

iBio, Inc.
Form 10-Q
November 14, 2011

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington D.C. 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 September 30, 2011

OR

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

For the transition period from _____ to _____

Commission File Number 001-53125

iBio, Inc.

(Exact name of small business registrant in its charter)

Delaware

26-2797813

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

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

**9 Innovation Way, Suite 100,
Newark, DE**

19711

*(Address of principal executive
offices)*

(Zip Code)

(302) 355-0650

(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 and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x

No o

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 to submit and post such files).

Edgar Filing: iBio, Inc. - Form 10-Q

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. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting
company

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

Yes

No

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

<i>Class</i>	<i>Outstanding at November 14, 2011</i>
Common Stock, \$0.001 par value	32,382,095 Shares

Edgar Filing: iBio, Inc. - Form 10-Q

iBio, Inc.
FORM 10-Q
For the Three Month Period Ended September 30, 2011

INDEX

	<u>Page</u>
PART I	FINANCIAL INFORMATION
Item 1	Financial Statements
	<u>Condensed balance sheets as of September 30, 2011 (unaudited) and June 30, 2011</u>
	1
	<u>Condensed statements of operations (unaudited) for the three months ended September 30, 2011 and 2010</u>
	2
	<u>Condensed statement of stockholders' equity (unaudited) for the three months ended September 30, 2011</u>
	3
	<u>Condensed statements of cash flows (unaudited) for the three months ended September 30, 2011 and 2010</u>
	4
	<u>Notes to condensed financial statements (unaudited)</u>
	5-12
<u>Item 2</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
	13
<u>Item 3</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
	17
<u>Item 4</u>	<u>Controls and Procedures</u>
	17
PART II	OTHER INFORMATION
	18
<u>Item 1</u>	<u>Legal Proceedings</u>
	18
<u>Item 1A</u>	<u>Risk Factors</u>
	18
<u>Item 6</u>	<u>Exhibits</u>
	18
Signatures	19

PART I FINANCIAL INFORMATION

iBio, Inc.
Condensed Balance Sheets

	As of	
	September 30, 2011 (Unaudited)	June 30, 2011 (Note A)
Assets		
Current assets:		
Cash	\$ 1,522,652	\$ 2,843,300
Accounts receivable	320,348	344,085
Prepaid expenses	296,526	763,583
Other current assets	389,211	349,210
Total current assets	2,528,737	4,300,178
Fixed assets, net	7,353	8,412
Intangible assets, net	3,040,651	3,027,239
Total assets	\$ 5,576,741	\$ 7,335,829
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	\$ 2,980,785	\$ 2,895,359
Accrued expenses	226,579	56,059
Derivative instrument liability	1,483,277	4,187,769
Total liabilities	4,690,641	7,139,187
Commitments and contingencies		
Stockholders equity:		
Preferred stock, no par value, 1,000,000 shares authorized, no shares outstanding	0	0
Common stock, \$0.001 par value, 100,000,000 shares authorized, 32,382,095 issued and outstanding as of September 30, 2011 and June 30, 2011, respectively	32,382	32,382
Additional paid-in capital	26,132,518	25,826,203
Accumulated deficit	(25,278,800)	(25,661,943)
Total stockholders equity	886,100	196,642
Total liabilities and stockholders equity	\$ 5,576,741	\$ 7,335,829

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

iBio, Inc.
Condensed Statements of Operations
(Unaudited)

	Three Months Ended September 30,	
	2011	2010
Revenues	\$ 320,348	\$
Operating expenses:		
Research and development	1,456,640	157,543
General and administrative	1,188,734	1,213,264
Total	2,645,374	1,370,807
Operating loss	(2,325,026)	(1,370,807)
Other income (expense):		
Interest income	1,598	695
Interest expense	(9,576)	(13,125)
Royalty income	11,655	6,698
Change in the fair value of derivative instrument	2,704,492	(1,441,392)
Total	2,708,169	(1,447,124)
Income (loss) before provision for income taxes	383,143	(2,817,931)
Provision for income taxes		
Net income (loss)	383,143	(2,817,931)
Net income (loss) per common share - Basic	\$ 0.01	\$ (0.10)
Net income (loss) per common share - Diluted	\$ 0.01	\$ (0.10)
Weighted average common shares outstanding - Basic	32,382,095	28,272,655
Weighted average common shares outstanding - Diluted	34,670,933	28,272,655

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

iBio, Inc.
Condensed Statement of Stockholders Equity
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance, June 30, 2011	32,382,095	\$ 32,382	\$ 25,826,203	\$ (25,661,943)	\$ 196,642
Share-based compensation			338,292		338,292
Warrants issued for services			(31,977)		(31,977)
Net income				383,143	383,143
Balance, September 30, 2011	32,382,095	\$ 32,382	\$ 26,132,518	\$ (25,278,800)	\$ 886,100

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

iBio, Inc.
Condensed Statements of Cash Flows
(Unaudited)

	Three Months Ended September 30,	
	2011	2010
Cash flows used in operating activities:		
Net income (loss)	\$ 383,143	\$ (2,817,931)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Change in the fair value of derivative instrument liability	(2,704,492)	1,441,392
Depreciation and amortization	79,977	92,870
Share-based compensation expense	338,292	408,767
Issuance of warrants for services	(31,977)	255,907
Changes in operating assets and liabilities:		
Decrease in accounts receivable	23,737	
Decrease (increase) in prepaid expenses and other current assets	427,056	(60,284)
Increase in accounts payable	85,426	153,518
Increase (decrease) in accrued expenses	170,520	(468)
	(1,228,318)	(526,229)
Cash flows used in investing activities		
Additions to intangible assets	(92,330)	(69,877)
	(92,330)	(69,877)
Net decrease in cash		
	(1,320,648)	(596,106)
Cash - Beginning of period	2,843,300	909,932
	\$ 1,522,652	\$ 313,826

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

iBio, Inc.
Notes to Condensed Financial Statements (Unaudited)

NOTE A - BUSINESS

iBio, Inc. (iBio or the Company) is a biotechnology company focused on commercializing its proprietary technology, the iBioLaunch platform, for biologics including vaccines and therapeutic proteins. The Company's strategy is to promote its commercial products through collaborations and license arrangements. iBio expects to receive upfront license fees, milestone revenues, service revenue and royalties on end products. The Company believes its technology offers the opportunity to develop products that might not otherwise be commercially feasible, and to work with both corporate and government clients to reduce their costs during product development and meet their needs for low cost, high quality biologics manufacturing systems. The Company's near-term focus is to establish business arrangements for use of our technology by licensees for the development and production of products for both therapeutic and vaccine uses.

Liquidity and Basis of Presentation

The accompanying financial information at September 30, 2011 and for the three months ended September 30, 2011 and 2010, is unaudited and includes all adjustments (consisting only of normal recurring adjustments) which, in the opinion of management, are necessary to state fairly the condensed financial information set forth therein in accordance with accounting principles generally accepted in the United States of America. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with US GAAP have been omitted as permitted by regulations of the Securities and Exchange Commission. The interim results are not necessarily indicative of results to be expected for the full fiscal year. The balance sheet amounts as of June 30, 2011 were derived from the audited financial statements. These unaudited condensed financial statements should be read in conjunction with the audited financial statements for the year ended June 30, 2011 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission.

The Company has incurred significant losses and negative cash flows from operations since its spinoff from its former parent, Integrated BioPharma, Inc. (IBP) in August 2008. As of September 30, 2011, the Company's accumulated deficit approximated \$25,279,000 and cash used in operations for the three months September 30, 2011 and 2010 approximated \$1,228,000 and \$526,000, respectively. The Company has historically financed its activities through the sale of common stock and warrants. To date, the Company has dedicated most of its financial resources to investing in its iBioLaunch platform, advancing its intellectual property, and general and administrative activities. Cash on hand as of September 30, 2011 was approximately \$1,523,000 and is expected to support the Company's activities through January 2012.

The Company plans to fund its development and commercialization activities through January 2012 and beyond through milestone receipts from licensing arrangements including royalties and/or the sale of equity securities. The Company cannot be certain that such funding will be available on acceptable terms or available at all or that the receipts from its licensing arrangements will be sufficient to cover its operating costs and research and development activities. To the extent that the Company raises additional funds by issuing equity securities, its stockholders may experience significant dilution. If the Company is unable to raise funds when required or on acceptable terms or generate sufficient revenues, it may have to: a) Significantly delay, scale back, or discontinue the development and/or commercialization of one or more product candidates; b) Seek collaborators for product candidates at an earlier stage than would otherwise be desirable and/or on terms that are less favorable than might otherwise be available; or c) Relinquish or otherwise dispose of rights to technologies, product candidates, or products that it would otherwise seek to develop or commercialize itself and possibly cease operations. These matters raise substantial doubt about the Company's ability to continue as a going concern. These financial statements were prepared under the assumption that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of that uncertainty.

In addition to the normal risks associated with a new business venture, there can be no assurance that the Company's research and development will be successfully completed or that any product will be approved or commercially viable.

Edgar Filing: iBio, Inc. - Form 10-Q

iBio, Inc. Notes to Condensed Financial Statements (Unaudited)

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, dependence on collaborative arrangements, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with Food and Drug Administration (FDA) and other governmental regulations and approval requirements.

Significant Accounting Policies.

The Company's significant accounting policies are described in Note B to its audited Financial Statements included in its June 30, 2011 Form 10-K. There have been no significant changes to these policies or changes in accounting pronouncements during the three months ended September 30.

Earnings (Loss) Per Share

Basic earnings per share is computed by dividing net income allocated to common shares by the weighted average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing net income allocated to common shares by the weighted average number of common shares outstanding during the period, plus the dilutive effect of outstanding stock options and warrants using the treasury stock method. For the three months ended September 30, 2010, the Company incurred a loss, therefore, basic and diluted EPS were the same, since the common shares issuable pursuant to the exercise of stock options and warrants in the calculation of diluted net loss per common share have been excluded given that the effect would have been anti-dilutive.

There were 10,009,769 and 6,915,811 options and warrants for the three months ended September 30, 2011 and 2010 that were excluded from the calculation of dilutive earnings per share because they are anti-dilutive.

The following table summarizes our basic and diluted EPS computations for the three months ended September 30, 2011 and 2010:

	Three Months Ended September 30,	
	2011	2010
Net income (loss) for basic and diluted earnings per share calculation	\$ 383,143	\$ (2,817,931)
Weighted average shares for basic earnings per share calculation	32,382,095	28,272,655
Dilutive effect of options and warrants	2,288,838	0
Weighted average shares for diluted earnings per share calculation	34,670,933	28,272,655
Basic net income (loss) per share	\$ 0.01	\$ (0.10)
Dilutive effect of options and warrants per share calculation	\$ 0.00	\$ N/A
Diluted net income (loss) per share	\$ 0.01	\$ (0.10)

Fair Value of Financial Instruments

The Company's financial instruments primarily include cash, accounts receivable, other current assets, accounts payable, and derivative liabilities. Due to the short-term nature of cash, accounts receivable, current assets and accounts payable, the carrying amounts of these assets and liabilities approximate their fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

Edgar Filing: iBio, Inc. - Form 10-Q

iBio, Inc.
Notes to Condensed Financial Statements (Unaudited)

Level 1 - Quoted prices in active markets for identical assets or liabilities.

Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following table sets forth the Company's assets and liabilities measured at fair value on a recurring basis, by input level, in the balance sheet at September 30, 2011 and June 30, 2011.

The Company categorizes its derivative financial instrument liability in Level 2 of the hierarchy. The derivatives are valued using the Black-Scholes model, using assumptions consistent with the determination of fair value. The fair value of the derivative financial instrument liability is based principally on Level 2 inputs. For this liability, the Company developed its own assumptions based on observable inputs or available market data to support the fair value.

Fair value measurement at reporting date using

	Quoted prices In active Market for Identical assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
At September 30, 2011				
Liabilities:				
Recurring				
Derivative financial instrument liability	\$	\$ 1,483,277	\$	\$ 1,483,277
	_____	_____	_____	_____
	Quoted prices In active Market for Identical assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
At June 30, 2011				
Liabilities:				
Recurring				
Derivative financial instrument liability	\$	\$ 4,187,769	\$	\$ 4,187,769
	_____	_____	_____	_____

The above valuations were determined using level 2 inputs. The reconciliation of the derivative financial instrument liability measured at fair value on a recurring basis using observable inputs (Level 2) is as follows:

Edgar Filing: iBio, Inc. - Form 10-Q

iBio, Inc.
Notes to Condensed Financial Statements (Unaudited)

	<u>2011</u>	<u>2010</u>
Balance, June 30,	\$ 4,187,769	\$ 1,714,084
Change in fair value of derivative financial instrument liability	(2,704,492)	1,441,392
	<u> </u>	<u> </u>
Balance, September 30,	<u>\$ 1,483,277</u>	<u>\$ 3,155,476</u>

The fair value of the derivative financial instrument liability is determined using the Black-Scholes option pricing model and is affected by changes in inputs to that model including our stock price, expected stock price, volatility, the contractual term, and the risk-free interest rate.

The assumptions made in calculating the fair value of these derivative instruments as of September 30, 2011 and 2010 and June 30, 2011 were as follows:

	<u>September 30, 2011</u>	<u>June 30, 2011</u>	<u>September 30, 2010</u>
Risk-free interest rate	0.2%	0.41%	0.6%
Dividend yield	None	None	None
Volatility	94.8%	96.7%	98%
Remaining contractual term (in years)	1.9	2.2	2.9

Recently Issued Pronouncements

In May 2011, the Financial Accounting Standards Board (FASB) issued new guidance for fair value measurements to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and International Financial Reporting Standards. The guidance changes certain fair value measurement principles and enhances the disclosure requirements, particularly for level 3 fair value measurements. The guidance is effective for interim and annual periods beginning after December 15, 2011. The adoption of this standard for fair value measurements is not expected to have a material effect on the Company's financial position, results of operations, and cash flows.

iBio, Inc.
Notes to Condensed Financial Statements (Unaudited)

NOTE B INTANGIBLE ASSETS

Intangible assets consist of the following:

	September 30, 2011	June 30, 2011
	<u> </u>	<u> </u>
Intellectual property	\$ 3,100,000	\$ 3,100,000
Patents	1,625,696	1,533,366
	<u>4,725,696</u>	<u>4,633,366</u>
Accumulated amortization - Intellectual property	(1,192,635)	(1,153,710)
Accumulated amortization patents	(492,410)	(452,417)
	<u>(1,685,045)</u>	<u>(1,606,127)</u>
Net	<u>\$ 3,040,651</u>	<u>\$ 3,027,239</u>

Intellectual property consists of technology for producing targeted proteins in plants for the development and manufacture of novel vaccines and therapeutics for humans and certain veterinary applications. The Company accounts for intangible assets at their historical cost and records amortization utilizing the straight-line method based upon their estimated useful lives. Intellectual property is amortized over a period from eighteen to twenty-three years and patents over ten years. The Company reviews the carrying value of its intangible assets for impairment whenever events or changes in business circumstances indicate the carrying amount of such assets may not be fully recoverable. Evaluating for impairment requires judgment, including the estimation of future cash flows, future growth rates and profitability and the expected life over which cash flows will occur. Changes in the Company's business strategy or adverse changes in market conditions could impact impairment analyses and require the recognition of an impairment charge equal to the excess of the carrying value over its estimated fair value. The veterinary application intellectual property and certain patents were determined to have been impaired during the year ended June 30, 2011. There was no impairment during the three months ended September 30, 2011.

Amortization expense for intangible assets is recorded utilizing the straight-line method, was included in and general and administrative expenses and approximated \$79,000 and \$92,000, for the three months ended September 30, 2011 and 2010, respectively.

NOTE C STOCKHOLDERS EQUITY**Share-Based Compensation - Stock Options and Warrants**

The Company accounts for options granted to employees by measuring the cost of services received in exchange for the award of equity instruments based upon the fair value of the award on the date of grant. The fair value of that award is then ratably recognized as expense over the period during which the recipient is required to provide services in exchange for that award. Options and warrants granted to consultants and other non-employees are recorded at fair value as of the grant date and subsequently adjusted to fair value at the end of each reporting period until such options and warrants vest, and the fair value of such instruments, as adjusted, is expensed over the related vesting period. Adjustments to fair value at each reporting date may result in income or expense, depending upon the estimate of fair value and the amount of expense recorded prior to the adjustment.

On August 12, 2008, the Company adopted the iBioPharma, Inc. 2008 Omnibus Equity Incentive Plan (the "Plan") for employees, officers, directors, or external service providers. Under the provisions of the Plan, the Company may grant options to purchase stock and/or make awards of restricted stock up to an aggregate amount of 10,000,000 shares. There are 5,650,000 options available for future issuance under the Plan. Options granted under the Plan may be either incentive stock options within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended, or non

Edgar Filing: iBio, Inc. - Form 10-Q

iBio, Inc.
Notes to Condensed Financial Statements (Unaudited)

-statutory stock options at the discretion of the Board of Directors and as reflected in the terms of the written option agreement. Options granted under the Plan vest ratably at the end of each twelve month period within either a three or five year period from the date of grant.

Share-based compensation expense was recorded as follows:

	Three Months Ended September 30,	
	2011	2010
Research and development	\$ (15,270)	\$ 88,068
General and administrative	353,562	320,699
Totals	\$ 338,292	\$ 408,767

A summary of the changes in options outstanding during the three months ended September 30, 2011 and the year ended June 30, 2011 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at June 30, 2010	2,210,000	\$ 0.58	9.1	\$ 1,770,000
Granted	2,140,000	\$ 2.44		
Outstanding at June 30, 2011	4,350,000	\$ 1.49	8.7	\$ 6,112,000
Outstanding at September 30, 2011 and expected to vest at September 30, 2011	4,350,000	\$ 1.49	8.5	\$ 2,291,000
Options exercisable at September 30, 2011	2,532,000	\$ 1.28	8.3	\$ 1,669,000

There were no options granted during the three months ended September 30, 2011. The weighted average fair value of options granted during the three months ended September 30, 2010 was \$1.31 per share on the date of grant using the Black-Scholes option-pricing model. Options granted and options required to be revalued each reporting period were calculated with the following assumptions:

	Three Months Ended September 30,	
	2011	2010
Risk free interest rate	2.0% to 3.0%	1.3% to 1.9%
Dividend yield	None	None
Volatility	94.8% to 95.3%	98.0%
Expected term (in years)	8.6 to 8.8	1.3 to 6.5

Edgar Filing: iBio, Inc. - Form 10-Q

iBio, Inc. Notes to Condensed Financial Statements (Unaudited)

On October 21, 2011, the Board of Directors authorized the grant of options to purchase 1,000,000 shares of common stock at \$1.96 per share to certain officers, Board of Directors and an employee. The options vest between three to five years and expire in ten years.

A summary of the changes in warrants outstanding during the three months ended September 30, 2011 and year ended June 30, 2011 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share
Outstanding at June 30, 2010	3,085,811	\$ 2.47
Granted	5,257,796	\$ 1.99
Exercised	(95,000)	\$ 1.54
Cancelled	(300,000)	\$ 1.38
	7,948,607	\$ 2.21
Outstanding at June 30, 2011 and September 30, 2011	7,948,607	\$ 2.21
Exercisable at September 30, 2011	7,748,607	\$ 2.24

NOTE D - RELATED PARTY TRANSACTIONS

- 1) The Company has a license agreement with IBP and earned royalties of approximately \$12,000 and \$7,000 during the three months ended September 30, 2011 and 2010, respectively. A shareholder of the Company is an officer of IBP.
- 2) During the three months ended September 30, 2011, the Company had three services arrangements with the Center for Molecular Biotechnology of Fraunhofer USA, Inc. (FhCMB) for research and development.
 - (A) In 2003, the Company entered into a Technology Transfer Agreement., as amended (TTA) which requires FhCMB to provide the Company with research and development services related to the commercialization of the Technology and allows FhCMB to apply the Technology to the development and production of certain vaccines for use in developing countries as defined in the agreement. The most recent amendment to the TTA requires: 1) the Company to make payments to FhCMB of \$2,000,000 per year for five years, aggregating \$10,000,000, for such services beginning in November 2009; and 2) FhCMB to expend at least equal amounts during the same timeframe for research and development services related to the commercialization of the Technology. Additionally, under the terms of the TTA and for a period of fifteen years: 1) the Company shall pay FhCMB a defined percent (per the agreement) of all receipts derived by the Company from sales of products produced utilizing the Technology and a defined percentage (per the agreement) of all receipts derived by the Company from licensing the Technology to third parties with an overall minimum annual payment of \$200,000 beginning with the twelve months ended December 2010; and 2) FhCMB shall pay the Company a defined percentage (per the agreement) of all receipts from sales, licensing, or commercialization of the Technology in developing countries as defined in the agreement.
 - (B) In December 2010, the Company and FhCMB entered into a \$1,660,000 research services agreement for research for selected targeted gene expressions optimization utilizing the Company s technology.
 - (C) In March 2011, the Company and FhCMB entered into a \$432,000 research services agreement for research regarding the use of a certain enzyme as a carrier molecule.

Edgar Filing: iBio, Inc. - Form 10-Q

iBio, Inc.
Notes to Condensed Financial Statements (Unaudited)

Below are expenses recorded with transactions associated with FhCMB for the three months ended September 30, 2011 and 2010 and as of September 30, 2011 and June 30, 2011, respectively.

	Three Months Ended September 30,	
	2011	2010
Research and development expense	\$ 1,372,000	\$ 0
Royalty	50,000	50,000
	As of September 30, 2011	As of June 30, 2011
Prepaid and other current assets	\$ 443,000	\$ 760,000
Accounts payable	2,181,000	2,360,000

Item 2 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following information should be read together with the financial statements and the notes thereto and other information included elsewhere in this quarterly report on Form 10-Q.

Forward-Looking Statements

This quarterly report on Form 10-Q, including the sections entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations", contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements regarding iBio expected future financial position, results of operations, cash flows, business strategy, budgets, projected costs, capital expenditures, products, competitive positions, growth opportunities, plans and objectives of management for future operations, as well as statements that include the words such as "expects," "reaffirms," "intends," "anticipates," "plans," "believes," "seeks," "estimates," or variations of and similar expressions, are forward-looking statements. These forward looking statements are not guarantees of future performance and are subject to risks and uncertainties. Investors are cautioned that actual events or results may differ from our expectations. Factors that may affect our actual results achieved include, without limitation, our ability to develop existing and new products, future actions by the FDA or other regulatory agencies, results of pending or future clinical trials, the results of ongoing litigation, overall economic conditions, general market conditions, market acceptance, foreign currency exchange rate fluctuations, the effects on pricing from group purchasing organizations and competition, as well as our ability to integrate purchased businesses. Other risks and uncertainties include, but are not limited to, the factors described from time to time in our reports filed with the SEC, including our Form 10-K for the year ended June 30, 2011.

Although we believe that the assumptions underlying the forward-looking statements contained herein are reasonable, any of the assumptions could be inaccurate and, therefore, there can be no assurance that the forward-looking statements included in this quarterly report on Form 10-Q will prove to be accurate. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation by us or any other person that our objectives and plans will be achieved. Any forward-looking statements are made pursuant to the Private Securities Litigation Reform Act of 1995 and, as such, speak only as of the date made. iBio disclaims any obligation to update the forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements which speak only as of the date stated, or if no date is stated, as of the date of this document.

Overview

iBio, Inc. ("iBio" and the "Company") is a biotechnology company focused on commercializing its proprietary technology, the iBioLaunch platform, for biologics including vaccines and therapeutic proteins. Our strategy is to promote our technology through commercial product collaborations and license arrangements. We expect to share in the increased value our technology provides through upfront license fees, milestone revenues, service revenues, and royalties on end products. We believe our technology offers the opportunity to develop products that might not otherwise be commercially feasible, and to work with both corporate and government clients to reduce their costs during product development and meet their needs for low cost, high quality biologics manufacturing systems. Our near-term focus is to establish business arrangements for use of our technology by licensees for the development and production of products for both therapeutic and vaccine uses. Vaccine candidates presently being advanced on our proprietary platform are applicable to newly emerging strains of H1N1 swine-like influenza, and H5N1 avian influenza, yellow fever, and anthrax. Therapeutic candidates presently being advanced on our proprietary platform include human alpha-galactosidase A for the treatment of Fabry disease, human C1 esterase inhibitor for the treatment of hereditary angioedema (HAE), human alpha-1 antitrypsin for treatment of disorders caused by a lack or deficiency of alpha-1 antitrypsin, a therapeutic vaccine for human papilloma virus (HPV), and several other therapeutic protein targets for which preliminary product feasibility has been demonstrated.

In order to attract appropriate licensees and increase the value of our share of such intended contractual arrangements, we engaged the Center for Molecular Biotechnology of Fraunhofer USA, Inc., or FhCMB, in 2003 to perform research and development activities to develop the platform and to create our first product candidate. We selected a plant-based influenza vaccine for human use as the product candidate to exemplify the value of the platform. Based on research conducted by FhCMB, our proprietary technology is applicable to the production of vaccines for any strain of influenza including the newly-emerged strains of H1N1 swine-like influenza. A Phase I clinical trial of a vaccine candidate for H1N1 influenza, based on iBio's technology, was initiated in September 2010. We announced positive interim results in June 2011. The vaccine candidate demonstrated strong induction of dose correlated immune responses, with or without adjuvant, as assessed by virus microneutralization antibody assays and hemagglutination inhibition (HAI) responses. The vaccine was safe and well tolerated at all doses when administered with and without adjuvant.

In connection with the research and development agreement, FhCMB agreed to use its best efforts to obtain grants from governmental and non-governmental entities to fund additional development of our proprietary plant-based technology. Consequently, in addition to the funding we have provided, FhCMB has received funding from the Bill & Melinda Gates Foundation for development of various vaccines based upon our proprietary technology including an experimental vaccine for H5N1 avian influenza. A Phase I clinical trial of a vaccine candidate for H5N1 influenza, based on iBio's technology, was initiated in December 2010 and is ongoing. The results of this trial are expected to be released toward the end of fourth quarter calendar year 2011.

In addition to the platform and product development engagements, in 2006, the Company engaged FhCMB to create a prototype production module for products made through the use of the platform. The purpose of this engagement was to demonstrate the ease and economy with which platform-based products could be manufactured in order to attract potential licensees and increase the value of our share of such business arrangements. The prototype design, which encompasses the entire production process from the seeding through pre-infiltration plant growth, infiltration with agrobacteria, harvesting of plant tissue and purification of target proteins, was completed in May 2008. A pilot plant based upon this prototype was subsequently constructed in the FhCMB facility in Newark, Delaware. This pilot plant, and the equipment in it, are owned by FhCMB and have been validated for cGMP production. It will be used for cGMP production of protein targets for clinical trials of product candidates utilizing our platform technology.

In January 2011, we announced the grant of a commercial, royalty-bearing license to Fiocruz/Bio-Manguinhos of Brazil to develop, manufacture and sell certain vaccines based upon our proprietary technology. Fiocruz/Bio-Manguinhos will invest \$6.5 million to bring the first product candidate, a Yellow Fever vaccine, through a Phase I clinical trial. Yellow Fever is a viral infection in the group of diseases known as hemorrhagic fevers. The virus is transmitted by mosquitoes, and is common in South America and sub-Saharan Africa. The disease, which causes fever, nausea and pain, varies in severity, but is frequently lethal when it progresses to bleeding or to liver damage. The World Health Organization has estimated that 200,000 unvaccinated people contract Yellow Fever each year, and 30,000 die from the disease.

Development of the Yellow Fever vaccine candidate will be performed through a commercial collaboration among the Company, Fiocruz/Bio-Manguinhos, and FhCMB. The license covers the nations of Latin America, the Caribbean and Africa. The Company retains the right to sell the products developed under the license and collaboration agreement in any other territory with a royalty back to Fiocruz/Bio-Manguinhos. Bio-Manguinhos is a unit of the Oswaldo Cruz Foundation (Fiocruz), a central agency of the Ministry of Health of Brazil. Fiocruz/Bio-Manguinhos produces and develops immunobiological items to respond to public health demands. Its product line consists of vaccines, reagents and biopharmaceuticals. Fiocruz/Bio-Manguinhos is a leading company in the national export of human vaccines and a major participant in total export sales of the Brazilian pharmaceutical sector. Fiocruz/Bio-Manguinhos is one of the main producers of vaccines and diagnostics for infectious diseases in Latin America. Fiocruz/Bio-Manguinhos is a certified World Health Organization provider to United Nations agencies, and is a leading world manufacturer of Yellow Fever vaccine, which it has exported to over 60 countries.

The Company established non-commercial arrangements among the Company, certain government entities, a non-governmental organization (which we refer to herein as a NGO) and FhCMB, pursuant to which the Company grants non-commercial rights to use its platform for the development and production by FhCMB of product candidates selected by the government entities and NGO, in consideration for grants by the government entities and NGO directly to FhCMB to fund such research and development.

Through (i) the Company/FhCMB contracts and (ii) the non-commercial arrangements described above (which we refer to collectively as the business structure), the Company retains ownership of the intellectual property and exclusive worldwide commercial rights in the fields of human health and veterinary influenza applications of the intellectual property. The Company licenses or otherwise grants use rights (a) to government and NGO entities for not-for-profit applications of the intellectual property for the development or application for which they granted or were granted funding, and (b) to FhCMB for research purposes and applications in other fields.

This business structure helps the Company to enhance the value of commercial rights and the scope of applications of its platform technology. It also helps the Company demonstrate the validity and apparent value of the platform to parties to whom it will offer licenses or other business opportunities. Outsourcing our research and development work allows us to develop our product candidates, and thereby promote the value of our platform for licensing and product development purposes, without bearing the full risk and expense of establishing and maintaining our own research and development staff and facilities. FhCMB is engaged to perform research and development for the fever vaccine project for their expertise. The expected contract with FhCMB is expected to be \$6.5 million. Service revenues and research expense under this arrangement commenced in February 2011. The amount billed for revenues and this agreement and related research and development expenses for the three months ended September 30, 2011 were approximately \$320,000.

The Company s platform technology is sometimes referred to as iBioLaunch technology or the iBioLaunch platform, and the category of this technology is sometimes referred to as plant-based technology or as a plant-based platform. The Company has exclusive control over, and the rights to ownership of, the intellectual property related to all human health and veterinary influenza applications of the plant-based technology developed by FhCMB. Current development projects include conducting proof-of-principle preclinical studies and conducting clinical studies of proprietary influenza vaccines. Many biotech drugs have been on the market long enough for patents on them to expire. Emerging opportunities for biosimilars (also known as biogenerics or follow-on biologics) create potential for our platform technology to be used by potential licensees to enter the market utilizing what the Company expects to be an economical production system. The Company is seeking commercial partners for this category of products and is unlikely to develop products in this category without the financial and marketing support of a commercial partner.

Our proposed products are in the preclinical or early clinical stage of development and will require significant further research, development, clinical testing and regulatory clearances. They are subject to the risks of failure inherent in the development of products based on innovative technologies. These risks include, but are not limited to, the possibilities that any or all of the proposed products will be found to be ineffective or unsafe, or otherwise fail to receive necessary regulatory clearances; that the proposed products, although effective, will be uneconomical to market; that third parties may now or in the future hold proprietary rights that preclude us from marketing them; or that third parties will market superior or equivalent products. Accordingly, we are unable to predict whether our research and development activities will result in any commercially viable products or applications. Further, due to the extended testing and regulatory review process required before marketing clearance can be obtained, we do not expect to be able to commercialize any therapeutic drug for at least four years, either directly or through our current or prospective partners or licensees. There can be no assurance that our proposed products will prove to be safe or effective or receive regulatory approvals that are required for commercial sale. Historically, in addition to the development of the platform technology described in the preceding paragraphs, the Company has also generated sales of nutritional supplements utilizing plants as sources of high-quality nutritional minerals. The Company has a patented process for hydroponic growth of edible plants that causes them to accumulate high levels of important nutritional minerals such as chromium, selenium, iron and zinc. The Company utilized the services of various wholly-owned subsidiaries of our former parent company, Integrated BioPharma, Inc. (Integrated BioPharma or Former Parent) to support the production, marketing and sales of these phytomineral products.

Results of Operations

For the three months ended September 30, 2011 versus September 30, 2010

Revenues for the three months ended September 30, 2011 were approximately \$320,000 and none for the three months ended September 30, 2010. Revenues were attributable to providing technology services to a licensee, Fiocruz/Bio-Manguinhos, to assist them in implementing the Company s technology.

Research and development expense

Research and development expense for the three months ended September 30, 2011 was approximately \$1,457,000 compared to \$158,000 for the comparable period in 2010, an increase of \$1,299,000 over the comparable period in 2010. This increase for the three months ended September 30, 2011 primarily relates to two new research agreements that were entered into with FhCMB for selected targeted gene expressions optimization and the use of a certain enzyme as a carrier molecule for \$475,000. In addition, FhCMB was engaged to outsource the Fiocruz/Bio-Manguinhos agreement for their research and development expertise to advance the Yellow Fever vaccine project using iBio's technology and such expense was approximately \$320,000 for the three months ended September 30, 2011. Cost incurred under the Technology Transfer Agreement was approximately \$576,000 for the three months ended September 30, 2011 and \$0 of the comparable period for the prior year. There are two \$1 million obligation payments that are due during a five-year period and such agreement commenced in 2003. The May 2010 obligation was expensed upfront for the completion of the Pilot Plant at FhCMB as services were fully rendered through June 30, 2010. The accounting for the TTA agreement has been to expense such amounts as services are rendered. Share-based compensation expense - options decreased by approximately \$103,000 primarily due to certain options that are revalued each month-end using the Black-Scholes option pricing model. The Company's share price decreased at September 30, 2011 as compared to June 30, 2011, as compared to an increase in the Company's stock price at September 30, 2010 as compared to June 30, 2010.

General and administrative expenses

General and administrative expense for the three months ended September 30, 2011 was \$1,189,000 compared to \$1,213,000 of the comparable period in 2010, a decrease of \$24,000. There was approximately \$91,000 of share-based compensation expense - warrants for the three months September 30, 2011 that did not have a corresponding expense for the three months September 30, 2010. A certain portion of the share-based compensation expense - warrants decreased by approximately \$197,000. These warrants are revalued at the end of each reporting period using the Black-Scholes option pricing model and the Company's share price decreased at September 30, 2011 as compared to June 30, 2011 as compared to an increase in the Company's stock price at September 30, 2010 as compared to June 30, 2010. The decrease of share-based compensation expense was offset by an increase in salaries and benefits of \$146,000 from the hiring of two employees, and salary increases for the CEO and President. In addition, professional fees, primarily for legal expenses, increased by \$123,000.

Other income (expenses)

The derivative instrument liability non-cash income for the three months ended September 30, 2011 was approximately \$2,704,000 as compared to a non-cash charge of \$1,441,000 for the comparable period in 2010. The decrease of \$4,145,000 primarily reflects the decrease in the Company's stock price at September 30, 2011 as compared to June 30, 2011 and the increase in the stock price at September 30, 2010 as compared to June 30, 2010. The calculation of this derivative liability is affected by factors which are subject to significant fluctuations and are not under the Company's control. This liability resulted from warrants included in the August 2008 equity financing with a down round provision. Therefore, the resulting effect upon our net income or loss is subject to significant fluctuations and will continue to be subject to significant fluctuations until the warrants either expire in August 2013 or are exercised. The accounting guidance applicable to these warrants requires the Company (assuming all other inputs to the pricing model remain constant) to record a non-cash charge when the Company's stock price is increasing and recording non-cash income when the Company's stock price is decreasing.

Provision for income taxes

The Company did not record a provision income taxes for the three months ended September 30, 2011 since the income before taxes resulted from non taxable income from the change in the fair value of derivative instrument liability of \$2,704,000.

Liquidity and Capital Resources

The Company has incurred significant losses and negative cash flows from operations since its spinoff from its Former Parent in August 2008. As of September 30, 2011, the Company had an accumulated deficit of approximately \$25,279,000 and cash used in operations for the three months ended September 30, 2011 and 2010 approximated \$1,228,000 and \$526,000, respectively. The Company has historically financed its activities through the sale of common stock and warrants. To date, the Company has dedicated most of its financial resources to investing in its iBioLaunch platform, advancing intellectual property and general and administrative activities. Cash on hand as of September 30, 2011 of approximately \$1,523,000 is expected to support the Company's activities through January 2012.

The Company plans to fund its development and commercialization activities through January 2012 and beyond through milestone receipts from licensing arrangements including royalties and/or the sale of equity securities. The Company cannot be certain that such funding will be available on acceptable terms or available at all. To the extent that the Company raises additional funds by issuing equity securities, its stockholders may experience significant dilution. If the Company is unable to raise funds when required or on acceptable terms, it may have to: a) Significantly delay, scale back, or discontinue the development and/or commercialization of one or more product candidates; b) Seek collaborators for product candidates at an earlier stage than would otherwise be desirable and/or on terms that are less favorable than might otherwise be available; or c) Relinquish or otherwise dispose of rights to technologies, product candidates, or products that it would otherwise seek to develop or commercialize itself and possibly cease operations.

These matters raise substantial doubt about the Company's ability to continue as a going concern. These financial statements were prepared under the assumption that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of that uncertainty.

On July 26, 2011 we filed with the SEC a Registration Statement on Form S-3 under the Securities Act, which was declared effective by the SEC on July 28, 2011. This registration statement allows us, from time to time, to offer and sell shares of common stock, preferred stock, warrants to purchase our securities and/or debt securities, up to a maximum aggregate amount of \$100 million of such securities. To date, we have not issued any securities under this registration statement and we currently have no firm agreements with any third-parties for the sale of our securities pursuant to this registration statement, or otherwise. There can be no assurance that additional financing, if at all available, can be obtained on terms acceptable to us. If we raise additional funds by selling shares of common stock or convertible securities, the ownership of our existing shareholders will be diluted. Further, if additional funds are raised through the issuance of equity or debt securities, such additional securities may have powers, designations, preferences or rights senior to our currently outstanding securities. Any inability to obtain required financing on sufficiently favorable terms could have a material adverse effect on our business, results of operations and financial condition. If we are unsuccessful in raising additional capital we will need to reduce costs and operations substantially. Further, if expenditures required to achieve our plans are greater than projected we will need to raise a greater amount of funds than currently expected.

COMMITMENTS AND CONTINGENCIES

Please refer to Note F in our Annual Report on Form 10-K for the year ended June 30, 2011 under the heading Commitments and Contingencies.

Item 3 QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide this information under this item.

Item 4 CONTROLS AND PROCEDURES

a) Evaluation of Disclosure Controls and Procedures

As of September 30, 2011, the end of the period covered by this report, our management, including our Chief Executive Officer and our Chief Financial Officer, reviewed and evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended). Such disclosure controls and procedures are designed to ensure that material information we must disclose in this report is recorded, processed, summarized and filed or submitted on a timely basis. Based upon that evaluation, our management, Chief Executive Officer and Chief Financial Officer, concluded that our disclosure controls and procedures were effective as of September 30, 2011.

(b) Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the first quarter of fiscal 2012 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II OTHER INFORMATION

Item 1 LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

Item 1A RISK FACTORS

NYSE Amex LLC has sent the Company notice of non-compliance with continued listing standards, which could ultimately result in the delisting of the Company's common stock from NYSE Amex LLC.

On November 4, 2011, the Company received notice from NYSE Amex LLC (the Exchange) that the Company currently is below certain of the Exchange's continued listing standards. The Exchange indicated that its review of the Company's Form 10-K for the year ended June 30, 2011, indicates that the Company is not in compliance with Section 1003(a)(iv), which applies if a listed company has sustained losses that are so substantial in relation to its overall operations or its existing financial resources, or its financial condition has become so impaired that it appears questionable, in the opinion of the Exchange, as to whether the company will be able to continue operations and/or meet its obligations as they mature.

The Company is afforded the opportunity to submit a plan of compliance to the Exchange by November 28, 2011, that demonstrates the Company's ability to regain compliance with Section 1003(a)(iv) of the Company Guide by January 25, 2012. If the Company does not submit a plan of compliance, or if the plan is not accepted by the Exchange, the Company will be subject to delisting procedures as set forth in Section 1010 and Part 12 of the Company Guide.

The Company believes it can provide the Exchange with a satisfactory plan by November 28, 2011, to show that it will be able to return to compliance with Section 1003(a)(iv) of the Company Guide by January 25, 2012.

If the Company's common stock is delisted from the Exchange, the price and liquidity of the common stock could be adversely affected.

Item 2 UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

Item 3 DEFAULTS UPON SENIOR SECURITIES

None.

Item 5 OTHER INFORMATION

None.

Item 6 EXHIBITS

Exhibit Number

31.1	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by Chief Executive Officer.
31.2	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by Chief Financial Officer.
32.1	Certification of periodic financial report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 by Chief Executive Officer.
32.2	Certification of periodic financial report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 by Chief Financial Officer.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document

Edgar Filing: iBio, Inc. - Form 10-Q

101.CAL XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF XBRL Extension Definition
101.LAB XBRL Taxonomy Extension Label Linkbase Document
101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

Edgar Filing: iBio, Inc. - Form 10-Q

SIGNATURES

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

iBio, Inc.

Date: November 14, 2011

By: /s/ Robert B. Kay

Robert B. Kay,
Chief Executive Officer

Date: November 14, 2011

By: /s/ Douglas Beck, CPA

Douglas Beck, CPA
Chief Financial Officer

19
