

Orgenesis Inc.  
Form 10-Q  
April 20, 2012

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, DC 20549

**FORM 10-Q**

Quarterly Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the quarterly period ended **February 29, 2012**

Transition Report pursuant to 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period to

Commission File Number: **000-54329**

**ORGENESIS INC.**

(Exact name of registrant as specified in its charter)

**NEVADA**

(State or other jurisdiction of incorporation or  
organization)

**98-0583166**

(IRS Employer Identification No.)

**21 Sparrow Circle, White Plains, NY, 10605**

(Address of principal executive offices)

**845.591.3144**

(Registrant's telephone number, including area code)

**Not Applicable**

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes     No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required

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to submit and post such files).

Yes    No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes    No

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

As of April 16, 2012, there were 48,517,903 shares of common stock, par value \$0.0001 outstanding.

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**PART I - FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

These financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and the SEC instructions to Form 10-Q. In the opinion of management, all adjustments considered necessary for a fair statement have been included. Operating results for the interim period ended February 29, 2012 are not necessarily indicative of the results that can be expected for the full year.

**ORGENESIS INC.**  
**(FORMERLY BUSINESS OUTSOURCING SERVICES, INC.)**

**(A development stage company)**

**CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**AS OF FEBRUARY 29, 2012**

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**ORGENESIS INC.**  
**(FORMERLY BUSINESS OUTSOURCING SERVICES, INC.)**  
**(A development stage company)**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(UNAUDITED)**  
U.S. dollars

	February 29, 2012	November 30, 2011
<b>Assets</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	353,781	1,275
Prepaid expenses	13	1,065
Total assets	353,794	2,340
<b>Liabilities and stockholders' equity</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	16,951	44,513
Employee and related payables	35,987	-
Accrued expenses	61,272	5,000
Due to related parties	45,500	35,500
Total current liabilities	159,710	85,013
<b>Commitments (Note 2)</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Common stock of \$0.0001 par value - authorized: 1,750,000,000 shares at February 29, 2012 and at November 30, 2011; issued and outstanding: 48,517,903 and 80,500,000 shares at February 29, 2012 and November 30, 2011, respectively	4,852	8,050
Additional paid-in capital	1,180,766	46,950
Deficit accumulated during the development stage	(991,534)	(137,673)
Total stockholders' equity (deficit)	194,084	(82,673)
Total liabilities and stockholders' equity (deficit)	353,794	2,340

**The accompanying notes are an integral part of these condensed consolidated financial statements.**

**ORGENESIS INC.**  
**(FORMERLY BUSINESS OUTSOURCING SERVICES, INC.)**  
**(A development stage company)**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(UNAUDITED)**  
U.S. dollars

	<b>Three months ended</b>		<b>Period from June 5, 2008 (inception) through</b>
	<b>February 29, 2012</b>	<b>February 28, 2011</b>	<b>February 29, 2012</b>
<b>RESEARCH AND DEVELOPMENT EXPENSES</b>	719,671	-	719,671
<b>GENERAL AND ADMINISTRATIVE EXPENSES</b>	134,091	5,436	271,764
<b>OPERATING LOSS</b>	853,762	5,436	991,435
<b>FINANCIAL EXPENSE ( INCOME), net</b>	99	-	99
<b>NET LOSS FOR THE PERIOD</b>	853,861	5,436	991,534

**LOSS PER COMMON STOCK:**

Basic and diluted	\$	0.01	\$	0.00
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**WEIGHTED AVERAGE NUMBER OF SHARES USED IN  
COMPUTATION OF BASIC AND DILUTED LOSS PER  
COMMON STOCK:**

69,839,301	80,500,000
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The accompanying notes are an integral part of these condensed consolidated financial statements.

**ORGENESIS INC.**  
**(FORMERLY BUSINESS OUTSOURCING SERVICES, INC.)**  
**(A development stage company)**

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY  
(UNAUDITED)  
U.S. dollars

	Common Stock		Additional	Deficit	Total
	Shares	\$	paid-in	accumulated	stockholders'
			capital	during the	Deficit
				development	
				stage	
<b>Balance at June 5, 2008</b> (inception)	-	-	-	-	-
<b>Changes during the period</b> <b>from June 5,</b> <b>2008 through November 30,</b> <b>2010</b>					
Shares issued to founder on June 5, 2008					
0.125\$ Per Share	1,600,000	1,600	18,400	-	20,000
Private Placement at 0.05\$ Per Share	700,000	700	34,300	-	35,000
Net Loss	-	-	-	(65,321)	(65,321)
<b>Balance as of November 30, 2010</b>	2,300,000	2,300	52,700	(65,321)	(10,321)
Effect of 35:1 stock split	78,200,000	5,750	(5,750)	-	-
Net Loss	-	-	-	(72,352)	(72,352)
<b>Balance as of November 30, 2011</b>	80,500,000	8,050	46,950	(137,673)	(82,673)
<b>Changes during the three</b> <b>month period</b> <b>ended February 29, 2012</b> (Unaudited)					
Shares cancelled	(33,873,049)	(3,387)	3,387	-	-
Warrants and shares issued for cash, net of					
issuance expenses	500,000	50	471,611	-	471,661
Stock based compensation related to options					
granted to employees	-	-	149,335	-	149,335
Shares issued for services	1,390,952	139	509,483	-	509,622
Net loss for the period	-	-	-	(853,861)	(853,861)
<b>Balance at February 29, 2012</b>	48,517,903	4,852	1,180,766	(991,534)	194,084

The accompanying notes are an integral part of these condensed consolidated financial statements.



**ORGENESIS INC.**  
**(FORMERLY BUSINESS OUTSOURCING SERVICES, INC)**  
**(A development stage company)**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(UNAUDITED)**  
U.S. dollars

	<b>Three months ended</b>		<b>Period from June 5,</b>
	<b>February 29,</b>	<b>February 28,</b>	<b>2008 (inception date)</b>
	<b>2012</b>	<b>2011</b>	<b>through</b>
			<b>February 29,</b>
			<b>2012</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	(853,861)	(5,436)	(991,534)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Write-off of website development costs	-	-	15,000
Stock based compensation related to options granted to employees	149,335	-	149,335
Shares issued for services	509,622	-	509,622
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	1,052	153	(13)
Accounts payable and other payables	28,709	(3,971)	78,223
Due to related parties	10,000	15,000	45,500
Employees and related payables	35,987	-	35,987
Total net cash used in operating activities	(119,155)	5,746	(157,880)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Website development costs	-	-	(15,000)
Total net cash derived from (used in) investing activities	-	-	(15,000)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from Warrants and shares issued for cash, net of issuance expenses	471,661	-	526,661
Net cash provided by financing activities	471,661	-	526,661
<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>352,506</b>	<b>5,746</b>	<b>353,781</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>1,275</b>	<b>1,464</b>	<b>-</b>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>353,781</b>	<b>7,210</b>	<b>353,781</b>

The accompanying notes are an integral part of these condensed consolidated financial statements.



**NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES:**

**a. General:**

**1. Operations**

Orgenesis Inc. (formerly Business Outsourcing Services, Inc.) ( the Company ), incorporated in the state of Nevada on June 5, 2008 is currently developing a new technology for regeneration of functional insulin-producing cells, thus, enabling normal glucose regulated insulin secretion, via cell therapy.

On August 31, 2011, the Company changed its name from Business Outsourcing Services, Inc. to Orgenesis Inc. , by way of merger with its wholly-owned subsidiary Orgenesis Inc., which was formed solely for the change of name.

On October 11, 2011, the Company incorporated a wholly-owned subsidiary in Israel, Orgenesis Ltd. (the "Subsidiary"), which is engaged in research and development. Unless the context indicates otherwise, the term Group refers to Orgenesis Inc. and its Israeli subsidiary, Orgenesis Ltd (the Subsidiary ).

On February 2, 2012, the Subsidiary entered into an agreement with Tel Hashomer Medical Research, Infrastructure and Services Ltd (the "Licensor"). The Subsidiary was granted a worldwide royalty bearing, exclusive license to certain information regarding a molecular and cellular approach directed at converting liver cells into functional insulin producing cells, as treatment for diabetes.

The Group is engaged in research and development in the biotechnology field and is considered a development stage company in accordance with ASC Topic 915 Development Stage Entities .

**2. Basis Of Presentation**

The accompanying unaudited interim condensed consolidated financial statements as of February 29, 2012 have been prepared in accordance with accounting principles generally accepted in the United States. Accordingly, they do not include all the information and footnotes required for annual financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair statement have been included. The accounting principles applied in the preparation of the interim statements are consistent with those applied in the preparation of the annual financial statements; however, the interim statements do not include all the information and explanations required for the annual financial statements. The condensed consolidated balance sheet data as of November 30, 2011 was derived from the Company s audited financial statements, but does not include all disclosures required by generally accepted accounting principles. For additional information, including the Company s significant accounting policies, refer to the consolidated financial statements and related footnotes in the Company s fiscal 2011 Annual Report on Form 10-K. Operating results for the three months ended February 29, 2012, are not necessarily indicative of the results that may be expected for the year ending November 30, 2012.

**3. Research and development**

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, payroll taxes and employee benefits. All costs associated with research and development are expensed as incurred.



**NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES:** (continued):

**4. Principles of consolidation**

The consolidated financial statements include the accounts of the company and its Subsidiary. All material inter-company transactions and balances have been eliminated in consolidation.

**5. Functional currency**

The currency of the primary economic environment in which the operations of the Company and Subsidiary are conducted is the US dollar ( \$ or dollar ).

Most of the Group expenses are incurred in dollars and all their financing is in dollars. Thus, the functional currency of the Company and Subsidiary is the dollar.

Transactions and balances originally denominated in dollars are presented at their original amounts. Balances in foreign currencies are translated into dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. For foreign transactions and other items reflected in the statements of operations, the following exchange rates are used: (1) for transactions exchange rates at transaction dates or average rates and (2) for other items (derived from non-monetary balance sheet items such as depreciation) historical exchange rates. The resulting transaction gains or losses are carried to financial income or expenses, as appropriate.

**6. Going concern considerations**

The accompanying unaudited interim condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company has net losses for the period from inception (June 5, 2008) through February 29, 2012, of \$991,534 as well as negative cash flow from operating activities. Presently, the Company does not have sufficient cash resources to meet its requirements in the twelve months following February 29, 2012. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management is in the process of evaluating various financing alternatives, as the Company will need to finance future research and development activities and general and administrative expenses through fund raising in the public or private equity markets. Although there is no assurance that the Company will be successful with those initiatives, management believes that it will be able to secure the necessary financing as a result of ongoing financing discussions with third party investors and existing shareholders, including via future issuance of 1,000,000 shares of common stock in a total amount of \$1,000,000 as mentioned in note 3(2).

These consolidated financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern. The Company's continuation as a going concern is dependent on its ability to obtain additional financing as may be required and ultimately to attain profitability.

**NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES:** (continued):

**7. Income Taxes**

Income taxes are computed using the asset and liability method. Under the asset and liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the currently enacted tax rates and laws. A valuation allowance is provided for the amount of deferred tax assets that, based on available evidence, are not expected to be realized in the foreseeable future. It is the Company's policy to classify interest and penalties on income taxes as interest expense or penalties expense.

**8. Stock-Based Compensation**

The Company accounts for employee stock-based compensation in accordance with the guidance of ASC Topic 718, Compensation which requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. The fair value of the equity instrument is charged directly to compensation expense and credited to additional paid-in capital over the period during which services are rendered.

The Company follows ASC Topic 505-50, formerly EITF 96-18, Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods and Services, for stock options and warrants issued to consultants and other non-employees. In accordance with ASC Topic 505-50, these stock options and warrants issued as compensation for services provided to the Company are accounted for based upon the fair value of the services provided or the estimated fair market value of the option or warrant, whichever can be more clearly determined.

**9. Reclassifications**

Certain figures in respect of prior years have been reclassified to conform to the current year presentation.

**10. Newly issued and recently adopted Accounting Pronouncements**

1. In May 2011, the Financial Accounting Standard Board ("FASB") issued an accounting update that amends ASC No. 820, "Fair Value Measurement" regarding fair value measurements and disclosure requirements. The amendments are effective during interim and annual periods beginning after December 15, 2011 and are to be applied prospectively. The accounting update will be applicable to the Company beginning in the third quarter of fiscal year 2012. As applicable to the Company, the adoption of the new guidance is not expected to have a material impact on the consolidated financial statements.
2. In June 2011, the FASB issued an update to ASC No. 220, Presentation of Comprehensive Income, which eliminates the option to present other comprehensive income and its components in the statement of shareholders' equity. The Company can elect to present the items of net income and other comprehensive income in a single continuous statement of comprehensive income or in two separate, but consecutive, statements. Under either method the statement would need to be presented with equal prominence as the other primary financial statements. The amended guidance, which must be applied retroactively, is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011, with earlier

adoption permitted. In December 2011, the FASB issued another update on the topic, which deferred the effective date pertaining only to the presentation of reclassification adjustments on the face of the financial statements. The adoption of the new guidance is not expected to have a material impact on the consolidated financial statements.

**NOTE 2 - COMMITMENTS:**

1. On February 2, 2012 the Subsidiary entered into a licensing agreement with the Licensor According to the agreement, the Subsidiary was granted a worldwide royalty bearing, exclusive license to certain information regarding a molecular and cellular approach directed at converting liver cells into functional insulin producing cells, as treatment for diabetes.

As consideration for the Licensed Information (as defined), the Subsidiary will pay the following to the Licensor:

- a. A royalty of 3.5% of net sales.
- b. 16% of all sublicensing fees received.
- c. An annual license fee of \$15,000, which commenced on January 1, 2012 and shall be paid once every year thereafter (the "Annual Fee"). The Annual Fee is non-refundable, but it shall be credited each year due, against the royalty noted above, to the extent that such are payable, during that year.
- d. Milestone payments as follows:
  1. \$50,000 on the date of initiation of phase I clinical trials in human subjects;
  2. \$50,000 on the date of initiation of phase II clinical trials in human subjects;
  3. \$150,000 on the date of initiation of phase III clinical trials in human subjects;
  4. \$750,000 on the date of initiation of issuance of an approval for marketing of the first Product by the FDA.
  5. \$2,000,000, when worldwide net sales of Products have reached the amount of \$150,000,000 for the first time, (The "Sales Milestone").
  6. In the event of closing of an acquisition of all of the issued and outstanding share capital of the subsidiary of the company and/or consolidation of the Subsidiary or the Company into or with another corporation ("Exit"), the Licensor shall be entitled to choose whether to receive from the Company a one-time payment based, as applicable, on the value of either 5,563,809 shares of Common Stock of the Company at the time of the Exit or the value of 1,000 common shares of the subsidiary at the time of the Exit.

There was no upfront payment by the Company as part of the licensing agreement.

2. On February 2, 2012 the Company entered into an agreement with Mintz, Levin, Ferris, Glovsky and Popeo, P.c. for professional services related to the patent registration. In addition to an amount of \$80,000 paid to this service provider, the Company issued 1,390,952 shares of common stock that will be held in escrow for two years. As a result of the escrow, the fair value of these shares issued for services were \$509,622 based on a 34.57% discount calculated, on the price per share on February 2, 2012. The Company will pay an additional \$50,000 upon consummation of the earlier of:
  1. The purchase of all the Company's common shares and/or amalgamation of Company or the Subsidiary into or with another Corporation.
  2. The Company sublicensing the technology to a non-affiliate of the Company.
  3. \$20,000 upon each of the following milestones (but in any event no more than \$50,000 in total):



**NOTE 2 - COMMITMENTS:** (continued):

1. Initiation by the Company of phase I clinical trials for the Company's product in Human subjects.
  2. Initiation by the Company of phase II clinical trials in human subjects.
  3. Initiation by the Company of phase III clinical trials in human subjects.
3. On February 2, 2012, the Company entered into a consultancy agreement with Weinberg Dalyo Inc, for financial consulting services for a consideration of \$3,000 per month. During the period of this agreement, if the consultant locates an investor, which the Company enters into a binding investment agreement, the consultant is entitled to 2% from the total investment in cash.
  4. On February 2, 2012, the Company entered into an agreement with Ms. Vered Caplan to serve as the Company's Chairman of the Board of Directors for a consideration of NIS 10,000 ( \$2,655 as of February 29,2012 ) per month . In the event the Company receives an aggregate financing of at least \$2,000,000 while she is still serving as a member of the Board of Directors, she will be entitled to a one-time payment in the amount of \$100,000.

**NOTE 3 - SHARE CAPITAL:**

1. Share capital:

The share capital is composed of common stock of \$0.0001 par value each: 1,750,000,000 shares authorized at February 29, 2012 and February 28, 2011; 48,517,903 and 80,500,000 shares issued and outstanding at February 29, 2012 and November 30, 2011 .

On February 2, 2012, two of the Company's shareholders have cancelled 33,873,049 of the common stock of the Company held by them in connection with the capital raising and other changes in the capital.

2. Financing:

On February 2, 2012 the Company entered into a subscription agreement for the sale of 500,000 shares of the Company's common stock at a purchase price of \$1.00 per share, for total consideration of \$500,000. Under the agreement the subscribers committed to purchase additional 1,000,000 shares of the Company's common stock at a purchase price of \$1.00 per share. Half of the shares will be issued for an additional consideration of \$500,000, upon the earlier of: (i) the Company or its Subsidiary signing an agreement with a clinical center, and (ii) 6 months following the closing of the placement of shares, and the other half of the shares will be issued for an additional consideration of \$500,000, upon the feasibility of enhancement of cell propagation capability if achieve from three years from closing.

**NOTE 4 STOCK BASED COMPENSATION**

1. On February 2, 2012, 2,781,905 options were granted to Prof. Sara Ferber, the Company's Chief Scientific Officer, at an exercise price of \$0.0001 per share. The options vest in twelve equal monthly installments from the date of grant and expire on February 2, 2022 .The fair value of these options on the date of grant was \$1,557,867 using the Black and Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 101%; risk free interest of 1.86%, and an expected life of 10 years.



2. On February 2, 2012, 2,781,905 options were granted to Mr Jacob BenArie, the Company's CEO, at an exercise price of \$0.69 per share, the options vest in twelve equal quarterly installments from the date of grant and expire on February 2, 2022. The fair value of these options as of the date of grant was \$1,383,421 using the Black and Scholes option-pricing model based on the following assumptions: dividend yield of 0% for all years; expected volatility of 101%; risk free interest of 1.86%, and an expected life of 10 years.

The fair value of each option grant is estimated on the date of grant using the Black Scholes option-pricing model with the following assumptions:

	For options granted during the three months ended February 29, 2012
Expected option life (years)	10.0
Expected stock price volatility (%)	101%
Risk free interest rate (%)	1.86
Expected dividend yield (%)	0.0

A summary of the status of the stock options granted to employees as of February 29, 2012 and changes for the three months ended February 29, 2012 is presented below:

	<b>Three months ended February 29, 2012</b>	
	<b>Number of options</b>	<b>Weighted average exercise price \$</b>
Options outstanding at beginning of year	-	-
Changes during the year:		
Granted - at market price	5,563,810	0.345
Expired	-	-
Options outstanding at end of the period	5,563,810	-
Options exercisable at end of the period	-	-

Costs incurred in respect of stock based compensation for employees, for the three months ended ended February 29, 2012 and February 28, 2011 were \$149,335 and \$0, respectively. The weighted average period of the remaining unearned compensation of \$2,791,953 at February 29, 2012 will be recorded over 1.9 years.

The following table presents summary information concerning the options granted to employees outstanding as of February 29, 2012:

<b>Exercise prices \$</b>	<b>Number outstanding</b>	<b>Remaining Contractual Life Years</b>	<b>intrinsic value \$</b>
0.0001	2,781,905	9.93	1,919,236
0.69	2,781,905	9.93	-
	5,563,810	9.93	1,919,236

As of February 29, 2012 the options granted to employees are not exercisable.

#### **NOTE 5 TAXES ON INCOME**

##### **1. Corporate taxation in the U.S.**

The applicable corporate tax rate for the Company is 34%.

##### **2. Corporate taxation in Israel:**

The Subsidiary is taxed in accordance with Israeli tax laws. The regular corporate tax rate in Israel for 2012 is 25%.

**3. Deferred income taxes:**

	<b>February 29 2012</b>	<b>November 30 2011</b>
In respect of:		
Net operating loss carryforward	\$ 279,375	\$ 46,810
R&D expenses	\$ 1,235	\$ 0
Vacation accrual	\$ 534	\$ 0
Less - Valuation allowance	\$ 281,144	(46,810)
Net deferred tax assets	\$ ,-,	\$ ,-,

Realization of deferred tax assets is dependent upon sufficient future taxable income during the period that deductible temporary differences and carryforwards are expected to be available to reduce taxable income. As the achievement of required future taxable income is uncertain, the Company recorded a full valuation allowance.

**NOTE 6 - SUBSEQUENT EVENT**

On March 2, 2012 the Subsidiary entered into a research service agreement with the Licensor. According to the agreement, the Licensor will perform a study at the facilities and use the equipment and personnel of the Chaim Sheba Medical Center (the "Hospital"), for the total consideration of approximately \$74,000.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### Forward-Looking Statements

This report contains forward-looking statements. Forward-looking statements are projections in respect of 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 of these terms or other comparable terminology. Forward-looking statements made in a quarterly report on Form 10-Q includes statements about:

- our intention to develop to the clinical stage a new technology for regeneration of functional insulin-producing cells, thus enabling normal glucose regulated insulin secretion, via cell therapy;
- our belief that our treatment seems to be safer than other options;
- our belief that our major competitive advantage is in our cell transformation technology;
- our expectation that the demand for our products will eventually increase; and
- our expectation that we will be able to raise capital when we need it.

These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks in the section entitled "Risk Factors" and the risks set out below, any of which 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. These risks include, by way of example and not in limitation:

- general economic and business conditions;
- our ability to identify attractive products and negotiate their acquisition or licensing;
- our ability to effectively develop and market products that we acquire or license;
- volatility in prices for our products;
- risks inherent in the pharmaceutical industry;
- competition for, among other things, capital, pharmaceutical products and skilled personnel; and
- other factors discussed under the section entitled "Risk Factors".

These risks may cause our company's or our industry's actual results, levels of activity or performance to be materially different from any future results, levels of activity or performance 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 or performance. 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.

## Edgar Filing: Orgenesis Inc. - Form 10-Q

As used in this quarterly report on Form 10-Q and unless otherwise indicated, the terms "we", "us", "our", or the Company refer to Orgenesis Inc. and our wholly owned subsidiary, Orgenesis Ltd., an Israeli corporation (the "Subsidiary"). Unless otherwise specified, all dollar amounts are expressed in United States dollars.

### *Corporate Overview*

We were incorporated in the state of Nevada on June 5, 2008, under the name Business Outsourcing Services, Inc.

Effective August 31, 2011, we completed a merger with our subsidiary, Orgenesis Inc., a Nevada corporation which was incorporated solely to effect a change in our name. As a result, we changed our name from "Business Outsourcing Services, Inc." to "Orgenesis Inc."

Effective August 31, 2011 we effected a 35 to one forward stock split of our authorized and issued and outstanding common stock. As a result, our authorized capital has increased from 50,000,000 shares of common stock with a par value of \$0.001 to 1,750,000,000 shares of common stock with a par value of \$0.0001. Unless otherwise noted, all references in this quarterly report to number of shares, price per share or weighted average number of shares outstanding have been adjusted to reflect the stock split on a retroactive basis.

### *Our Current Business*

We were previously engaged in the business of providing online accounting and bookkeeping services to small and medium sized companies who seek to save money by outsourcing these services.

On August 5, 2011, we entered into a letter of intent with Prof. Sarah Ferber and Ms. Vered Caplan according to which, inter alia, Prof. Ferber has agreed to use commercially reasonable efforts to cause Tel Hashomer Medical Research, Infrastructure and Services Ltd (the "Licensor") to license all of the assets associated with "Methods Of Inducing Regulated Pancreatic Hormone Production" and "Methods Of Inducing Regulated Pancreatic Hormone Production In Non-Pancreatic Islet Tissues", as defined.

On October 11, 2011 we incorporated Orgenesis Ltd. as our wholly-owned subsidiary under the laws of Israel. On February 2, 2012, Orgenesis Ltd. signed and closed a definitive agreement (the License Agreement ) to license patents and knowhow related to the development of AIP (Autologous Insulin Producing) cells.

Based on the licensed know how and patents, our intention is to develop to the clinical stage a new technology for regeneration of functional insulin-producing cells, thus enabling normal glucose regulated insulin secretion, via cell therapy. By using a therapeutic agent (i.e., PDX-1, or additional pancreatic transcription factors in adenovirus-vector) that efficiently converts a sub-population of liver cells into pancreatic islets phenotype and function, this approach allows the diabetic patient to be the donor of his own therapeutic tissue. The development of AIP cells is based on the licensed patents and knowhow. We believe that our major competitive advantage is in our cell transformation technology.

This technology was licensed based on the published work of Prof. Ferber. Prof. Ferber has developed this technology, as a researcher in Tel Hashomer, and has established a proof of concept that demonstrates the capacity to induce a shift in the developmental fate of cells in liver and convert them into 'pancreatic beta cell like' cells. Furthermore, those cells were found to be resistant to the autoimmune attack.

We intend to develop our business by further developing the technology to a clinical stage. We intend to dedicate most of our capital to research and development with no expectation of revenue from product sales in the foreseeable future.

### **Results of Operations**

The following summary of our results of operations should be read in conjunction with our condensed financial statements for the three months ended February 29, 2012.



Edgar Filing: Orgenesis Inc. - Form 10-Q

Our operating results for the three months ended February 29, 2012 are summarized as follows in comparison to our operating results for the three months ended February 28, 2011:

	<b>Three Months Ended</b>	
	<b>February 29, 2012</b>	<b>February 28, 2011</b>
Research and development expenses <sup>(1)</sup>	\$ 719,671	-
General and administration expenses	\$ 134,091	\$ 5,436
Net Loss	\$ 853,861	\$ 5,436

(1)The amount includes compensation expenses of \$589,622 to our patent lawyer s related to the patent registration. The compensation is in stock based and cash.

*Revenue*

We have not earned any revenues since our inception and we do not anticipate earning revenues in the near future.

*Research and development expenses*

	<b>Three Months Ended</b>	
	<b>February 29, 2012</b>	<b>February 28, 2011</b>
Patents Registrations	\$ 589,622	\$ -
Salaries and related expenses	\$ 127,549	\$ -
Others	\$ 2,500	\$ -
Total	\$ 719,671	\$ -

The increase in our research and development expenses compared to the same period last year is mainly because of legal expenses to our patent lawyer s related to the patent registration, and Stock based compensation related to options granted to employees.

General and Administrative Expenses

	<b>Three Months Ended</b>	
	<b>February 29, 2012</b>	<b>February 28, 2011</b>
Accounting and Legal	\$ 47,106	\$ 4,253
Transfer agent and filing fees	\$ 2,793	\$ 975
General and Administrative	\$ 84,192	\$ 208
Total	\$ 134,091	\$ 5,436

The increase in our expenses compared to the same period last year is because of expenses to our legal adviser in respect of the changing of the Company's operations and business model.

**Liquidity and Financial Condition**

*Working Capital*

	<b>February 29 2012</b>	<b>February 28 2011</b>
Current Assets	\$ 353,794	\$ 7,210
Current Liabilities	\$ 159,710	\$ 22,967
Working Capital (Deficiency)	\$ 194,084	\$ (15,757)

The increase in our working capital as at February 29, 2012, as compared to February 28, 2011, is due to the closing of a financing (the Financing ) on February 2, 2012. The Financing consisted of the sale of 500,000 units (each, a Unit ) at a purchase price of \$1.00 per Unit, for total consideration of \$500,000. Each Unit is comprised of one common

share in our capital (each, a Share ) and two non-transferrable share purchase warrants (each, a "Warrant").

*Cash Flows*

	<b>February 29 2012</b>	<b>February 28 2011</b>
Net cash from (used in) operations	\$ (119,155)	\$ 5,746
Net cash provided by financing activities	\$ 471,661	\$ -
Increase (Decrease) in Cash During the Period	\$ 352,506	\$ 5,746

The increase in net cash compared to the same period last year is because of the closing of the Financing, which was partly offset by legal expenses relating to the change in the Company's operations and business model and the costs of the Company's patents registration.

**Going Concern**

The accompanying unaudited interim condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company has net losses for the period from inception (June 5, 2008) through February 29, 2012, of \$1,260,845 as well as negative cash flow from operating activities. Presently, the Company does not have sufficient cash resources to meet its requirements in the twelve months following February 29, 2012. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management is in the process of evaluating various financing alternatives, as the Company will need to finance future research and development activities and general and administrative expenses through fund raising in the public or private equity markets. Although there is no assurance that the Company will be successful with those initiatives, management believes that it will be able to secure the necessary financing as a result of ongoing financing discussions with third party investors and existing shareholders, including via future issuance of 1,000,000 Shares in a total amount of \$1,000,000 pursuant to the Warrants.

These consolidated financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern. The Company's continuation as a going concern is dependent on its ability to obtain additional financing as may be required and ultimately to attain profitability.

**Cash Requirements**

Our primary objectives for the next twelve month period are to further develop the technology of producing AIP cells and to advance the technology so that it may be appropriate for clinical safety testing.

Our plan of operation over the next 12 months is to:

- initiate regulatory activities in Asia, Europe and USA;
- collaborate with clinical center, specifically those performing Pancreatic Islet transplantations, in order to carry out clinical studies;
- locate suitable centers and sign a collaboration agreement;
- Identify optional technologies for scale up of the cells production process (this activity will be carried out at subcontracted facilities of Sheba Medical Center);
- initialize efforts to validate the manufacturing process (in certified labs); and

- raise sufficient capital to perform initial clinical safety testing.

We estimate our operating expenses and working capital requirements for the next 12 months to be as follows:

<b>Expense</b>		<b>Amount</b>
Product development	\$	153,506
Employee compensation		570,394
General and administration		38,552
Professional services fees		372,131
Regulation and compliance		107,000
Business development		270,000
<b>Total:</b>	<b>\$</b>	<b>1,511,585</b>

### **Future Financing**

We will require additional funds to implement our growth strategy for our new business. These funds may be raised through equity financing, debt financing, or other sources, which may result in further dilution in the equity ownership of our shares. Our only current source of funding is the exercise of the Warrants pursuant to the Financing. Each Warrant is exercisable into one additional Share and shall expire after three years. The holders of such Warrants must exercise half of their Warrants, at a price of \$1.00 per Share, for additional equity of \$500,000, upon the earlier of: (i) our company or our subsidiary signing an agreement with a clinical center, and (ii) 6 months following the closing of such placement of Units, and the other half, at a price of \$1.00 per Share, for additional equity of \$500,000, upon the feasibility of enhancement of cell propagation capability for three years from closing.

There can be no assurance that additional financing will be available to us when needed or, if available, that it can be obtained on commercially reasonable terms. If we are not able to obtain the additional financing on a timely basis should it be required, or generate significant material revenues from operations, we will not be able to meet our other obligations as they become due and we will be forced to scale down or perhaps even cease our operations.

### **Off Balance Sheet Arrangements**

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to stockholders.

### **Significant Accounting Policies**

Our significant accounting policies are more fully described in the notes to our condensed consolidated financial statements included in our annual report on Form 10-K for the fiscal year ended November 30, 2011. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

#### *Income Taxes*

Deferred taxes are determined utilizing the asset and liability method based on the estimated future tax effects of differences between the financial accounting and tax bases of assets and liabilities under the applicable tax laws. Deferred tax balances are computed using the tax rates expected to be in effect when those differences reverse. A valuation allowance in respect of deferred tax assets is provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. We have provided a full valuation allowance with respect to its deferred tax assets.

#### *Stock-Based Compensation*

We granted options to purchase shares of our common stock to employees and non-employees.

We account for share-based payments in accordance with the guidance that requires awards classified as equity awards be accounted for using the grant-date fair value method. The fair value of share-based payment transactions is recognized as an expense over the requisite service period, net of estimated forfeitures.

We elected to recognize compensation cost for an award with only service conditions that has a graded vesting schedule using the accelerated method based on the multiple-option award approach.

When stock based compensation are granted as consideration for services provided by consultants and other non-employees, the transaction is accounted for based on the fair value of the consideration received or the fair value of the stock based compensation issued, whichever is more reliably measurable, pursuant to the guidance. The fair value of the stock based compensation is measured on each reporting date, and the gains (losses) are recorded to earnings over the related service period using the straight-line method.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not Applicable

### **ITEM 4. CONTROLS AND PROCEDURES**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our president and chief executive officer (who is our principal executive officer) and our chief financial officer, treasurer, and secretary (who is our principal financial officer and principal accounting officer) to allow for timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As of February 29, 2012, the end of the three month period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer and principal accounting officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on the foregoing, we concluded that our disclosure controls and procedures were ineffective as of the end of the period covered by this quarterly report due to the three material weaknesses that were identified in our annual report on Form 10-K for the fiscal year ended November 30, 2011.

#### *Management's Remediation Initiatives*

In an effort to remediate the identified material weaknesses and other deficiencies and enhance our internal controls, we have initiated, the following series of measures:

During the three months ended February 29, 2012, we appointed a professional outsourcing service as our bookkeepers and financial advisors. It will act as our external controller.

After February 29, 2012, we appointed a new director to our board of directors. We plan to appoint two more outside directors to our board of directors and form an audit committee comprised of independent directors. We plan that this audit committee will undertake the oversight of establishing and monitoring required internal controls and procedures, such as reviewing and approving estimates and assumptions made by management when funds are available to us.

Management believes that the appointment of one or more outside directors, who shall be appointed to a fully functioning audit committee, will remedy the lack of a functioning audit committee and a lack of a majority of outside directors on our board of directors.

*Changes in internal control over financial reporting*

Besides the changes discussed above under the heading "Management's Remediation Initiatives", there were no changes in our internal control over financial reporting during the three months ended February 29, 2012 that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

**PART II OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

We know of no material pending legal proceedings to which our company or our subsidiary is a party or of which any of our properties, or the properties of our subsidiary, is the subject. In addition, we do not know of any such proceedings contemplated by any governmental authorities.

We know of no material proceedings in which any of our directors, officers or affiliates, or any registered or beneficial stockholder is a party adverse to our company or our subsidiary or has a material interest adverse to our company or our subsidiary.

**ITEM 1A. RISK FACTORS**

An investment in our common stock involves a number of very significant risks. You should carefully consider the following risks and uncertainties in addition to other information in this report in evaluating our company and its business before purchasing shares of our company's common stock. Our business, operating results and financial condition could be seriously harmed due to any of the following risks. You could lose all or part of your investment due to any of these risks.

**Risks Related to Our Company**

*The worldwide economic downturn may reduce our ability to obtain the financing necessary to continue our business and may reduce the number of viable products and businesses that we may wish to acquire. If we cannot raise the funds that we need or find a suitable product or business to acquire, we may go out of business and investors will lose their entire investment in our company.*

Since 2008, there has been a downturn in general worldwide economic conditions due to many factors, including the effects of the subprime lending and general credit market crises, slower economic activity, decreased consumer confidence, reduced corporate profits and capital spending, adverse business conditions, increased unemployment and liquidity concerns. In addition, these economic effects, including the resulting recession in various countries and slowing of the global economy, will likely result in fewer business opportunities as companies face increased financial hardship. Tightening credit and liquidity issues will also result in increased difficulties for our company to raise capital for our continued operations. We may not be able to raise money through the sale of our equity securities or through borrowing funds on terms we find acceptable. If we cannot raise the funds that we need or find a suitable product or business to acquire, we will go out of business. If we go out of business, investors will lose their entire investment in our company.

*Our independent auditors have expressed substantial doubt about our ability to continue as a going concern.*

We have not generated any revenue from operations since our incorporation. We expect that our operating expenses will increase over the next 12 months as we ramp-up our business. We have net losses for the period from inception (June 5, 2008) through February 29, 2012, of \$991,534 as well as negative cash flow from operating activities. Presently, we do not have sufficient cash resources to meet our requirements in the twelve months following February 29, 2012. This amount could increase if we encounter difficulties that we cannot anticipate at this time. As we cannot



assure a lender that we will be able to successfully acquire and develop pharmaceutical assets, we will almost certainly find it difficult to raise debt financing from traditional lending sources. If we cannot raise the money that we need in order to continue to operate our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these were to occur, there is a substantial risk that our business would fail.

If we are unable to meet our debt service obligations and other financial obligations, we could be forced to restructure or refinance, seek additional equity capital or sell our assets. We might then be unable to obtain such financing or capital or sell our assets on satisfactory terms

*We may need to raise additional funds in the future which may not be available on acceptable terms or at all.*

We may consider issuing additional debt or equity securities in the future to fund potential acquisitions or investments, to refinance existing debt, or for general corporate purposes. If we issue equity or convertible debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we incur additional debt, it may increase our leverage relative to our earnings or to our equity capitalization, requiring us to pay additional interest expenses. We may not be able to market such issuances on favorable terms, or at all, in which case, we may not be able to develop or enhance our products, execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated customer requirements.

*We are an early-stage company with a limited operating history, which may hinder our ability to successfully meet our objectives.*

We are an early-stage company with only a limited operating history upon which to base an evaluation of our current business and future prospects. As a result, the revenue and income potential of our business is unproven. In addition, because of our limited operating history, we have limited insight into trends that may emerge and affect our business. Errors may be made in predicting and reacting to relevant business trends and we will be subject to the risks, uncertainties and difficulties frequently encountered by early-stage companies in evolving markets. We may not be able to successfully address any or all of these risks and uncertainties. Failure to adequately do so could cause our business, results of operations and financial condition to suffer.

*Because our directors and officers are not all residents of the United States, investors may find it difficult to enforce, within the United States, any judgments obtained against our sole director and officer.*

Our directors and officer are not all residents of 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 directors and officers, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any state thereof.

*If we are unable to successfully recruit and retain qualified personnel, we may not be able to continue our operations.*

In order to successfully implement and manage our business plan, we will depend upon, among other things, successfully recruiting and retaining qualified personnel having experience in the pharmaceutical industry. Competition for qualified individuals is intense. We may not be able to find, attract and retain qualified personnel on acceptable terms. If we are unable to find, attract and retain qualified personnel with technical expertise, our business operations could suffer.

*Future growth could strain our resources, and if we are unable to manage our growth, we may not be able to successfully implement our business plan.*

We hope to experience rapid growth in our operations, which will place a significant strain on our management, administrative, operational and financial infrastructure. Our future success will depend in part upon the ability of our executive officers to manage growth effectively. This will require that we hire and train additional personnel to manage our expanding operations. In addition, we must continue to improve our operational, financial and management controls and our reporting systems and procedures. If we fail to successfully manage our growth, we may be unable to execute upon our business plan.



## **Risks Relating to our Operations in Israel**

*Conditions in Israel and the surrounding Middle East may materially adversely affect our subsidiaries' operations and personnel.*

Our subsidiary has significant operations in Israel, including research and development. Since the establishment of the State of Israel in 1948, a number of armed conflicts and terrorist acts have taken place, which in the past, and may in the future, lead to security and economic problems for Israel. In addition, certain countries in the Middle East adjacent to Israel, including Egypt and Syria, recently experienced and some continue to experience political unrest and instability marked by civil demonstrations and violence, which in some cases resulted in the replacement of governments and regimes. Current and future conflicts and political, economic and/or military conditions in Israel and the Middle East region may affect our operations in Israel. The exacerbation of violence within Israel or the outbreak of violent conflicts involving Israel may impede our subsidiary's ability to engage in research and development, or otherwise adversely affect its business or operations. In addition, our subsidiary's employees in Israel may be required to perform annual mandatory military service and are subject to being called to active duty at any time under emergency circumstances. The absence of these employees may have an adverse effect on our subsidiary's operations. Hostilities involving Israel may also result in the interruption or curtailment of trade between Israel and its trading partners, which could materially adversely affect our results of operations.

*The ability of our subsidiary to pay dividends is subject to limitations under Israeli law and dividends paid and loans extended by our subsidiary may be subject to taxes.*

The ability of our subsidiary to pay dividends is governed by Israeli law, which provides that dividends may be paid by an Israeli corporation only out of its earnings as defined in accordance with the Israeli Companies Law of 1999, provided that there is no reasonable concern that such payment will cause such subsidiary to fail to meet its current and expected liabilities as they come due. Cash dividends paid by an Israeli corporation to United States resident corporate parents are subject to provisions of the Convention for the Avoidance of Double Taxation between Israel and the United States, which may result in our subsidiary having to pay taxes on any dividends it declares.

## **Risks Relating to the Pharmaceutical Business**

*THM may cancel the License Agreement.*

Pursuant to the terms of the License Agreement, we are required to submit to THM the Development Plan within 18 months from the date of the License Agreement. We must develop, manufacture, sell and market the Products pursuant to the milestones and time schedule specified in the Development Plan. In the event we fail to fulfill the terms of the Development Plan, THM shall be entitled to terminate the License Agreement by providing us with written notice of such a breach and we do not cure such breach within one year of receiving the notice. If THM cancels the License Agreement, our business may be materially adversely affected. THM may also terminate the License Agreement if we breach an obligation contained in the License Agreement and do not cure it within 180 days of receiving notice of the breach.

*If we are unable to successfully acquire, develop or commercialize new products, our operating results will suffer.*

Our future results of operations will depend to a significant extent upon our ability to successfully develop and commercialize new products and businesses in a timely manner. There are numerous difficulties in, developing and commercializing new products, including:

- there are still major developmental steps required to bring the product to a clinical testing stage; clinical testing may not be positive;
- developing, testing and manufacturing products in compliance with regulatory standards in a timely manner;

- failure to receive requisite regulatory approvals for such products in a timely manner or at all;

- developing and commercializing a new product is time consuming, costly and subject to numerous factors, including legal actions brought by our competitors, that may delay or prevent the development and commercialization of new products;
- incomplete, unconvincing or equivocal clinical trials data;
- experiencing delays or unanticipated costs;
- significant and unpredictable changes in the payer landscape, coverage and reimbursement for our products;
- experiencing delays as a result of limited resources at FDA or other regulatory agencies.
- changing review and approval policies and standards at FDA and other regulatory agencies.

As a result of these and other difficulties, products in development by us may or may not receive timely regulatory approvals, or approvals at all, necessary for marketing by us or other third-party partners. If any of our products are not approved in a timely fashion or, when acquired or developed and approved, cannot be successfully manufactured, commercialized or reimbursed, our operating results could be adversely affected. We cannot guarantee that any investment we make in developing products will be recouped, even if we are successful in commercializing those products.

*Our expenditures may not result in commercially successful products.*

We cannot be sure our business expenditures will result in the successful acquisition, development or launch of products that will prove to be commercially successful or will improve the long-term profitability of our business. If such business expenditures do not result in successful acquisition, development or launch of commercially successful brand products our results of operations and financial condition could be materially adversely affected.

*Third parties may claim that we infringe their proprietary rights and may prevent us from manufacturing and selling some of our products.*

The manufacture, use and sale of new products that are the subject of conflicting patent rights have been the subject of substantial litigation in the pharmaceutical industry. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. Litigation may be costly and time-consuming, and could divert the attention of our management and technical personnel. In addition, if we infringe on the rights of others, we could lose our right to develop, manufacture or market products or could be required to pay monetary damages or royalties to license proprietary rights from third parties. Although the parties to patent and intellectual property disputes in the pharmaceutical industry have often settled their disputes through licensing or similar arrangements, the costs associated with these arrangements may be substantial and could include ongoing royalties. Furthermore, we cannot be certain that the necessary licenses would be available to us on commercially reasonable terms, or at all. As a result, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products, and could have a material adverse effect on our business, results of operations, financial condition and cash flows.

*Extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing and distribution capabilities.*

All pharmaceutical companies are subject to extensive, complex, costly and evolving government regulation. For the U.S., this is principally administered by the FDA and to a lesser extent by the DEA and state government agencies, as well as by varying regulatory agencies in foreign countries where products or product candidates are being manufactured and/or marketed. The Federal Food, Drug and Cosmetic Act, the Controlled Substances Act and other federal statutes and regulations, and similar foreign statutes and regulations, govern or influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of our products.



Under these regulations, we may become subject to periodic inspection of our facilities, procedures and operations and/or the testing of our products by the FDA, the DEA and other authorities, which conduct periodic inspections to confirm that we are in compliance with all applicable regulations. In addition, the FDA and foreign regulatory agencies conduct pre-approval and post-approval reviews and plant inspections to determine whether our systems and processes are in compliance with GMP and other regulations. Following such inspections, the FDA or other agency may issue observations, notices, citations and/or warning letters that could cause us to modify certain activities identified during the inspection. FDA guidelines specify that a warning letter is issued only for violations of regulatory significance for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action. We may also be required to report adverse events associated with our products to FDA and other regulatory authorities. Unexpected or serious health or safety concerns would result in labeling changes, recalls, market withdrawals or other regulatory actions.

The range of possible sanctions includes, among others, FDA issuance of adverse publicity, product recalls or seizures, fines, total or partial suspension of production and/or distribution, suspension of the FDA's review of product applications, enforcement actions, injunctions, and civil or criminal prosecution. Any such sanctions, if imposed, could have a material adverse effect on our business, operating results, financial condition and cash flows. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Similar sanctions as detailed above may be available to the FDA under a consent decree, depending upon the actual terms of such decree. If internal compliance programs do not meet regulatory agency standards or if compliance is deemed deficient in any significant way, it could materially harm our business.

For Europe, the European Medicines Agency ( **EMA** ) will regulate our products. Regulatory approval by the EMA will be subject to the evaluation of data relating to the quality, efficacy and safety of our products for its proposed use. The time taken to obtain regulatory approval varies between countries. Different regulators may impose their own requirements and may refuse to grant, or may require additional data before granting, an approval, notwithstanding that regulatory approval may have been granted by other regulators. Regulatory approval may be delayed, limited or denied for a number of reasons, including insufficient clinical data, the product not meeting safety or efficacy requirements or any relevant manufacturing processes or facilities not meeting applicable requirements.

Further trials and other costly and time-consuming assessments of the product may be required to obtain or maintain regulatory approval. Medicinal products are generally subject to lengthy and rigorous pre-clinical and clinical trials and other extensive, costly and time-consuming procedures mandated by regulatory authorities. We may be required to conduct additional trials beyond those currently planned, which could require significant time and expense.

*The pharmaceutical industry is highly competitive.*

The pharmaceutical industry has an intensely competitive environment that will require an ongoing, extensive search for technological innovations and the ability to market products effectively, including the ability to communicate the effectiveness, safety and value of products to healthcare professionals in private practice, group practices and payers in managed care organizations, group purchasing organizations and Medicare & Medicaid services. We are smaller than almost all of our competitors. Most of our competitors have been in business for a longer period of time than us, have a greater number of products on the market and have greater financial and other resources than we do. Furthermore, recent trends in this industry are toward further market consolidation of large drug companies into a smaller number of very large entities, further concentrating financial, technical and market strength and increasing competitive pressure in the industry. If we directly compete with them for the same markets and/or products, their financial strength could prevent us from capturing a profitable share of those markets. It is possible that developments by our competitors will make any products or technologies that we acquire noncompetitive or obsolete.

### **Risks Relating to Our Common Stock**

*If we issue additional shares in the future, it will result in the dilution of our existing shareholders.*



Our articles of incorporation authorize the issuance of up to 1,750,000,000 shares of common stock with a par value of \$0.0001 per share. Our board of directors may choose to issue some or all of such shares to acquire one or more companies or products and to fund our overhead and general operating requirements. The issuance of any such shares will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our common stock. If we issue any such additional shares, such issuance will reduce the proportionate ownership and voting power of all current shareholders. Further, such issuance may result in a change of control of our corporation.

*Trading of our stock is restricted by the Securities Exchange Commission's penny stock regulations, which may limit a stockholder's ability to buy and sell our common 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 broker-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-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 Securities and Exchange Commission, which provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-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-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-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 broker-dealers to trade our securities. We believe that the penny stock rules discourage investor interest in and limit the marketability of our common stock.

*FINRA 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 Financial Industry Regulatory Authority (known as **FINRA**) has adopted rules that require that in recommending an investment to a customer, a broker-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, broker-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, FINRA believes that there is a high probability that speculative low priced securities will not be suitable for at least some customers. FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our stock and have an adverse effect on the market for our shares.

*Our common stock is illiquid and the price of our common stock may be negatively impacted by factors which are unrelated to our operations.*

Although our common stock is currently listed for quotation on the OTC Bulletin Board, there is no market for our common stock. Even when a market is established and trading begins, trading through the OTC Bulletin Board is frequently thin and highly volatile. There is no assurance that a sufficient market will develop in our stock, in which case it could be difficult for shareholders to sell their stock. The market price of our common stock could fluctuate substantially due to a variety of factors, including market perception of our ability to achieve our planned growth, quarterly operating results of our competitors, trading volume in our common stock, changes in general conditions in the economy and the financial markets or other developments affecting our competitors or us. In addition, the stock market is subject to extreme price and volume fluctuations. This volatility has had a significant effect on the market price of securities issued by many companies for reasons unrelated to their operating performance and could have the same effect on our common stock.



*We do not intend to pay dividends on any investment in the shares of stock of 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 investment in our company will need to come through an increase in the stock's price. This may never happen and investors may lose all of their investment in our company.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not Applicable

**ITEM 5. OTHER INFORMATION**

None

**ITEM 6. EXHIBITS**

No.	Description
3.1	Articles of Incorporation (incorporated by reference to an exhibit to a registration statement on Form S-1 filed on April 2, 2009)
3.2	Certificate of Change (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 2, 2011)
3.3	Articles of Merger (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 2, 2011)
3.4	Certificate of Amendment to Articles of Incorporation (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 21, 2011)
3.5	Amended and Restated Bylaws (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 21, 2011)
3.6	Certificate of Correction dated February 27, 2012 (incorporated by reference to an exhibit to a current report on Form 8-K/A filed on March 16, 2012)
10.1	Form of Private Placement Subscription Agreement (incorporated by reference to an exhibit to a current report on Form 8-K filed on February 8, 2012)
10.2	Licensing Agreement dated February 2, 2012 with Tel Hashomer - Medical Research, Infrastructure and Services Ltd. (incorporated by reference to an exhibit to a current report on Form 8-K filed on February 8, 2012)
10.3	Employment Agreement dated February 2, 2012 between our company and Prof. Sarah Ferber (incorporated by reference to an exhibit to a current report on Form 8-K filed on February 8, 2012)
10.4	Stock Option Agreement dated February 2, 2012 between our company, Prof. Sarah Ferber and Clark Wilson LLP (incorporated by reference to an exhibit to a current report on Form 8-K filed on February 8,

	2012)
10.5	Fee Service Agreement dated February 2, 2012 between our company and Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. (incorporated by reference to an exhibit to a current report on Form 8-K filed on February 8, 2012)
10.6	Compensation Letter dated February 2, 2012 between our company and Vered Caplan (incorporated by reference to an exhibit to a current report on Form 8-K filed on February 8, 2012)
10.7	Personal Employment Agreement with Jacob Ben Arie dated February 2, 2012 (incorporated by reference to our current report on Form 8-K filed on March 13, 2012)

No.	Description
10.8	Consultancy Agreement dated March 2, 2012 with Weinberg Dalyo Inc. (incorporated by reference to our current report on Form 8-K filed on March 13, 2012)
<u>31.1*</u>	<u>Certification Statement of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
<u>31.2*</u>	<u>Certification Statement of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
<u>32.1*</u>	<u>Certification Statement of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
<u>32.2*</u>	<u>Certification Statement of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
101*	Interactive Data Files pursuant to Rule 405 of Regulation S-T.

\*Filed herewith

**SIGNATURES**

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

ORGENESIS INC.

By:

/s/ Jacob BenArie

Jacob Ben Arie

Chief Executive Officer and President

(Principal Executive Officer)

Date: April 19, 2012

/s/ Dov Weinberg

Dov Weinberg

Chief Financial Officer, Treasurer and Secretary

(Principal Financial Officer and Principal Accounting Officer)

Date: April 19, 2012