptions. Our securities are covered by the penny stock rules, which impose additional sales practice requirements on brokers or dealers who sell to persons other than established customers and accredited investors. The term accredited investor refers generally to institutions with assets in excess of \$5,000,000 or individuals with a net worth in excess of \$1,000,000 or annual income exceeding \$200,000 or \$300,000 jointly with their spouse. The penny stock rules require a broker or dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document in a form prepared by the SEC, which provides information about penny stocks and the nature and level of risks in the penny stock market. The broker or dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker or dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker or dealer and salesperson compensation information, must be given to the customer orally or in writing prior to effecting the transaction and must be given to the customer in writing before or with the customer's confirmation. In addition, the penny stock rules require that prior to a transaction in a penny stock not otherwise exempt from these rules, the broker or dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for the stock that is subject to these penny stock rules. Consequently, these penny stock rules may affect the ability of brokers or dealers to trade our securities. We believe that the penny stock rules discourage investor interest in and limit the marketability of our common stock. This may limit your ability to buy and sell our stock and cause the price of the shares to decline.

***NASD sales practice requirements may also limit a stockholder's ability to buy and sell our stock.***

In addition to the penny stock rules described above, the National Association of Securities Dealers (NASD) has adopted rules that require that in recommending an investment to a customer, a broker or dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low priced securities to their non-institutional customers, brokers or dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, the NASD believes that there is a high probability that speculative low priced securities will not be suitable for at least some customers. The NASD requirements make it more difficult for brokers or dealers to recommend that their customers buy our common stock, which may prevent you from reselling your shares and may cause the price of the shares to decline.

### **Item 3. Controls and Procedures.**

As required by Rule 13a-15 under the Exchange Act, as of the end of the period covered by this report, being November 30, 2006, we have carried out an evaluation of the effectiveness of the design and operation of our company's disclosure controls and procedures. This evaluation was carried out under the supervision and with the participation of our management, including our chief executive officer, Nadav Kidron, and our chief financial officer, George Drazenovic. Based upon that evaluation, they concluded that our disclosure controls and procedures are not effective as of the end of the period covered by this report. The deficiencies in internal control relate to the recording stock-based compensation expense. There have been no significant changes in our internal controls over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect our internal controls over financial reporting.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our company's reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our president and chief executive officer as appropriate, to allow timely decisions regarding required disclosure.





## **PART II - OTHER INFORMATION**

### **Item 1. Legal Proceedings.**

Other than disclosed below, we know of no material, active or pending legal proceedings against us, nor are we involved as a plaintiff in any material proceedings or pending litigation:

On June 21, 2006, we commenced a legal action in the Supreme Court of the State of New York against John Choi, Bernard Perini and Epifanio Almodovar to enjoin them from selling, assigning, transferring, pledging, encumbering or otherwise disposing their shares of our common stock. Collectively Messrs. Choi, Perini and Almodovar obtained 2,897,342 shares of our common stock pursuant to an aborted merger between our company and Integrated Security Technologies, Inc., a privately held New Jersey Corporation, in 2004. It is our position that Messrs. Choi, Perini and Almodovar are possessed of stock that either should never have been issued to them at all or which should have been returned to our company when our merger with Integrated Security Technologies, Inc., the privately held New Jersey Corporation, was unwound. The court subsequently granted us a temporary injunction to restrain Messrs. Choi, Perini and Almodovar from selling their shares of our common stock.

On August 10, 2006, we reached a settlement with Bernard Perini and Epifanio Almodovar for the legal action in the Supreme Court of the State of New York initiated by our company against them. As a result, the temporary injunction to restrain Messrs. Perini and Almodovar from selling their shares of our common stock has been lifted. Furthermore, pursuant to the settlement, all claims by and between our company and Bernard Perini and Epifanio Almodovar have been mutually released and discontinued with prejudice. Messrs. Perini and Almodovar agreed to ask their legal counsel to hold their shares of our common stock as an escrow agent, subject to a scheduled release.

There are no proceedings in which any of our directors, officers or affiliates, or any registered or beneficial shareholder are an adverse party or has a material interest adverse to us.

### **Item 2. Recent Sales of Unregistered Securities and Use of Proceeds**

On November 23, 2006, we entered issued stock options to one consultant and one director of our company, granting options to purchase an aggregate of 750,000 shares of our common stock at an exercise price of \$0.76 per share, exercisable for a period of three years pursuant to the stock option agreements.

On December 27, 2006, we issued 125,000 shares of our common stock to Swiss Caps Ag pursuant to an agreement whereby Swiss Caps Ag has agreed to manufacture oral gel capsules for clinical testing of our oral insulin project.

### **Item 3. Defaults Upon Senior Securities.**

None.

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

None.

### **Item 5. Other Information.**

N/A.

**Item 6. Exhibits**

*Exhibits required by Item 601 of Regulation S-B*

**(3) Articles of Incorporation and By-laws**

- 3.1 Articles of Incorporation (incorporated by reference from our Registration Statement on Form SB-2, filed on November 29, 2002).
- 3.2 Bylaws (incorporated by reference from our Current Report on Form 8-K filed on April 10, 2006).
- 3.3 Articles of Merger filed with the Nevada Secretary of State on March 29, 2006 (incorporated by reference to our Current Report on Form 8-K filed on April 10, 2006).

**(4) Instruments defining rights of security holders, including indentures**

- 4.1 Specimen Stock Certificate (incorporated by reference from our Registration Statement on Form SB-2, filed on November 29, 2002).

**(10) Material Contracts**

- 10.1 Form of Securities Purchase Agreement for February 6, 2006 private placement (incorporated by reference from our current report on Form 8-K filed February 6, 2006)
- 10.2 Agreement between our company and Hadasit Medical Services and Development Ltd. dated February 17, 2006 concerning the acquisition of U.S. patent application 60/718716 (incorporated by reference from our current report on Form 8-K filed February 17, 2006).
- 10.3 Consulting Agreement between our company and Dr. Miriam Kidron (incorporated by reference from our current report on Form 8-K filed February 17, 2006).
- 10.4 Agreement between our company and Swiss Caps Ag dated October 30, 2006 (incorporated by reference from our current report on Form 8-K filed October 26, 2006).

**(31) Section 302 Certification**

- 31.1 Certification of Nadav Kidron
- 31.2 Certification of George Drazenovic

**(32) Section 906 Certification**

- 32.1 Certification of Nadav Kidron
  - 32.2 Certification of George Drazenovic
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**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**Oramed Pharmaceuticals Inc.**

By: /s/ Nadav Kidron

Nadav Kidron, President, CEO and Director

(Principal Executive Officer)

Date: January 19, 2007

By: /s/ George Drazenovic

George Drazenovic, CFO, Secretary, Treasurer and Director

(Principal Financial Officer and Principal Accounting Officer)

Date: January 19, 2007

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

By: /s/ Nadav Kidron

Nadav Kidron, President, CEO and Director

Date: January 19, 2007

By: /s/ George Drazenovic

George Drazenovic, CFO, Secretary, Treasurer and Director

Date: January 19, 2007

