Actinium Pharmaceuticals, Inc.
Form 10-Q
May 10, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended **March 31, 2016**

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: **000-52446**

ACTINIUM PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**74-2963609**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
275 Madison Ave, 7th Floor	
	10016
New York, NY	
(Address of Principal Executive Offices)	(Zip Code)

(732) 243-9495

(Registrant's Telephone Number, Including Area Code)

(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 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	Smaller reporting company
(Do not check if a 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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of May 9, 2016: 46,950,180.

Actinium Pharmaceuticals, Inc.

FORM 10-Q

For quarterly period ended March 31, 2016

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PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

The accompanying consolidated financial statements have been prepared by the Company and are unaudited. In the opinion of management, all adjustments (which include only normal recurring adjustments) necessary to present fairly the financial position at March 31, 2016 and December 31, 2015, and the results of operations and cash flows for the three months ended March 31, 2016 and 2015 have been made. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted. It is suggested that these financial statements be read in conjunction with the financial statements and notes thereto included in the Company's audited financial statements for the year ended December 31, 2015, filed with the SEC in the Company's Annual Report on Form 10-K on March 11, 2016. The results of operations for the three months ended March 31, 2016 are not necessarily indicative of the operating results for the full year.

Actinium Pharmaceuticals, Inc.

Consolidated Balance Sheets

(Unaudited)

	March 31, 2016	December 31, 2015
Assets		
Current Assets:		
Cash and cash equivalents	$22,206,956	$25,643,273
Restricted cash - current	34,733	34,733
Prepaid expenses and other current assets	937,069	803,463
Total Current Assets	23,178,758	26,481,469
Property and equipment, net of accumulated depreciation	115,582	106,112
Security deposit	49,859	-
Total Assets	$23,344,199	$26,587,581
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	$1,852,813	$1,473,936
Accounts payable and accrued expenses - related parties	25,000	25,000
Notes payable	178,119	265,695
Derivative liabilities	1,230,048	2,848,902
Total Current Liabilities	3,285,980	4,613,533
Total Liabilities	3,285,980	4,613,533
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.001 par value; 50,000,000 authorized, 0 shares issued and outstanding	-	-
Common stock, $0.001 par value; 200,000,000 shares authorized; 44,925,176 and 44,066,541 shares issued and outstanding, respectively	44,925	44,067
Additional paid-in capital	136,646,670	134,160,059
Accumulated deficit	(116,633,376)	(112,230,078)
Total Stockholders' Equity	20,058,219	21,974,048
Total Liabilities and Stockholders' Equity	$23,344,199	$26,587,581

See accompanying notes to the unaudited consolidated financial statements.

Actinium Pharmaceuticals, Inc.

Consolidated Statements of Operations
(Unaudited)

	For the Three Months Ended March 31,	
	2016	2015
Revenue	$—	$—
Operating expenses:		
Research and development, net of reimbursements	3,765,452	4,048,714
General and administrative	2,218,467	3,806,405
Depreciation expense	18,120	10,395
Total operating expenses	6,002,039	7,865,514
Loss from operations	(6,002,039)	(7,865,514)
Other income (expense):		
Interest expense	(2,658)	(5,727)
Gain on change in fair value of derivative liabilities	1,601,399	4,796,378
Total other income	1,598,741	4,790,651
Net loss	$(4,403,298)	$(3,074,863)
Net loss per common share – basic and diluted	$(0.10)	$(0.09)
Weighted average common shares outstanding – basic and diluted	44,253,793	33,256,352

See accompanying notes to the unaudited consolidated financial statements.

Actinium Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows

(Unaudited)

	For the Three Months Ended March 31,	
	2016	2015
Cash Flows From Operating Activities:		
Net loss	$(4,403,298)	$(3,074,863)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	984,837	2,908,167
Depreciation expense	18,120	10,395
Gain on change in fair value of derivative liabilities	(1,601,399)	(4,796,378)
Changes in operating assets and liabilities:		
(Increase) decrease in:		
Prepaid expenses and other current assets	(133,606)	65,806
Increase (decrease) in:		
Accounts payable and accrued expenses	378,877	(1,019,732)
Accounts payable and accrued expenses - related parties	—	93,555
Net Cash Used In Operating Activities	(4,756,469)	(5,813,050)
Cash Flows From Investing Activities:		
Purchase of property and equipment	(27,590)	—
Security deposit	(49,859)	—
Net Cash Used In Investing Activities	(77,449)	—
Cash Flows From Financing Activities:		
Payments on note payable	(87,576)	(93,794)
Sales of common stock, net of offering costs	1,485,177	18,484,998
Net Cash Provided By Financing Activities	1,397,601	18,391,204
Net change in cash	(3,436,317)	12,578,154
Cash and cash equivalents at beginning of period	25,643,273	6,706,802
Cash and cash equivalents at end of period	$22,206,956	$19,284,956
Supplemental disclosures of cash flow information:		
Cash paid for interest	$2,658	$5,727
Cash paid for income taxes	$—	$—
Supplemental disclosure of non-cash investing and financing activities:		

Fair value of warrants issued with stock	$—	$4,738,161
Transfer warrant derivatives from liability to equity classification	$17,455	$48,691

See accompanying notes to the unaudited consolidated financial statements.

Actinium Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements

(Unaudited)

Note 1 - Description of Business and Summary of Significant Accounting Policies

Nature of Business - Actinium Pharmaceuticals, Inc. (the "Company" or "Actinium") is a biotechnology company committed to developing breakthrough therapies for life threatening diseases using its alpha particle immunotherapy ("APIT") platform and other related and similar technologies. Actinium, together with its wholly owned subsidiary, MedActinium, Inc., is hereinafter referred to collectively as "Actinium" or the "Company". The Company's most advanced products are Actimab™-A, an antibody-drug construct containing actinium 225 (Ac-225), currently in human clinical trials for acute myeloid leukemia (AML) and Iomab™-B, an antibody-drug construct containing iodine 131 (I-131), used in myeloconditioning for hematopoietic stem cells transplantation (HSCT) in various indications. The Company is currently preparing for a Phase 3 trial of Iomab™-B for bone marrow conditioning for HSCT in relapsed and refractory AML patients age of 55 and older, which upon successful completion of our clinical trials we intend to submit for marketing approval. Actinium is also considering filing an application with the U.S. Food and Drug Administration (FDA) for breakthrough therapy designation for Actimab™-A and/or Iomab™-B. The Company is developing our cancer drugs using our expertise in radioimmunotherapy. In addition, our Ac-225 based drug development relies on the patented APIT platform technology co-developed with Memorial Sloan Kettering Cancer Center (MSKCC), whose indirect subsidiary, Actinium Holdings Ltd., is a significant stockholder in our company. The APIT technology couples monoclonal antibodies (mAb) with extremely potent but comparatively safe alpha particle emitting radioactive isotopes, in particular actinium 225 and bismuth 213. The final drug construct is designed to specifically target and kill cancer cells while minimizing side effects. Actinium intends to develop a number of products for different types of cancer and derive revenue from partnering relationships with large pharmaceutical companies and/or direct sales of its products in specialty markets in the United States.

On December 16, 2015, Company announced that the FDA cleared the Company's IND filing for Iomab-B, and that it will proceed with the pivotal, Phase 3 clinical trial. Actinium anticipates the Phase 3, controlled, randomized, pivotal trial will begin enrolling patients in the first half of 2016 and assuming that the trial meets its end points, it will form the basis for a Biologics Licensing Application (BLA). The Company, in its recently approved IND filing, established an agreement with the FDA that the path to a Biologics License Application submission would include a single, pivotal Phase 3 clinical study if it is successful. The population in this two arm, randomized, controlled, multicenter trial will be refractory and relapsed AML patients over the age of 55. The trial size was set at 150 patients with 75 patients per arm. The primary endpoint in the pivotal Phase 3 trial is durable complete remission, defined as a complete remission lasting at least 6 months and the secondary endpoint will be overall survival at one year. There are currently no effective treatments approved by the FDA for AML in this patient population and there is no defined standard of care. Iomab-B has completed several physicians sponsored clinical trials examining its potential as a conditioning regimen prior to HSCT in various blood cancers, including the Phase 1/2 study in relapsed and/or refractory AML patients. The results of these studies in over 300 patients have demonstrated the potential of Iomab-B

to create a new treatment paradigm for bone marrow transplants by: expanding the pool to ineligible patients who do not have any viable treatment options currently; enabling a shorter and safer preparatory interval for HSCT; reducing post-transplant complications; and showing a clear survival benefit including curative potential.

Basis of Presentation - Unaudited Interim Financial Information – The accompanying unaudited interim consolidated financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information, and in accordance with the rules and regulations of the United States Securities and Exchange Commission (the "SEC") with respect to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The unaudited interim consolidated financial statements furnished reflect all adjustments (consisting of normal recurring adjustments) which are, in the opinion of management, necessary for a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of the results for the full year. These unaudited interim consolidated financial statements should be read in conjunction with the audited consolidated financial statements of the Company for the year ended December 31, 2015 and notes thereto contained in the Company's annual report on Form 10-K for the year ended December 31, 2015, as filed with the SEC on March 11, 2016.

Principles of Consolidation - The consolidated financial statements include the Company's accounts and those of the Company's wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

Use of Estimates in Financial Statement Presentation - The preparation of these consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents - The Company considers all highly liquid accounts with original maturities of three months or less to be cash equivalents. Balances held by the Company are typically in excess of FDIC insured limits. At March 31, 2016 and December 31, 2015, all of the Company's cash was deposited in one bank.

Property and Equipment - Machinery and equipment are recorded at cost and depreciated on a straight-line basis over estimated useful lives of three years. Furniture and fixtures are recorded at cost and depreciated on a straight-line basis over estimated useful lives of three years. When assets are retired or sold, the cost and related accumulated depreciation are removed from the accounts, and any related gain or loss is reflected in operations. Repairs and maintenance expenditures are charged to operations.

Impairment of Long-Lived Assets - Management reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be realizable or at a minimum annually during the fourth quarter of the year. If an evaluation is required, the estimated future undiscounted cash flows associated with the asset are compared to the asset’s carrying value to determine if an impairment of such asset is necessary. The effect of any impairment would be to expense the difference between the fair value of such asset and its carrying value.

Derivatives - All derivatives are recorded at fair value on the balance sheet. Where market prices are not readily available, fair values are determined using market based pricing models incorporating readily observable market data and requiring judgment and estimates.

Fair Value of Financial Instruments - Fair value is defined as the price that would be received to sell an asset, or paid to transfer a liability, in an orderly transaction between market participants. A fair value hierarchy has been established for valuation inputs that gives the highest priority to quoted prices in active markets for identical assets or liabilities and the lowest priority to unobservable inputs. The fair value hierarchy is as follows:

Level 1 Inputs - Unadjusted quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 Inputs - Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. These might include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (such as interest rates, volatilities, prepayment speeds, credit risks, etc.) or inputs that are derived principally from or corroborated by market data by correlation or other means.

Level 3 Inputs - Unobservable inputs for determining the fair values of assets or liabilities that reflect an entity's own assumptions about the assumptions that market participants would use in pricing the assets or liabilities.

The following tables set forth assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy as of March 31, 2016 and December 31, 2015. As required by ASC 820 "*Fair Value Measurements and Disclosures"*, financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment, and may affect the valuation of fair value assets and liabilities and their placement within the fair value hierarchy levels.

	Level 1	Level 2	Level 3	Total
Derivative liabilities:				
At March 31, 2016	$ -	$ -	$1,230,048	$1,230,048
At December 31, 2015	$ -	$ -	$2,848,902	$2,848,902

Income Taxes - The Company uses the asset and liability method in accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and income tax carrying amounts of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company reviews deferred tax assets for a valuation allowance based upon whether it is more likely than not that the deferred tax asset will be fully realized. A valuation allowance, if necessary, is provided against deferred tax assets, based upon management's assessment as to their realization.

Research and Development Costs - Research and development costs are expensed as incurred. Research and development reimbursements and grants are recorded by the Company as a reduction of research and development costs.

Share-Based Payments - The Company estimates the fair value of each stock option award at the grant date by using the Black-Scholes option pricing model. The fair value determined represents the cost for the award and is recognized over the vesting period during which an employee is required to provide service in exchange for the award. As share-based compensation expense is recognized based on awards ultimately expected to vest, the Company reduces the expense for estimated forfeitures based on historical forfeiture rates. Previously recognized compensation costs may be adjusted to reflect the actual forfeiture rate for the entire award at the end of the vesting period. Excess tax benefits, if any, are recognized as an addition to paid-in capital.

Earnings (Loss) Per Common Share - The Company calculates net loss per common share in accordance with ASC 260 “Earnings Per Share” (“ASC 260”). Basic earnings (loss) per common share is computed by dividing the net income (loss) available to common stockholders by the weighted average number of common shares outstanding during the reporting period. For the three months ended March 31, 2016 and 2015, the Company’s potentially dilutive shares, which include outstanding common stock options and warrants have not been included in the computation of diluted net loss per share as the result would have been anti-dilutive.

	March 31, 2016	March 31, 2015
Options	4,116,083	3,549,084
Warrants	8,770,313	9,886,547
Total	12,886,396	13,435,631

Recent Accounting Pronouncements – In April 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-09, “Compensation – Stock Compensation” (topic 718). The FASB issued this update to improve the accounting for employee share-based payments and affect all organizations that issue share-based payment awards to their employees. Several aspects of the accounting for share-based payment award transactions are simplified, including: (a) income tax consequences; (b) classification of awards as either equity or liabilities; and (c) classification on the statement of cash flows. The updated guidance is effective for annual periods beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption of the update is permitted. The Company is currently evaluating the impact of the new standard.

In February 2016, FASB issued ASU No. 2016-02 “Leases” (topic 842), which creates new accounting and reporting guidelines for leasing arrangements. The new guidance requires organizations that lease assets to recognize assets and liabilities on the balance sheet related to the rights and obligations created by those leases, regardless of whether they are classified as finance or operating leases. Consistent with current guidance, the recognition, measurement, and presentation of expenses and cash flows arising from a lease primarily will depend on its classification as a finance or operating lease. The guidance also requires new disclosures to help financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. The new standard is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period, with early application permitted. The new standard is to be applied using a modified retrospective approach. The Company is currently evaluating the impact of the new pronouncement on its financial statements.

Management does not believe that any recently issued, but not yet effective accounting pronouncements, when adopted, will have a material effect on the accompanying consolidated financial statements.

Subsequent Events - The Company’s management reviewed all material events through the date of the consolidated financial statements were issued for subsequent event disclosure consideration.

Note 2 - Related Party Transactions

MSKCC:

On February 11, 2002, the Company entered into a License, Development and Commercialization Agreement with Sloan-Kettering Institute of Cancer Research ("SKI"), an entity related to MSKCC, a majority shareholder of the Company. The agreement was amended in August 2006. Pursuant to the agreement, the Company licensed certain intellectual property from SKI, including critical patents with respect to the Company's core technology that also supports ongoing research and clinical development of related drug candidates. MSKCC agreed, subject to certain conditions, to utilize the funds paid for certain clinical and preclinical programs and activities related to the Company's drug development and clinical study programs, including the payment of certain costs and expenses that would otherwise have been borne by the Company.

The Company is obligated to make the following milestone payments:

Milestones	Payments
(1) filing of an New Drug Application ("NDA") or regulatory approval for each licensed product	$750,000
(2) upon the receipt of regulatory approval from the U.S. FDA for each licensed product	1,750,000

Under the agreement, the Company shall pay to MSKCC on a country-by-country basis a royalty of 2% of net sales of all licensed products until the later of: (1) 10 years from the first commercial sale, or (2) when the patents expire.

For the three months ended March 31, 2016 and 2015, the Company incurred $0 and $0.1 million, respectively, for maintenance fees and research conducted by MSKCC. As of March 31, 2016 and December 31, 2015, no balance was due to MSKCC.

On December 21, 2015, Actinium entered into an investor rights agreement with MSKCC. Under the terms of the agreement, MSKCC has agreed to forebear from transferring or otherwise disposing of its approximately 5.7 million shares of the Company's common stock (other than pursuant to a piggyback registration as described below) until the start of the Actimab-A Phase 2 clinical study (but, in no event until later than March 31, 2016). Thereafter MSKCC shall be permitted to sell its shares subject to a weekly volume limitation of 150,000 shares (which limit may be increased to up to 250,000 shares per week to the extent any prior weekly allotments are not fully used) and applicable law so long as MSKCC maintains at least 25% of its current shareholding in Actinium through December 31, 2016. Actinium has granted MSKCC piggyback registration rights that would be triggered in the event Actinium were to engage in a public registered offering of its shares for its own account where other shareholders are participating as selling shareholders or where such public registered offering is for the account of other selling shareholders. In addition, following December 31, 2016, Actinium granted MSKCC unlimited Form S-3 registration rights with respect to its shares.

Placement Agent:

On December 9, 2013, the Company entered into an engagement agreement with a Healthcare Investment Bank ("Placement Agent") as its placement agent for the 2013 Common Stock Offering whereby a director of the Company was the former Head of its Healthcare Investment Banking team ("the 2013 Offering"). The 2013 Offering was completed in two tranches, December 9, 2013 and January 10, 2014. The agreement entered in on December 9, 2013 included a cash fee equal to 10% of the gross proceeds raised, a non-accountable expense reimbursement equal to 2% of the gross proceeds raised and warrants to purchase shares of the Company's Common Stock in an amount equal to 10% of the shares of common stock issued or issuable. Subsequent to the closing of the 2013 Offering, the placement agent continued to provide certain financial advisory services to the Company until three months after the Company had up-listed its securities for trading on a U.S. National Exchange for a monthly fee of $25,000. On May 28, 2014, the Company and the placement agent agreed to terminate the December 9, 2013 engagement agreement. As of March 31, 2016 and December 31, 2015, the Company owed its placement agent $25,000.

On February 11, 2015 the Company completed a public offering that totaled 4,444,444 common shares, representing gross proceeds of approximately $20.0 million and a net amount of approximately $18.5 million after deducting the underwriting discount and the other offering expenses. The Placement Agent acted as the sole book-running manager for the offering. The offering was made pursuant to a shelf registration statement previously filed with and declared effective by the U.S. Securities and Exchange Commission. The placement agent received a cash fee of approximately $1.4 million.

On June 9, 2015, the Company completed a registered direct offering of $5.0 million of its common stock. Under the terms of the subscription agreements, the Company issued an aggregate of 1,923,078 shares of the Company's common stock at a purchase price of $2.60 per share. The Placement Agent acted as the sole placement agent with respect to the offering. The Placement Agent received a cash fee of approximately $0.4 million.

Note 3 - Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following at March 31, 2016 and December 31, 2015:

	March 31,	December 31,

	2016	2015
Prepaid insurance	$292,494	$ 376,906
Prepaid clinical trial expenses	549,798	283,430
Other prepaid expenses	94,777	143,127
Total prepaid expenses and other current assets	$937,069	$ 803,463

Note 4 - Property and Equipment

Property and equipment consisted of the following at March 31, 2016 and December 31, 2015:

	Lives	March 31, 2016	December 31, 2015
Lab equipment	3 years	$116,070	$ 116,070
Office equipment	3 years	110,564	82,974
Less: accumulated depreciation		(111,052)	(92,932)
Property and equipment, net		$115,582	$ 106,112

Depreciation expense for the three months ended March 31, 2016 and 2015 was $18,120 and $10,395, respectively.

Note 5 - Note Payable

On December 28, 2015, the Company entered into a premium finance agreement for its director and officer liability insurance policy in the amount of $0.3 million. Pursuant to the agreement, the Company is required to pay $30,077 in monthly installments for nine months.

As of March 31, 2016 and December 31, 2015, the outstanding balance related to the premium finance agreement was $0.2 million and $0.3 million, respectively.

Note 6 - Derivatives

The Company has determined that certain warrants the Company has issued contain provisions that protect holders from future issuances of the Company's common stock at prices below such warrants' respective exercise prices and these provisions could result in modification of the warrants' exercise price based on a variable that is not an input to the fair value of a "fixed-for-fixed" option as defined under FASB ASC Topic No. 815 - 40. The warrants granted in connection with the issuance of the 2012 Common Stock Offering, and the placement agent warrants contain anti-dilution provisions that provide for a reduction in the exercise price of such warrants in the event that future common stock (or securities convertible into or exercisable for common stock) is issued (or becomes contractually issuable) at a price per share (a "Lower Price") that is less than the exercise price of such warrant at the time. The amount of any such adjustment is determined in accordance with the provisions of the warrant agreement and depends upon the number of shares of common stock issued (or deemed issued) at the Lower Price and the extent to which the Lower Price is less than the exercise price of the warrant at the time.

Activities for derivative warrant instruments during the three months ended March 31, 2016 were as follows:

	Shares subject to warrants	Fair Value
Balance, December 31, 2015	1,627,369	$2,848,902
Transfer from liability to equity classification	(12,109)	(17,455)
Change in fair value	-	(1,601,399)

Balance, March 31, 2016	1,615,260	$1,230,048

During the three months ended March 31, 2016, 183,718 warrants were exercised, of which 12,109 were derivative warrants. The fair value of these derivative warrants totaling $17,455 were measured on the exercise date and reclassified to additional paid-in capital.

The fair values of the derivative warrants were calculated using a modified binomial valuation model with the following assumptions at each balance sheet date.

	March 31, 2016	December 31, 2015
Market value of common stock on measurement date (1)	$1.99	$ 3.23
Adjusted exercise price	$2.48	$ 2.48
Risk free interest rate (2)	0.73 %	1.06 %
Warrant lives in years	1.7 years	2.0 years
Expected volatility (3)	87 %	87 %
Expected dividend yield (4)	-	-
Probability of stock offering in any period over 5 years (5)	100 %	100 %
Offering price (6)	$2.60	$ 2.60

(1) The market value of common stock at the above measurement dates is based on the Company’s closing price quoted on the NYSE MKT.

(2) The risk-free interest rate was determined by management using the Treasury Bill rate as of the respective measurement date.

(3) As of March 31, 2016 and December 31, 2015, the volatility was estimated using the historical volatilities of the Company's common stock traded in NYSE MKT market.

(4) Management determined the dividend yield to be 0% based upon its expectation that it will not pay dividends for the foreseeable future.

(5) Management determines the probability of future stock offering at each evaluation date.

(6) Represents the estimated offering price in future offerings as determined by management.

Note 7 - Commitments and Contingencies

License and Research Agreements

The Company has entered into license and research and development agreements with third parties under which the Company is obligated to make upfront payments as well as milestone and royalty payments. Notable inclusions in this category are:

a. AbbVie Biotherapeutics Corp. - The Company entered into a Product Development and Patent License Agreement with AbbVie Biotherapeutics Corp. in 2003 to secure exclusive rights to a specific antibody when conjugated with alpha emitting radioisotopes. Upon execution of the agreement, the Company made a license fee payment of $3,000,000.

The Company agreed to make milestone payments totaling $7,750,000 for the achievement of the following agreed to and contracted milestones:

Milestones	Payments
(1) when Company initiates a Phase 1 Clinical Trial of a licensed product	$750,000
(2) when Company initiates a Phase 2 Clinical Trial of a licensed product	750,000
(3) when Company initiates a Phase 3 Clinical Trial of a licensed product	1,500,000

(4) Biological License Application filing with U.S. FDA	1,750,000
(5) First commercial sale	1,500,000
(6) after the first $10,000,000 in net sales	1,500,000

Under the agreement, the Company shall pay to AbbVie Biotherapeutics Corp. on a country-by-country basis a royalty of 12% of net sales of all licensed products until the later of: (1) 12.5 years after the first commercial sale, or (2) when the patents expire.

The Company met its first milestone in 2012 and upon reaching the milestone the Company paid AbbVie Biotherapeutics Corp. a milestone payment of $750,000 on July 24, 2012. The milestone payment for the Phase 1 Clinical Trial was recorded as research and development expense. The Company has not initiated a Phase 2 Clinical Trial and no payment has been made to AbbVie Biotherapeutics Corp. since the July 24, 2012 payment.

b. MSKCC - see Note 2 - Related Party Transactions.

c. Oak Ridge National Laboratory (“ORNL”) – The Company is contracted to purchase radioactive material to be used for research and development, with a renewal option at the contract end. On December 21, 2015, the Company signed a contract with ORNL to purchase $0.9 million of radioactive material during 2016. During the three months ended March 31, 2016 and 2015, the Company purchased approximately $0.2 million and $0.1 million, respectively, of radioactive material with ORNL.

d. Icon Clinical Research, LLC (“Icon”) provides project management services for the study of the drug Ac-225-HuM195 (Actimab-A) used in the Company’s Phase 1 and Phase 2 clinical trials. The total project was estimated to cost approximately $1.9 million and required a 12.5% down payment of the total estimated project cost. The down payment totaling $0.2 million was paid in 2007 and 2012. On August 6, 2012, October 22, 2012 and May 16, 2013, the agreement was amended to provide for additional services. The total project is now estimated at approximately $2.7 million. Icon invoices the Company when services are rendered and the Company records the related expense to research and development expense.

For three months ended March 31, 2016 and 2015, the Company incurred expenses of approximately $0.2 million and $0.1 million, respectively, related to this agreement.

e. On June 15, 2012, the Company entered into a license and sponsored research agreement with Fred Hutchinson Cancer Research Center (“FHCRC”) to build upon previous and ongoing clinical trials, with BC8 (licensed antibody). FHCRC has currently completed both a Phase 1 and Phase 2 clinical trial with BC8 and the Company intends to start preparation for a pivotal trial leading to an FDA approval. The Company has been granted exclusive rights to the BC8 antibody and related master cell bank developed by FHCRC. The cost to develop the trial will range from $13.2 million to $23.5 million, depending on the trial design as required by the FDA. Under the terms of the sponsored research agreement, the Company will fund the FHCRC lab with $0.2 million per year for the first two years and $0.3 million thereafter. Payments made toward funding the lab will be credited toward royalty payments owed to FHCRC in the given year. A milestone payment of $1 million will be due to FHCRC upon FDA approval of the first drug. Upon commercial sale of the drug, royalty payments of 2% of net sales will be due to FHCRC.

For the three months ended March 31, 2016 and 2015, the Company incurred expenses of approximately $63,000 and $46,000, respectively, related to this agreement.

f. On August 28, 2012, the Company entered into a clinical trial agreement with The University of Texas M.D. Anderson Cancer Center. The total estimated cost of conducting the clinical trial is approximately $0.5 million, which includes a non-refundable institutional fee of $14,500. The estimated cost is based on treating 24 patients through 2015. Upon execution of the agreement, the Company paid $33,946. No patients were enrolled during the three months ended March 31, 2016 and 2015 and did not incur any charges.

g. On February 27, 2014, the Company entered into a manufacturing agreement with Goodwin Biotechnology Inc. ("Goodwin"). Goodwin oversees the current Good Manufacturing Practices (cGMP) production of a monoclonal antibody anticipated to be used in an upcoming phase 3 clinical trial of Iomab-B. Total cost of the agreement is $5.7 million. The Company made a non-refundable payment of $0.6 million upon execution of the agreement. Periodic payments will be made upon reaching certain milestones. As of March 31, 2016, the remaining cost of the agreement is approximately $2.0 million. Goodwin bills the Company when services are rendered and the Company records the related expense to research and development costs.

For the three months ended March 31, 2016 and 2015, the Company paid Goodwin approximately $0.1 million and $2.1 million, respectively. As of March 31, 2016 and December 31, 2015, the Company owed $0.1 million and $0.1 million, respectively, to Goodwin.

h. On September 30, 2014, the Company entered into a research agreement with the Albert Einstein College of Medicine of Yeshiva University (“Einstein”). According to the agreement, Einstein will use certain materials provided by the Company to complete a research project. The research project will explore the feasibility of using Actinium 225 to prepare patients with blood borne cancers to receive a hematopoietic stem cell transplant. Einstein will periodically provide the Company with reports showing project data or research. The total fixed price of the project is $0.2 million which is payable to Einstein in three payments.

During the three months ended March 31, 2016 and 2015, the Company paid Einstein approximately $36,678 and $55,000, respectively. As of March 31, 2016, the Company paid Einstein a total of $0.2 million.

i. On February 16, 2016, the Company entered into a CRO agreement with Medpace, Inc. (Medpace). Medpace provides project management services for the study of Iomab-B used for the intended Phase 3 clinical trial. The total project is estimated to cost approximately $6.6 million. The Company paid approximately $0.9 million during the three months ended March 31, 2016. Medpace bills the Company when services are rendered and the Company records the related expense to research and development costs.

Lease Agreements

The Company does not own any real property. On March 10, 2016 and effective as of January 1, 2016, Actinium entered into an Office Space License Agreement (the “License”) with Relmada Therapeutics, Inc. (“Relmada”), with whom we share two common board members, for office space located at 275 Madison Avenue, 7th Floor, New York, NY 10016. The License represents a substantial reduction in the per person cost over Actinium’s prior lease and the space allows for future growth. Both companies’ boards authorized the transaction. The term of the License is three years from the effective date, with an automatic renewal provision. The cost of the License is on a pass through basis for Relmada, and is approximately $16,620 per month for Actinium, subject to customary escalations and adjustments.

On April 22, 2014, the Company entered into a sublease agreement for office space located at 379 Thornall Street, Edison, NJ. This agreement expires on September 30, 2016. The Company issued a letter of credit for $34,733 to the existing tenant and maintained a $34,733 certified deposit as collateral for the letter of credit.

Future minimum obligations on the lease are:

For the year ending March 31, 2016	$255,448
For the year ending March 31, 2017	199,440
For the year ending March 31, 2018	149,580
Total	$604,468

Note 8 - Equity

During the three months ended March 31, 2016, the Company issued 717,273 shares of common stock for gross proceeds of $1.5 million as part of its At-The-Market (“ATM”) sales agreement with an investment bank.

During the three months ended March 31, 2016, the Company issued 125,862 common shares for the cashless exercise of warrants.

Restricted Stock

During the three months ended March 31, 2016, the Company granted 10,750 shares of restricted common stock to a consultant with a fair value of $19,350 based on the stock price on the grant date. The shares vested upon execution of the consulting agreement.

During the three months ended March 31, 2016 and 2015, the Company recorded approximately $0.1 million and $1.2 million, respectively, in stock-based compensation for all of the restricted shares outstanding.

During the three months ended March 31, 2016, 15,500 restricted shares vested and the Company issued common shares.

Stock Options

Following is a summary of option activities for the three months ended March 31, 2016:

	Number of Units	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, December 31, 2015	3,971,583	4.34	8.01	2,964,146
Granted	244,500	2.14	9.88	-
Cancelled	(100,000)	1.91	-	-
Outstanding, March 31, 2016	4,116,083	4.27	7.85	937,786
Exercisable, March 31, 2016	2,006,628	3.61	6.37	893,426

During the three months ended March 31, 2016, the Company granted employees 244,500 options to purchase the Company’s common stock with an exercise price ranging from $1.79 per share to $2.25 per share, a term of 10 years, and a vesting period of 4 years. The options have an aggregated fair value of $382,685 that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate range from 1.38% to 1.66% (2) expected life of 6 years, (3) expected volatility of 87.95%, and (4) zero expected dividends. During the three months ended March 31, 2016, the Company recorded $12,339 in stock-based compensation in relation to these options.

The fair value of all options issued and outstanding are being amortized over their respective vesting periods. The unrecognized compensation expense at March 31, 2016 was $6.6 million. During the three months ended March 31, 2016 and 2015, the Company recorded total option expense of $0.8 million and $1.0 million respectively.

Warrants

Following is a summary of warrant activities for the three months ended March 31, 2016:

	Number of Units	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, December 31, 2015	8,954,031	3.73	2.93	10,199,230
Exercised	(183,718)	-	-	-
Outstanding, March 31, 2016	8,770,313	3.78	2.68	4,782,278
Exercisable, March 31, 2016	8,485,313	3.65	2.50	4,782,278

During the three months ended March 31, 2016, 183,718 warrants were exercised by the warrant holders. The Company issued 125,862 shares of common stock as a result of these exercises.

During the three months ended March 31, 2016 and 2015, the Company recorded stock-based compensation expense related to the warrants of $57,144 and $56,516, respectively.

Note 10 - Subsequent Events

On April 22, 2016, the Company issued 500 shares of common stock to an employee for vested grant.

Subsequent to March 31, 2016, the Company sold 2,024,504 shares of common stock for gross proceeds of $4.1 million as part of the Sales Agreement with MLV.

Subsequent to March 31, 2016, the Company granted employees and board of directors 1,695,500 options to purchase the Company's common stock. These options were valued at approximately $2.4 million using Black-Scholes option pricing model.

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

FORWARD-LOOKING STATEMENT NOTICE

This Form 10-Q contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. For this purpose, any statements contained in this Form 10-Q that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, words such as "may," "will," "expect," "believe," "anticipate," "estimate" or "continue" or comparable terminology are intended to identify forward-looking statements. These statements by their nature involve substantial risks and uncertainties, and actual results may differ materially depending on a variety of factors, many of which are not within our control. These factors include but are not limited to economic conditions generally and in the industries in which we may participate; competition within our chosen industry, including competition from much larger competitors; technological advances and failure to successfully develop business relationships.

Description of Business

Actinium is a biotechnology company committed to developing breakthrough therapies for life threatening diseases using its alpha particle immunotherapy (APIT) platform and other related and similar technologies. Our most advanced products are Actimab™-A, an antibody-drug construct containing actinium 225 (Ac-225), currently in human clinical trials for acute myeloid leukemia (AML) and Iomab™-B, an antibody-drug construct containing iodine 131 (I-131), used in myeloconditioning for hematopoietic stem cells transplantation (HSCT) in various indications. We are currently preparing for a Phase 3 trial of Iomab™-B for bone marrow conditioning for HSCT in relapsed and refractory AML patients age of 55 and older, which upon successful completion of our clinical trials we intend to submit for marketing approval. We are currently also considering filing an application with the U.S. Food and Drug Administration (FDA) for breakthrough therapy designation for Actimab™-A and/or Iomab™-B. We are developing our cancer drugs using our expertise in radioimmunotherapy. In addition, our Ac-225 based drug development relies on the patented Alpha Particle Immunotherapy Technology (APIT) platform technology co-developed with Memorial Sloan Kettering Cancer Center (MSKCC), whose indirect subsidiary, Actinium Holdings Ltd., is a significant stockholder in our company. The APIT technology couples monoclonal antibodies (mAb) with extremely potent but comparatively safe alpha particle emitting radioactive isotopes, in particular actinium 225 and bismuth 213. The final drug construct is designed to specifically target and kill cancer cells while minimizing side effects. We intend to develop a number of products for different types of cancer and derive revenue from partnering relationships with large pharmaceutical companies and/or direct sales of its products in specialty markets in the United States.

On December 16, 2015, we announced that the FDA cleared our IND filing for Iomab-B, and that it will proceed with the pivotal, Phase 3 clinical trial. We anticipate the Phase 3, controlled, randomized, pivotal trial will begin enrolling

patients in the first half of 2016 and assuming that the trial meets its end points, it will form the basis for a Biologics Licensing Application (BLA). We, established an agreement with the FDA that the path to a Biologics License Application submission would include a single, pivotal Phase 3 clinical study if it is successful. The population in this two arm, randomized, controlled, multicenter trial will be refractory and relapsed AML patients over the age of 55. The trial size was set at 150 patients with 75 patients per arm. The primary endpoint in the pivotal Phase 3 trial is durable complete remission, defined as a complete remission lasting at least 6 months and the secondary endpoint will be overall survival at one year. There are currently no effective treatments approved by the FDA for AML in this patient population and there is no defined standard of care. Iomab-B has completed several physicians sponsored clinical trials examining its potential as a conditioning regimen prior to HSCT in various blood cancers, including the Phase 1/2 study in relapsed and/or refractory AML patients. The results of these studies in over 300 patients have demonstrated the potential of Iomab-B to create a new treatment paradigm for bone marrow transplants by: expanding the pool to ineligible patients who do not have any viable treatment options currently; enabling a shorter and safer preparatory interval for HSCT; reducing post-transplant complications; and showing a clear survival benefit including curative potential.

We were incorporated under the laws of the State of Nevada on October 6, 1997. We were a shell entity that was in the market for a merger with an appropriate operating company.

Plan of Operation

We develop drugs for the treatment of cancer with the intent to cure or significantly improve survival of the affected patients. As of now none of our drugs have been approved for sale in the United States or elsewhere. We have no commercial operations in sales or marketing of our products. All our product candidates are under development. In order to market and sell our products we must conduct clinical trials on patients and obtain regulatory approvals from appropriate regulatory agencies like the Food and Drug Administration (FDA) in the United States and similar agencies elsewhere in the world.

Our products under development are monoclonal antibodies labeled with radioisotopes. We have one program with an antibody labeled with a beta emitter and several programs based on a proprietary patent protected platform technology called APIT. Our APIT technology is based on attaching actinium 225 (Ac-225) or bismuth 213 (Bi-213) alpha emitting radioisotopes to monoclonal antibodies. Alpha emitting radioisotopes are unstable chemical elements that decay by releasing alpha particles. Alpha particles can kill any cell in the immediate proximity of where they are released. Monoclonal antibodies are genetically engineered proteins that specifically target certain cells, including cancer cells. It is crucial for the success of our drug candidates to contain monoclonal antibodies that can successfully seek cancer cells and can kill them with the attached isotope while not harming nearby normal cells. We do not have technology and operational capabilities to develop and manufacture such monoclonal antibodies and we therefore rely on collaboration with third parties to gain access to such monoclonal antibodies. We have secured rights to two monoclonal antibodies, HuM195 (Lintuzumab), in 2003 through a collaborative licensing agreement with Abbvie Biotherapeutics Corp and BC8 in 2012 with the Fred Hutchinson Cancer Research Center (“FHCRC”). We expect to negotiate collaborative agreements with other potential partners that would provide us with access to additional monoclonal antibodies. Establishing and maintaining such collaborative agreements is a key to our success as a company.

Under our own sponsorship as well as activity at FHCRC, we have four product candidates in active clinical trials: Actimab-A (HuM195-Ac-225), Iomab-B (BC8-I-131), BC8-Y-90 and BC8-SA. At this time, the Company is actively pursuing development of Actimab-A and Iomab-B while BC8-Y-90 and BC8-SA are in physician sponsored clinical phase 1 trials at the FHCRC. Actimab-A is a combination of the monoclonal antibody we have in-licensed, Lintuzumab (HuM195), and the alpha emitting isotope actinium 225. Actimab-A has shown promising results throughout preclinical development and an ongoing clinical trial started in 2006 in acute myeloid leukemia (AML) in the elderly. We have expanded the number of patients and number of clinical centers by commencing a new AML clinical trial which we have launched in 2012. This trial targets newly diagnosed AML patients over the age of 60. In order to conduct the trial we are engaged in funding, monitoring and quality assurance and control of the Lintuzumab antibody; procurement of actinium 225 isotope; funding, monitoring and quality assurance and control of the drug candidate Actimab-A manufacturing and organizing and monitoring clinical trials. We estimate that the direct costs to completion of both parts of the ongoing Phase 1/2 trial will be approximately $7 million. Iomab-B is a combination of the in-licensed monoclonal antibody BC8 and the beta emitting radioisotope iodine 131. This construct has been extensively tested in Phase I and Phase 2 clinical trials in approximately 250 patients with different blood cancer indications who were in need of a hematopoietic stem cell transplantation (HSCT). Iomab-B is used to condition the bone marrow of these patients by destroying blood cancer cells in their bone marrow and elsewhere thus allowing for

a subsequent transplant containing healthy donor bone marrow stem cells. We have decided to develop this drug candidate by initially focusing on the patients over 50 with active acute myeloid leukemia in relapse and/or refractory to existing treatments. Our intention is to request the FDA in 2015 to allow us to enter into a pivotal trial with Iomab-B. We estimate the direct costs of such a trial to completion anticipated in 2017 will be approximately $25-30 million.

We have primarily management position employees and consultants who direct, organize and monitor the activities described above through contractors. Much of the in vivo laboratory and clinical work contracted for by the Company was conducted at MSKCC in New York. We also made clinical trial arrangements with other well-known cancer centers. Our Actimab-A drug candidate and its components are contract manufactured and maintained under our supervision by specialized contract manufacturers and suppliers in the United States, including IsoTex Diagnostics, Oak Ridge National Laboratory, Pacific GMP, Fischer Bioservices, and BioReliance.

We have never generated revenue. Currently, we do not have a recurring source of revenues to cover our operating costs. For the three months ended March 31, 2016 and 2015, we incurred a net loss of approximately $4.4 million and $3.1 million, respectively. We believe that we have sufficient cash on hand to fund our operations through the next 12 months.

Opportunities, Challenges and Risks

The market for drugs for cancer treatment is a large market in need of novel products, in which successful products can command multibillion dollars in annual sales. A number of large pharmaceutical and biotechnology companies regularly acquire products in development, with preference given to products in Phase 2 or later clinical trials. These deals are typically structured to include an upfront payment that ranges from several million dollars to tens of million dollars or more and additional milestone payments tied to regulatory submissions and approvals and sales milestones. Our goal is to develop our product candidates through Phase 2 clinical trials and enter into partnership agreements with one or more large pharmaceutical and/or biotechnology companies.

We believe our future success will be heavily dependent upon our ability to successfully conduct clinical trials and preclinical development of our drug candidates. This will in turn depend on our ability to continue our collaboration with MSKCC and our Clinical Advisory Board members. In addition, we plan to continue and expand other research and clinical trial collaborations. Moreover, we will have to maintain sufficient supply of actinium 225 and successfully maintain and if and when needed replenish or obtain our reserves of monoclonal antibodies. We will have to maintain and improve manufacturing procedures we have developed for production of our drug candidates from the components that include the iodine 131 and actinium 225 isotopes, monoclonal antibodies and other materials. It is possible that despite our best efforts our clinical trials results may not meet regulatory requirements for approval. If our efforts are successful, we will be able to partner our development stage products on commercially favorable terms only if they enjoy appropriate patent coverage and/or considerable know-how and other protection that ensures market exclusivity. For that reason, we intend to continue our efforts to maintain existing and generate new intellectual property. Intellectual property is a key factor in the success of our business as well as market exclusivity.

To achieve the goals discussed above we intend to continue to invest in research and development at high and constantly increasing rates thus incurring further losses until one or more of our products are sufficiently developed to partner them to large pharmaceutical and biotechnology companies.

Results of Operations – Three Months Ended March 31, 2016 Compared to the Three Months Ended March 31, 2015

The following table sets forth, for the periods indicated, data derived from our statements of operations:

	For the Three Months Ended March 31,	
	2016	2015
Revenues	$ -	$ -
Operating expenses:		
Research and development, net of reimbursements	3,765,452	4,048,714
General and administrative	2,218,467	3,806,405
Depreciation expense	18,120	10,395
Total operating expenses	6,002,039	7,865,514
Other income (expense):		
Interest expense	(2,658)	(5,727)
Gain on change in fair value of derivative liabilities	1,601,399	4,796,378
Total other income (expense)	1,598,741	4,790,651

Net loss	$(4,403,298)	$(3,074,863)

Revenues

We recorded no commercial revenues for the three months ended March 31, 2016 and 2015.

Research and Development Expense

Research and development expenses decreased by approximately $0.2 million from $4.0 million for the three months ended March 31, 2015 to approximately $3.8 million for the three months ended March 31, 2016. Iomab-B manufacturing costs decreased by approximately $0.9 million for the three months ended March 31, 2016 as compared to the three months ended March 31, 2015. During the first quarter of 2015, we incurred significant manufacturing costs preparing for the Phase 3 clinical trial, which were not replicated during the three months ending March 31, 2016. The decrease Iomab-B manufacturing costs were partially offset by an increase of approximately $.6 million in Actimab™-A manufacturing costs. We expect to incur increased research and development costs in the future.

General and Administrative Expenses

Overall, total general and administrative expenses decreased by approximately $1.6 million from approximately $3.8 million for the three months ended March 31, 2015 to $2.2 million for the three months ended March 31, 2016. The decrease was largely attributable to decrease in salaries and stock compensation costs of $1.0 million and other related expenses and professional services. We expect to incur increased general and administrative costs in the future.

Other Income (Expense)

Other income (expense) for the three months ended March 31, 2016 and 2015 was approximately $1.6 million and $4.8 million, respectively. The other income (expense) is mainly associated with changes in our warrant derivative liability. The change is attributable to the fluctuation of our stock price from $2.47 per share at March 31, 2015 to $1.99 per share at March 31, 2016.

Liquidity and Capital Resources

We have financed our operations primarily through sales of the Company's common stock.

We do not have any cash or cash equivalents held in financial institutions located outside of the United States as of March 31, 2016 and December 31, 2015. We do not anticipate this practice will change in the future.

The following tables sets forth selected cash flow information for the periods indicated:

	For the Three Months Ended March 31,	
	2016	2015
Cash used in operating activities	$(4,756,469)	$(5,813,050)
Cash used in investing activities	(77,449)	-
Cash provided by financing activities	1,397,601	18,391,204
Net change in cash	$(3,436,317)	$12,578,154

Net cash used in operating activities was approximately $4.8 million and $5.8 million for the three months ended March 31, 2016 and 2015, respectively. Cash used in operations decreased due to the decrease in spending related to preparations and eventual launch and conduct of a multicenter clinical trial and also decrease in spending related to professional fees.

Net cash provided by financing activities was approximately $1.4 million and approximately $18.4 million for the three months ended March 31, 2016 and 2015, respectively. During the three months ended March 31, 2016, we issued common stock and received net proceeds of approximately $1.5 million from the sale of our common stock through our ATM compared to approximately $18.5 million received from the March 2015 finance. The issuance of stock during the two comparative periods were partially offset by payments on notes payable of $0.1 million for each of the three months ended March 31, 2016 and 2015.

Recent Equity Offerings

On March 24, 2014, we filed a shelf registration statement on Form S-3 (the "Registration Statement") and deemed effective on April 17, 2014. This Registration Statement contained two prospectuses: (i) a base prospectus which covers the offering, issuance and sale by the Company of up to $200,000,000 of its common stock, preferred stock, warrants and/or units; and (ii) a sales agreement prospectus covering the offering, issuance and sale by us of up to a maximum aggregate offering price of $75,000,000 of its common stock that may be issued and sold under a sales agreement (the "Sales Agreement") with MLV & Co. LLC ("MLV"). During the quarter ended March 31, 2016, the Company issued 717,273 shares of common stock for gross proceeds of $1.5 million. Since inception of this agreement through March 31, 2016, the Company issued 6,343,892 shares of common stock for gross proceeds of $16.7 million.

During the three months ended March 31, 2016, we issued 125,862 common shares for the cashless exercise of warrants. During the three months ended March 31, 2016, the Company issued common shares totaling 15,500 for restricted shares granted.

Off-Balance Sheet Arrangements

We do not have any 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 investors.

Seasonality

We do not have a seasonal business cycle. Our operating results are generally derived evenly throughout the calendar year.

Critical Accounting Policies

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. To prepare these consolidated financial statements, we must make estimates and assumptions that affect the reported amounts of assets and liabilities. These estimates also affect our expenses. Judgments must also be made about the disclosure of contingent liabilities. Actual results could be significantly different from these estimates. We believe that the following discussion addresses the accounting policies that are necessary to understand and evaluate our reported financial results.

Derivatives

All derivatives are recorded at fair value and recorded on the balance sheet. Fair values for securities traded in the open market and derivatives are based on quoted market prices. Where market prices are not readily available, fair values are determined using market based pricing models incorporating readily observable market data and requiring judgment and estimates.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset, or paid to transfer a liability, in an orderly transaction between market participants. A fair value hierarchy has been established for valuation inputs that gives the highest priority to quoted prices in active markets for identical assets or liabilities and the lowest priority to unobservable inputs. The fair value hierarchy is as follows:

Level 1 Inputs – Unadjusted quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 Inputs – Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. These might include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (such as interest rates, volatilities, prepayment speeds, credit risks, etc.) or inputs that are derived principally from or corroborated by market data by correlation or other means.

Level 3 Inputs – Unobservable inputs for determining the fair values of assets or liabilities that reflect an entity's own assumptions about the assumptions that market participants would use in pricing the assets or liabilities.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development reimbursements and grants are recorded by the Company as a reduction of research and development costs.

Share-Based Payments

The Company estimates the fair value of each stock option award at the grant date by using the Black-Scholes option pricing model. The fair value determined represents the cost for the award and is recognized over the vesting period during which an employee is required to provide service in exchange for the award. As share-based compensation expense is recognized based on awards ultimately expected to vest, the Company reduces the expense for estimated forfeitures based on historical forfeiture rates. Previously recognized compensation costs may be adjusted to reflect the actual forfeiture rate for the entire award at the end of the vesting period. Excess tax benefits, if any, are recognized as an addition to paid-in capital.

Recent Accounting Pronouncements

In April 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-09, “Compensation – Stock Compensation” (topic 718). The FASB issued this update to improve the accounting for employee share-based payments and affect all organizations that issue share-based payment awards to their employees. Several aspects of the accounting for share-based payment award transactions are simplified, including: (a) income tax consequences; (b) classification of awards as either equity or liabilities; and (c) classification on the statement of cash flows. The updated guidance is effective for annual periods beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption of the update is permitted. The Company is currently evaluating the impact of the new standard.

In February 2016, FASB issued ASU No. 2016-02 “Leases” (topic 842), which creates new accounting and reporting guidelines for leasing arrangements. The new guidance requires organizations that lease assets to recognize assets and liabilities on the balance sheet related to the rights and obligations created by those leases, regardless of whether they are classified as finance or operating leases. Consistent with current guidance, the recognition, measurement, and presentation of expenses and cash flows arising from a lease primarily will depend on its classification as a finance or operating lease. The guidance also requires new disclosures to help financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. The new standard is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period, with early

application permitted. The new standard is to be applied using a modified retrospective approach. The Company is currently evaluating the impact of the new pronouncement on its financial statements.

Management does not believe that any recently issued, but not yet effective accounting pronouncements, when adopted, will have a material effect on the accompanying consolidated financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Common Stock Price Risk

In December 2012, we issued common stock and warrants. Pursuant to ASC 815-40, we recorded the fair value of the warrants as a current liability. The fair value of the outstanding warrants is evaluated at each reporting period with any resulting change in the fair value being reflected in the condensed consolidated statements of operations. For the three months ended March 31, 2016 and 2015, we recognized the change in the value of warrants of approximately $1.6 million and $4.8 million, respectively, as a gain on the consolidated statement of operations. Fair value of the derivative instruments will be affected by estimates of various factors that may affect the respective instrument, including our stock price, the risk free rate of return and expected volatility in the fair value of our stock price. As the fair value of this derivative may fluctuate significantly from period to period, the resulting change in valuation may have a significant impact on our results of operations.

On March 24, 2014, we filed a shelf registration statement on Form S-3 (the “Registration Statement”) that was deemed effective on April 17, 2014. This Registration Statement contained two prospectuses: (i) a base prospectus which covers the offering, issuance and sale by the Company of up to $200,000,000 of its common stock, preferred stock, warrants and/or units; and (ii) a sales agreement prospectus covering the offering, issuance and sale by us of up to a maximum aggregate offering price of $75,000,000 of its common stock that may be issued and sold under a sales agreement (the “Sales Agreement”) with MLV. During the quarter ended March 31, 2016, the Company issued 717,273 shares of common stock for gross proceeds of $1.5 million. Since inception of this agreement through March 31, 2016, the Company issued 6,343,892 shares of common stock for gross proceeds of $16.7 million.

Sales of our common stock through MLV, if any, will be made on the NYSE MKT LLC, on any other existing trading market for the common stock or to or through a market maker. Subject to the terms and conditions of the Sales Agreement, MLV will use commercially reasonable efforts to sell our common stock from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay to MLV in cash, upon the sale of common stock pursuant to the Sales Agreement, an amount equal to 3.0% of the gross proceeds from the sale of common stock. We have also provided MLV with customary indemnification rights.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures. Under the supervision and with the participation of our management, including our chief executive officer and principal financial and accounting officer, we conducted an evaluation of the effectiveness, as of March 31, 2016, of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based upon such evaluation, our chief executive officer and principal financial and accounting officer have concluded that, as of March 31, 2016, our disclosure controls and procedures were effective to provide reasonable assurance that the information we are required to disclose in our filings with the Securities and Exchange Commission, or SEC, under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our chief executive officer and principal financial and accounting officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting. There were no changes in our system of internal controls over financial reporting during the period covered by this report that has materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None

ITEM 1A. RISK FACTORS

In analyzing our company, you should consider carefully the following risk factors, together with all of the other information included in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2015. Factors that could cause or contribute to differences in our actual results include those discussed in the following subsection, as well as those discussed above in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this Quarterly Report on Form 10-Q. Each of the following risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our Company The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to Our Business

We have generated no revenue from commercial sales to date and our future profitability is uncertain.

We have a limited operating history and our business is subject to all of the risks inherent in the establishment of a new business enterprise. Our likelihood of success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered in connection with this development and expansion. Since we began our business, we have focused on research, development and clinical trials of product candidates, and have incurred losses since inception. As of March 31, 2016, we had an accumulated deficit of approximately $116.6 million. Although we believe we have enough working capital for operations for the next 12 months, if we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. We expect to continue to operate at a net loss as we continue our research and development efforts, continue to conduct clinical trials and develop manufacturing, sales, marketing and distribution capabilities. There can be no assurance that the products under development by us will be approved for sale in the United States or elsewhere. Furthermore, there can be no assurance that if such products are approved they will be successfully commercialized, and the extent of our

future losses and the timing of our profitability are highly uncertain.

If we fail to obtain the capital necessary to fund our operations, we will be unable to continue or complete our product development and you will likely lose your entire investment.

Although we believe we have enough working capital for operations for the next 12 months, we do not currently have sufficient capital for the development and commercialization of our lead product candidate and we will need to continue to seek capital from time to time to continue development of our lead product candidates and to acquire and develop other product candidates. Our first product candidate is not expected to be commercialized, if approved, until at least 2018 and we do not expect that the partnering revenues it will generate will be sufficient to fund our ongoing operations. Our cash balance as of March 31, 2016 was approximately $22.2 million. During the three months ended March 31, 2016, we raised total net proceeds of approximately $1.5 million from the completion of public offerings of common stock. We believe we have enough cash for at least the next 12 months to finance research and development and to cover our ongoing working capital needs.

Our business or operations may change in a manner that would consume available funds more rapidly than anticipated and substantial additional funding may be required to maintain operations, fund expansion, develop new or enhanced products, acquire complementary products, business or technologies or otherwise respond to competitive pressures and opportunities, such as a change in the regulatory environment or a change in preferred cancer treatment modalities. However, we may not be able to secure funding when we need it or on favorable terms.

To raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock in future transactions may be higher or lower than the price per share in this offering. Additionally, you may incur dilution as a result of grants of equity awards under our equity incentive plans, or upon exercise of options or warrants currently outstanding with exercise prices at or below the public offering price of our common stock in this offering.

If we cannot raise adequate funds to satisfy our capital requirements, we will have to delay, scale-back or eliminate our research and development activities, clinical studies or future operations. We may also be required to obtain funds through arrangements with collaborators, which arrangements may require us to relinquish rights to certain technologies or products that we otherwise would not consider relinquishing, including rights to future product candidates or certain major geographic markets. We may further have to license our technology to others. This could result in sharing revenues which we might otherwise have retained for ourselves. Any of these actions may harm our business, financial condition and results of operations.

The amount of capital we may need depends on many factors, including the progress, timing and scope of our product development programs; the progress, timing and scope of our preclinical studies and clinical trials; the time and cost necessary to obtain regulatory approvals; the time and cost necessary to further develop manufacturing processes and arrange for contract manufacturing; our ability to enter into and maintain collaborative, licensing and other commercial relationships; and our partners' commitment of time and resources to the development and commercialization of our products.

We have limited access to the capital markets and even if we can raise additional funding, we may be required to do so on terms that are dilutive to you.

We have limited access to the capital markets to raise capital. The capital markets have been unpredictable in the recent past for radio-immunotherapy and other oncology companies and unprofitable companies such as ours. In addition, it is generally difficult for development stage companies to raise capital under current market conditions. The amount of capital that a company such as ours is able to raise often depends on variables that are beyond our control. As a result, we may not be able to secure financing on terms attractive to us, or at all. If we are able to consummate a financing arrangement, the amount raised may not be sufficient to meet our future needs. If adequate funds are not available on acceptable terms, or at all, our business, including our technology licenses, results of operations, financial condition and our continued viability will be materially adversely affected.

If we fail to obtain or maintain necessary FDA approval for our radio-immunotherapy products, or if such approvals are delayed, we will be unable to commercially distribute and market our products.

Our products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of seeking regulatory approval to market a radio-immunotherapy product is expensive and time-consuming and, notwithstanding the effort and expense incurred, approval is never guaranteed. If we are not successful in obtaining timely approval of Company products from the FDA, we may never be able to generate significant revenue and may be forced to cease operations. In particular, the FDA permits commercial distribution of a new radio-immunotherapy product only after a Biologics License Application (BLA) for the product has received FDA approval. The BLA process is costly, lengthy and inherently uncertain. Any BLA filed by us will

have to be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the product for its intended use. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects. In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

The approval process in the United States and in other countries could result in unexpected and significant costs for us and consume management's time and other resources. The FDA and other foreign regulatory agencies could ask us to supplement our submissions, collect non-clinical data, conduct additional clinical trials or engage in other time-consuming actions, or it could simply deny our applications. In addition, even if we obtain approval to market our products in the United States or in other countries, the approval could be revoked or other restrictions imposed if post-market data demonstrates safety issues or lack of effectiveness. We cannot predict with certainty how, or when, the FDA or other regulatory authorities will act. If we are unable to obtain the necessary regulatory approvals, our financial condition and cash flow may be materially adversely affected, and our ability to grow domestically and internationally may be limited. Additionally, even if we obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications that we request. The Company's products may not be approved for the specific indications that are most necessary or desirable for successful commercialization or profitability.

Our radio-immunotherapy product candidates are in the early stages of development; and we have not demonstrated that any of our products are safe and effective for any indication.

We currently have only two products in clinical development. We have commenced a Phase 1/2 multi- center AML trial with fractionated doses of Actimab™-A under its own federal Investigational New Drug Application (IND). Additionally, there are a number of physician IND trials at the FHCRC that have been conducted or are currently ongoing at FHCRC with single doses of Iomab™-B. In December 2015, the FDA cleared our IND filing for Iomab-B, and that we will proceed with the pivotal, Phase 3 clinical trial. We anticipate the Phase 3, controlled, randomized, pivotal trial to begin enrolling in the first half of 2016 and assuming that the trial meets its end points, it will form the basis for a Biologics Licensing Application (BLA).

We cannot predict whether we will encounter problems with any of our ongoing or planned clinical trials that will cause us or regulatory authorities to delay, suspend, or discontinue clinical trials or to delay the analysis of data from ongoing clinical trials. Any of the following could delay or disrupt the clinical development of our product candidates and potentially cause our product candidates to fail to receive regulatory approval:

conditions imposed on us by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;

delays in receiving, or the inability to obtain, required approvals from institutional review boards (IRBs) or other reviewing entities at clinical sites selected for participation in our clinical trials;

delays in enrolling patients into clinical trials;

a lower than anticipated retention rate of patients in clinical trials;

the need to repeat or discontinue clinical trials as a result of inconclusive or negative results or unforeseen complications in testing or because the results of later trials may not confirm positive results from earlier preclinical studies or clinical trials;

inadequate supply, delays in distribution deficient quality of, or inability to purchase or manufacture drug product, comparator drugs or other materials necessary to conduct our clinical trials;

unfavorable FDA or other foreign regulatory inspection and review of a clinical trial site or records of any clinical or preclinical investigation;

serious and unexpected drug-related side effects experienced by participants in our clinical trials, which may occur even if they were not observed in earlier trials or only observed in a limited number of participants;

a finding that the trial participants are being exposed to unacceptable health risks;

the placement by the FDA or a foreign regulatory authority of a clinical hold on a trial; or

delays in obtaining regulatory agency authorization for the conduct of our clinical trials.

We may suspend, or the FDA or other applicable regulatory authorities may require us to suspend, clinical trials of a product candidate at any time if we or they believe the patients participating in such clinical trials, or in independent third party clinical trials for drugs based on similar technologies, are being exposed to unacceptable health risks or for other reasons.

Further, individuals involved with our clinical trials may serve as consultants to us from time to time and receive stock options or cash compensation in connection with such services. If these relationships and any related compensation to the clinical investigator carrying out the study result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized. The delay, suspension or discontinuation of any of our clinical trials, or a delay in the analysis of clinical data for our product candidates, for any of the foregoing reasons, could adversely affect our efforts to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses and have a material adverse effect on our financial results.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRBs at the sites where the IRBs are overseeing a trial, or a data safety monitoring board, or DSMB, overseeing the clinical trial at issue, or other regulatory authorities due to a number of factors, including:

failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

varying interpretation of data by the FDA or similar foreign regulatory authorities;

failure to achieve primary or secondary endpoints or other failure to demonstrate efficacy;

unforeseen safety issues; or

lack of adequate funding to continue the clinical trial.

Additionally, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the cost, timing or successful completion of a clinical trial.

In addition, neither we nor any relevant collaborative partner(s) has yet undertaken any clinical assessment or investigation of Company radio-immunotherapy product candidates for other indications, including colon cancer or prostate cancer. Significant further investment may be required to acquire antibody rights and to undertake necessary research and continued development. Further laboratory and specific clinical testing will be required prior to regulatory approval of any product candidates. Adverse or inconclusive results from pre-clinical testing or clinical trials of product candidates may substantially delay, or halt entirely, any further development of one or more of our products. The projected timetables for continued development of the technologies and related product candidates by us may otherwise be subject to delay or suspension.

Modifications to our product candidates may require federal approvals.

The BLA application is the vehicle through which the company may formally propose that the FDA approve a new pharmaceutical for sale and marketing in the United States. Once a particular product candidate receives FDA approval, expanded uses or uses in new indications of our products may require additional human clinical trials and new regulatory approvals, including additional IND and BLA submissions and premarket approvals before we can begin clinical development, and/or prior to marketing and sales. If the FDA requires new approvals for a particular use or indication, we may be required to conduct additional clinical studies, which would require additional expenditures and harm our operating results. If the products are already being used for these new indications, we may also be subject to significant enforcement actions.

Conducting clinical trials and obtaining approvals can be a time-consuming process, and delays in obtaining required future approvals could adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

There is no guarantee that the FDA will approve BLAs for our product candidates and failure to obtain necessary approvals for our product candidates would adversely affect our ability to grow our business.

We have recently commenced a multi-center Phase 1/2 clinical trial for our lead product candidate, Actimab™-A, in AML and in the future expect to submit a BLA to the FDA for approval of this product. This product candidate is also the subject of an ongoing human safety trial being conducted under a physician IND at MSKCC. We are in the early stages of evaluating other product candidates consisting of conjugates of Ac-225 with human or humanized antibodies for pre-clinical and clinical development in other types of cancer. In June 2012, we acquired rights to Iomab™, a Phase 2 clinical stage monoclonal antibody with safety and efficacy data in more than 250 patients in need of HSCT. Product candidates utilizing this antibody would also require BLA approval before they can be marketed in the United States. The FDA may not approve these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may fail to approve any BLA we submit for new product candidates or for new intended uses or indications for approved products or future product candidates. Failure to obtain FDA approval for our products in the proposed indications would have an adverse effect on our ability to expand our business.

Clinical trials necessary to support approval of BLAs for our product candidates will be time consuming and expensive. Delays or failures in our clinical trials may prevent us from commercializing our product candidates and will adversely affect our business, operating results and prospects and could cause us to cease operations.

Initiating and completing clinical trials necessary to support FDA approval of a BLA for Actimab™-A and other product candidates, is a time-consuming and expensive process, and the outcome is inherently uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product candidate we advance into clinical trials may not have favorable results in later clinical trials. We have worked with the FDA to develop a clinical trial designed to test the initial safety and efficacy of Actimab™-A in newly diagnosed AML patients over the age of 60, and on October 6, 2008, and January 5, 2009, we submitted IND amendments to the FDA for the conduct of a multi-center Phase 1/2 clinical trial for treatment of AML. The trial is now underway with the purpose of examining the use of Actimab™-A in AML patients who are not eligible for approved forms of treatment with curative intent. The trial is not designed to support marketing approval for the product candidate, and one or more additional trials will have to be conducted in the future before we file a BLA. In addition, there can be no assurance that the data generated during the trial will meet our chosen safety and effectiveness endpoints or otherwise produce results that will eventually support the filing or approval of a BLA. Even if the data from this trial are favorable, these data may not be predictive of the results of any future clinical trials.

The issued patents, which are licensed by us for the HuM-195 antibody, our acute myeloid leukemia targeting antibody, may expire before we have commercialized Actimab™-A.

The humanized antibody which we use in the conjugated Actimab™-A product candidate is covered by the claims of issued patents that we license from Facet Biotech Corporation, a wholly-owned subsidiary of AbbVie Laboratories. After these patents expire, others may be eventually able to use an antibody with the same sequence, and we will then need to rely on additional patent protection covering alpha particle drug products comprising actinium 225. Any competing product based on the HuM-195 antibody is likely to require several years of development before achieving our product candidate's current status and may be subject to significant regulatory hurdles, but is nevertheless a possibility that can affect the Company's business in the future.

Additionally, because we expect that certain of these patents will expire prior to commercialization of Actimab™-A, we expect that in order to attract a commercialization partner for that product candidate, we may need to reach an agreement with AbbVie to reduce the milestone payments and royalties currently required to be paid under our license agreement for HuM-195. There can be no assurance that the parties will be able to agree on an amendment to the terms of the license. Failure to reach such an agreement could materially adversely affect our ability to find a commercialization partner for Actimab™-A which may materially harm our business.

Iomab™-B is not patent protected.

Neither the antibody portion nor the composition of matter as a whole for the conjugated Iomab™ product candidate is covered by the claims of any issued or pending patents. Accordingly, there are no patents that would prevent others from using an antibody with the same antibody sequence in any drug product (e.g., those comprising iodine 131 or alpha particle emitters). Any competing product based on the antibody used in Iomab-B™ is likely to require several years of development before achieving our product candidate's current status and may be subject to significant regulatory hurdles, but is nevertheless a possibility that could negatively impact the Company's business in the future.

We may be unable to obtain a sufficient supply of Ac-225 medical grade isotope in order to continue clinical trials and to allow for the manufacture of commercial quantities of Actimab™-A

There are limited quantities of Ac-225 available today. The existing supplier of Ac-225 to us is the ORNL, which is a science and energy national laboratory in the Department of Energy system. ORNL manufactures Ac-225 by eluting it from its supply of Thorium-229. Although this has proven to be a very reliable source of production for a number of years, it is limited by the quantity of Thorium-229 at ORNL. We believe that the current approximate maximum of Ac-225 production from this source is sufficient for approximately 1,000–2,000 patient treatments per year. Since our

needs are significantly below that amount at this time, and will continue to be below that for as long as we do not have a commercial product with a potential of selling more than 2,000 patient doses per year, we believe that this supply will be sufficient for completion of clinical trials and early commercialization. To secure supplies beyond this amount, we have developed what we believe to be a scalable cost-effective process for manufacturing Ac-225 in a cyclotron at an estimated cost in excess of $5 million. This work has been conducted at Technical University Munich (TUM) in Germany. We are now in possession of detailed descriptions of all the developed manufacturing procedures and have rights to all relevant patent applications and other intellectual property. However, we do not currently have access to a commercial cyclotron capable of producing medical grade Ac-225. Although beam time on such cyclotrons is commercially available, we do not currently have a relationship with any entity that owns or controls a suitable cyclotron. We have identified possible sources and estimate that we could secure the necessary beam time when needed at a cost of approximately $2 million per year. In the meantime, our contract for supply of this isotope from ORNL must be renewed yearly, and the current contract extends through the end of 2016. While we expect this contract will be renewed at the end of its term, there can be no assurance that ORNL will decide to renew the contract or that the United States Department of Energy will not change its policies that allow for the sale of isotope to us. Failure to acquire sufficient quantities of medical grade Ac-225 would make it impossible to effectively complete clinical trials and to commercialize Actimab™-A and would materially harm our business.

Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit.

Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population; the nature of the trial protocol; the availability of approved effective treatments for the relevant disease; competition from other clinical trial programs for similar indications; the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects; the availability of appropriate clinical trial investigators; support staff; and proximity of patients to clinical sites and ability to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our product candidates or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive product candidates. In addition, patients participating in refractory AML clinical trials are seriously and often terminally ill and therefore may not complete the clinical trial due to reasons including comorbid conditions or occurrence of adverse medical events related or unrelated to the investigational products, or death.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support approval.

The FDA may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. It may also require additional data on certain categories of patients, should it emerge during the conduct of our clinical trials that certain categories of patients are likely to be affected in different and/or additional manners than the rest of the patient population. In addition to FDA requirements, our clinical trials require the approval of the IRB at each site selected. We have submitted our clinical trial protocol for our current Actimab™-A clinical trial to the IRBs at participating sites for approval and we have thus far obtained approval from seven IRBs. Our clinical trial protocols have not been rejected by any IRB to date.

FDA may take actions that would prolong, delay, suspend, or terminate clinical trials of our product candidates, which may delay or prevent us from commercializing our product candidates on a timely basis, causing us to incur additional costs and delay our receipt of any revenue from potential product sales.

There can be no assurance that the data generated in our clinical trials will be acceptable to FDA or that if future modifications during the trial are necessary, that any such modifications will be acceptable to FDA. Certain modifications to a clinical trial protocol made during the course of the clinical trial have to be submitted to the FDA. This could result in the delay or halt of a clinical trial while the modification is evaluated. In addition, depending on the quantity and nature of the changes made, FDA could take the position that some or all of the data generated by the clinical trial is not usable because the same protocol was not used throughout the trial. This might require the enrollment of additional subjects, which could result in the extension of the clinical trial and the FDA delaying approval of a product candidate. If the FDA believes that its prior approval is required for a particular modification, it can delay or halt a clinical trial while it evaluates additional information regarding the change.

Serious injury or death resulting from a failure of one of our product candidates during current or future clinical trials could also result in the FDA delaying our clinical trials or denying or delaying approval of a product candidate.

The Phase 1 portion of the ongoing Phase 1/2 clinical trial for Actimab™-A being conducted at seven clinical centers in the United States (MSKCC, MD Anderson Cancer Center, Fred Hutchinson Cancer Research Center, Johns Hopkins Medicine, University of Pennsylvania Health System, Baylor Summons Cancer Center and Columbia University Medical Center) was designed to establish the maximum tolerated dose of the product. As the Company expected, patients receiving highest dose of the drug administered in the trial so far had prolonged bone marrow suppression which could lead to fatal infections and other severe consequences. Consequently, the dose levels of our drug in that trial were reduced as we continue our work on establishing maximum tolerated dose.

Even though an adverse event may not be the result of our product candidate, the FDA or an IRB could delay or halt a clinical trial for an indefinite period of time while an adverse event is reviewed, and likely would do so in the event of multiple such events.

Any delay or termination of our current or future clinical trials as a result of the risks summarized above, including delays in obtaining or maintaining required approvals from IRBs, delays in patient enrollment, the failure of patients to continue to participate in a clinical trial, and delays or termination of clinical trials as a result of protocol modifications or adverse events during the trials, may cause an increase in costs and delays in the filing of any submissions with the FDA, delay the approval and commercialization of our product candidates or result in the failure of the clinical trial, which could adversely affect our business, operating results and prospects. Lengthy delays in the completion of our Actimab™-A clinical trials would adversely affect our business and prospects and could cause us to cease operations.

If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, or fail to comply with applicable regulations and standards, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We do not have the ability to independently conduct our pre-clinical and clinical trials for our product candidates and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct such trials. Our reliance on these third parties for clinical development activities results in reduced control over these activities. Moreover, the FDA requires us to comply with regulations and standards, commonly referred to as GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. If we or any of our third party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under current good manufacturing practice, or cGMP, regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

To date, we believe our consultants, contract research organizations and other similar entities with which we are working have performed well; however, if these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with applicable regulations, we may be required to replace them. Although we believe that there are a number of other third-party contractors we could engage to continue these activities, we may not be able to enter into arrangements with alternative third-party contractors or to do so on commercially reasonable terms, which may result in a delay of our planned clinical trials. Accordingly, we may be delayed in obtaining regulatory approvals for our product candidates and may be delayed in our efforts to successfully develop our product candidates.

In addition, our third-party contractors are not our employees, and except for remedies available to us under our agreements with such third-party contractors, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our product candidates on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

The future results of our current or future clinical trials may not support our product candidate claims or may result in the discovery of unexpected adverse side effects.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA or foreign authorities will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses. If FDA concludes that the clinical trials for Actimab™-A, or any other product candidate for which we might seek approval, have failed to demonstrate safety and effectiveness, we would not receive FDA approval to market that product candidate in the United States for the indications sought. In addition, such an outcome could cause us to abandon the product candidate and might delay development of others. Any delay or termination of our clinical trials will delay or preclude the filing of any submissions with the FDA and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of a product candidate’s profile. In addition, our clinical trials for Actimab™-A involve a relatively small patient population. Because of the small sample size, their results may not be indicative of future results.

Our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

Our product candidates are regulated by the FDA as biologic products and we intend to seek approval for these products pursuant to the BLA pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated pathway for the approval of biosimilar and interchangeable biologic products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biologic products.

Actimab™-A and future product candidates may never achieve market acceptance.

Actimab™-A and future product candidates that we may develop may never gain market acceptance among physicians, patients and the medical community. The degree of market acceptance of any of product will depend on a number of factors, including the actual and perceived effectiveness and reliability of the product; the results of any long-term clinical trials relating to use of the product; the availability, relative cost and perceived advantages and disadvantages of alternative technologies; the degree to which treatments using the product are approved for reimbursement by public and private insurers; the strength of our marketing and distribution infrastructure; and the level of education and awareness among physicians and hospitals concerning the product.

Failure of Actimab™-A or any of our other product candidates to significantly penetrate current or new markets would negatively impact our business financial condition and results of operations.

To be commercially successful, physicians must be persuaded that using our product candidates for treatment of AML and other cancers, if approved for those indications, are effective alternatives to existing therapies and treatments.

We believe that oncologists and other physicians will not widely adopt a product candidate unless they determine, based on experience, clinical data, and published peer-reviewed journal articles, that the use of that product candidate provides an effective alternative to other means of treating specific cancers. Patient studies or clinical experience may indicate that treatment with our product candidates does not provide patients with sufficient benefits in extension of life or quality of life. We believe that recommendations and support for the use of each product candidate from influential physicians will be essential for widespread market acceptance. Our product candidates are still in the development stage and it is premature to attempt to gain support from physicians at this time. We can provide no assurance that such support will ever be obtained. If our product candidates do not receive such support from these physicians and from long-term data, physicians may not use or continue to use, and hospitals may not purchase or continue to purchase, them.

Both before and after marketing approval, our product candidates are subject to ongoing regulatory requirements and continued regulatory review, and if we fail to comply with these continuing regulatory requirements, we could be subject to a variety of sanctions and the sale of any approved products could be suspended.

Both before and after regulatory approval to market a particular product candidate, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and record keeping related to the product are subject to extensive, ongoing regulatory requirements enforced by FDA and other similar regulatory

bodies. Additionally, because our product candidates include radio-active isotopes, they will be subject to additional regulation and oversight from the United States Nuclear Regulatory Commission (NRC) and similar bodies in other jurisdictions. The FDA regulatory requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP requirements and GCP requirements for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with the regulatory requirements of the FDA and other applicable United States and foreign regulatory authorities could subject us to administrative or judicially imposed sanctions, including:

restrictions on the marketing of our products or their manufacturing processes;

warning letters;

civil or criminal penalties;

fines;

injunctions;

product seizures or detentions;

import or export bans;

voluntary or mandatory product recalls and related publicity requirements;

suspension or withdrawal of regulatory approvals;

total or partial suspension of production; and

refusal to approve pending applications for marketing approval of new products or supplements to approved applications.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Even if regulatory approval of a product candidate is granted, such approval may be subject to limitations on the intended uses for which a product may be marketed and reduce the potential to successfully commercialize that product and generate revenue from that product. If the FDA determines that the product promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we or our commercialization partners cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider such training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

Our revenue stream will depend upon third party coverage and reimbursement of our product candidates, if approved.

The commercial success of our product candidates in both domestic and international markets will be substantially dependent on whether third-party coverage and reimbursement is available for patients that use our products. However, the availability of insurance coverage and reimbursement for newly approved cancer therapies is uncertain, and therefore, third-party coverage may be particularly difficult to obtain even if our products are approved by the FDA as safe and efficacious. Patients using existing approved therapies are generally reimbursed all or part of the product cost by Medicare or other third-party payors. Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs, and, as a result, they may not cover or provide adequate payment for these products. Submission of applications for reimbursement approval generally does not occur prior to the filing of a BLA for that product and may not be granted until many months after BLA approval. In order to obtain coverage and reimbursement for these products, we or our commercialization partners may have to agree to a net sales price lower than the net sales price we might charge in other sales channels. The continuing efforts of government and third-party payors to contain or reduce the costs of healthcare may limit our revenue. Initial dependence on the commercial success of our products may make our revenues particularly susceptible to any cost containment or reduction efforts.

We have no manufacturing capacity and depend on third-party manufacturers to produce our pre-clinical and clinical trial drug supplies.

We do not currently operate manufacturing facilities for pre-clinical or clinical production of any of our product candidates. We lack experience in drug manufacturing, and we lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. As a result, we rely on a third-party manufacturer to supply, store, and distribute pre-clinical and clinical supply of our product candidates, and plan to continue to do so for the foreseeable future. Any performance failure on the part of our existing or future manufacturers could delay clinical development or regulatory approval of our product candidates or commercialization of any approved products, producing additional losses and depriving us of potential product revenue.

Our product candidates require precise, high quality manufacturing. Failure by our contract manufacturer to achieve and maintain high manufacturing standards could result in patient injury or death, product recalls or withdrawals, delays or failures in testing or delivery, cost overruns, or other problems that could seriously hurt our business. Contract manufacturers may encounter difficulties involving production yields, quality control, and quality assurance. These manufacturers are subject to ongoing periodic and unannounced inspections by the FDA and corresponding state and foreign agencies to ensure strict compliance with cGMPs and other applicable government regulations and corresponding foreign standards; however, we do not have control over third-party manufacturers' compliance with these regulations and standards.

If a contract manufacturer cannot perform as agreed, we may be required to replace it. We may incur added costs and delays in identifying and qualifying replacements because the FDA must approve any replacement manufacturer prior to manufacturing our product candidates. Such approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our product candidates after receipt of FDA approval.

We anticipate continued reliance on third parties for manufacturing and marketing, if we are successful in obtaining marketing approval from the FDA and other regulatory agencies for any of our product candidates. If we are not able to secure favorable arrangements with such third parties, our business and financial condition would be harmed, and our commercialization of any of our product candidates may be halted, delayed or made less profitable if those third parties fail to obtain such approvals, fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

To date, our product candidates have been manufactured in small quantities for preclinical and clinical testing by third-party manufacturers. If the FDA or other regulatory agencies approve any of our product candidates for commercial sale, we expect that we would continue to rely, at least initially, on third-party specialized manufacturers to produce commercial quantities of approved products. These manufacturers may not be able to successfully increase the manufacturing capacity for any approved product in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If third party manufacturers are unable to successfully increase the manufacturing capacity for a product candidate, or we are unable to establish our own manufacturing capabilities, the commercial launch of any approved products may be delayed or there may be a shortage in supply, which in turn could have a material adverse effect on our business.

In addition, the facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit a BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We also intend to partner with larger pharmaceutical companies for the commercialization of any of our product candidates that are approved. In connection with our efforts to commercialize our product candidates, we will seek to secure favorable arrangements with third parties to distribute, promote, market and sell them. If we are not able to secure favorable commercial terms or arrangements with third parties for distribution, marketing, promotion and sales of our product candidates, we may have to retain promotional and marketing rights and seek to develop the commercial resources necessary to promote or co-promote or co-market certain or all of our product candidates to the appropriate channels of distribution in order to reach the specific medical market that we are targeting. We may not be able to enter into any partnering arrangements on this or any other basis. If we are not able to secure favorable partnering arrangements, or are unable to develop the appropriate resources necessary for the commercialization of our product candidates, our business and financial condition could be harmed. In addition, we will have to hire additional employees or consultants, since our current employees have limited experience in these areas. Sufficient employees with relevant skills may not be available to us. Any increase in the number of our employees would increase our expense level, and could have an adverse effect on our financial position.

In addition, we, or our potential commercial partners, may not successfully introduce our product candidates or they may not achieve acceptance by patients, health care providers and insurance companies. Further, it is possible that we may not be able to secure arrangements to manufacture, market, distribute, promote and sell our product candidates at favorable commercial terms that would permit us to make a profit. To the extent that corporate partners conduct clinical trials, we may not be able to control the design and conduct of these clinical trials.

We may have conflicts with our partners that could delay or prevent the development or commercialization of our product candidates.

We may have conflicts with our partners, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our partners, such partner may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenues: unwillingness on the part of a partner to pay us milestone payments or royalties we believe are due under a collaboration; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the partner to cooperate in the development or manufacture of the product, including providing us with product data or materials; unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

Upon commercialization of our product candidates, we may be dependent on third parties to market, distribute and sell them.

Our ability to generate revenues may be dependent upon the sales and marketing efforts of any future co-marketing partners and third-party distributors. At this time, we have not entered into an agreement with any commercialization partner and only plan to do so after the successful completion of Phase 2 clinical trials and prior to commercialization. If we fail to reach an agreement with any commercialization partner, or if upon reaching such an agreement that partner fails to sell a large volume of our products, it may have a negative impact on our business, financial condition and results of operations.