

---

---

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

---

**FORM 10-Q**

---

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

For the quarterly period ended March 31, 2011.

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File Number: 000-52089

**InVivo Therapeutics Holdings Corp.**

(Exact name of registrant as specified in its charter)

Nevada  
(State or other jurisdiction of  
incorporation or organization)

One Broadway, 14<sup>th</sup> Floor, Cambridge MA  
(Address of principal executive offices)

36-4528166  
(I.R.S. Employer  
Identification Number)

02142  
(Zip code)

(617)-475-1520  
(Registrant's telephone number, including area code)

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input checked="" type="checkbox"/>

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

As of May 13, 2011, 51,674,712 shares of the registrant's Common Stock, \$0.00001 par value, were issued and outstanding.

---

---

[Table of Contents](#)

**INVIVO THERAPEUTICS HOLDINGS CORP.**  
**Quarterly report on Form 10-Q for the period ended March 31, 2011**

**TABLE OF CONTENTS**

**PART I**

**FINANCIAL INFORMATION**

<u>Item</u>	<u>Page</u>
<b><u>1. Financial Statements</u></b>	
<a href="#">Consolidated Balance Sheets as of March 31, 2011 and December 31, 2010</a>	2
<a href="#">Consolidated Statements of Operations for the three months ended March 31, 2011 and 2010</a>	3
<a href="#">Consolidated Statements of Cash Flows for the three months ended March 31, 2011 and 2010</a>	4
<a href="#">Notes to Financial Statements (Unaudited)</a>	6
<b><u>2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	12
<b><u>3. Quantitative and Qualitative Disclosures about Market Risk</u></b>	14
<b><u>4. Controls and Procedures</u></b>	14

**PART II**

**OTHER INFORMATION**

<b><u>2. Unregistered Sales of Equity Securities and Use of Proceeds</u></b>	14
<b><u>5. Other Information</u></b>	14
<b><u>6. Exhibits</u></b>	14

[Table of Contents](#)
**PART I – FINANCIAL INFORMATION**
**Item 1. Financial Statements.**
**InVivo Therapeutics Holdings Corp.  
(A Developmental Stage Company)**
**Consolidated Balance Sheets**

	<b>As of</b>	
	<b>March 31, 2011</b>	<b>December 31, 2010</b>
	<b>Unaudited</b>	
<b>ASSETS:</b>		
Current assets:		
Cash and cash equivalents	\$ 6,864,118	\$ 8,964,194
Restricted cash	105,000	—
Prepaid expenses	461,989	81,166
Total current assets	7,431,107	9,045,360
Property and equipment, net	500,566	280,181
Other assets	52,389	53,639
Total assets	<u>\$ 7,984,062</u>	<u>\$ 9,379,180</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT:</b>		
Current liabilities:		
Accounts payable	\$ 294,036	\$ 336,945
Capital lease payable-current portion	29,620	—
Derivative warrant liability	10,525,843	10,647,190
Accrued expenses	97,025	247,547
Total current liabilities	10,946,524	11,231,682
Capital lease payable-less current portion	58,712	—
Total liabilities	<u>11,005,236</u>	<u>11,231,682</u>
Commitments and contingencies		
Stockholders' deficit:		
Common stock , \$0.00001 par value; authorized 100,000,000 shares, issued and outstanding 51,674,712 and 51,647,171 shares outstanding at March 31, 2011 and December 31, 2010, respectively	516	516
Additional paid-in capital	12,491,459	12,382,141
Deficit accumulated during the development stage	(15,513,149)	(14,235,159)
Total stockholders' deficit	<u>(3,021,174)</u>	<u>(1,852,502)</u>
Total liabilities and stockholders' deficit	<u>\$ 7,984,062</u>	<u>\$ 9,379,180</u>

See notes to the consolidated financial statements.

**InVivo Therapeutics Holdings Corp.**  
**(A Developmental Stage Company)**  
**Consolidated Statements of Operations**  
**(Unaudited)**

	Three Months Ended March 31,		Period from November 28, 2005 (inception) to March 31, 2011
	2011	2010	
Operating expenses:			
Research and development	\$ 636,323	\$ 157,384	\$ 5,793,093
General and administrative	764,319	224,670	4,084,201
Total operating expenses	<u>1,400,642</u>	<u>382,054</u>	<u>9,877,294</u>
Operating loss	<u>(1,400,642)</u>	<u>(382,054)</u>	<u>(9,877,294)</u>
Other income (expense):			
Other income	—	—	383,000
Interest income	2,818	87	14,108
Interest expense	(1,513)	(72,021)	(1,055,168)
Derivatives gain (loss)	121,347	—	(4,977,547)
Other income (expense), net	<u>122,652</u>	<u>(71,934)</u>	<u>(5,635,607)</u>
Net loss	<u>\$ (1,277,990)</u>	<u>\$ (453,988)</u>	<u>\$(15,512,901)</u>
Net loss per share, basic and diluted	<u>\$ (0.02)</u>	<u>\$ (0.02)</u>	<u>\$ (0.56)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>51,660,942</u>	<u>26,259,515</u>	<u>27,737,458</u>

See notes to the consolidated financial statements.

**InVivo Therapeutics Holdings Corp.**  
**(A Developmental Stage Company)**  
**Consolidated Statements of Cash Flows**  
**(Unaudited)**

	Three Months Ended March 31,		Period from November 28, 2005 (inception) to March 31, 2011
	2011	2010	
Cash flows from operating activities:			
Net loss	\$(1,277,990)	\$(453,988)	\$(15,512,901)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	27,979	11,488	120,944
Non-cash derivatives (gain) loss	(121,347)	—	4,977,547
Non-cash interest expense	—	33,620	962,835
Share-based compensation expense	107,319	109,126	986,159
Changes in operating assets and liabilities:			
Restricted cash	(105,000)	—	(105,000)
Prepaid expenses	(380,823)	8,089	(461,989)
Other assets	—	—	(75,000)
Accounts payable	(42,909)	(31,669)	294,037
Accrued interest payable	—	(29,100)	(15,256)
Accrued expenses	(150,522)	(79,494)	97,025
Net cash used in operating activities	<u>(1,943,293)</u>	<u>(431,928)</u>	<u>(8,731,600)</u>
Cash flows from investing activities:			
Purchases of property and equipment	<u>(153,574)</u>	<u>(10,537)</u>	<u>(505,359)</u>
Net cash used in investing activities	<u>(153,574)</u>	<u>(10,537)</u>	<u>(505,359)</u>
Cash flows from financing activities:			
Proceeds from issuance of convertible notes payable	—	200,000	4,181,000
Proceeds from convertible bridge notes	—	—	500,000
(Repayment of) proceeds from loans payable and capital lease	—	45,000	—
Principal payments on capital lease obligation	(5,208)	—	(5,208)
Proceeds from issuance of common stock and warrants	1,999	—	11,425,285
Net cash provided (used in) by financing activities	<u>(3,209)</u>	<u>245,000</u>	<u>16,101,077</u>
Decrease (Increase) in cash and cash equivalents	(2,100,076)	(197,465)	6,864,118
Cash and cash equivalents at beginning of period	<u>8,964,194</u>	<u>226,667</u>	<u>—</u>
Cash and cash equivalents at end of period	<u>\$ 6,864,118</u>	<u>\$ 29,202</u>	<u>\$ 6,864,118</u>

(continued)

See notes to the consolidated financial statements.

**InVivo Therapeutics Holdings Corp.**  
**(A Developmental Stage Company)**  
**Consolidated Statements of Cash Flows (Concluded)**  
**(Unaudited)**

	Three Months Ended March 31,		Period from November 28, 2005 (inception) to March 31, 2011
	2011	2010	
Supplemental disclosure of cash flow information and non-cash transactions:			
Cash paid for interest	\$ 416	\$ —	\$ 97,933
Conversion of convertible notes payable and accrued interest into common stock	\$ —	\$3,328,128	\$4,672,484
Conversion of convertible bridge note payable and accrued interest into common stock	\$ —	\$ —	\$ 504,597
Asset acquired through capital lease obligation	\$93,540	\$ —	\$ 93,540
Beneficial conversion feature on convertible and bridge notes payable	\$ —	\$ —	\$ 134,410
Relative fair value of warrants issued with common stock in private placement	\$ —	\$ —	\$ 178,726
Issuance of founders shares	\$ —	\$ —	\$ 248

See notes to the consolidated financial statements.

**InVivo Therapeutics Holdings Corp.**  
**(A Development Stage Company)**  
**Notes to Consolidated Financial Statements**  
**Period Ended March 31, 2011 (Unaudited)**

**1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION**

***Business***

InVivo Therapeutics Corporation (“InVivo”) was incorporated on November 28, 2005 under the laws of the State of Delaware. InVivo is developing and commercializing biopolymer scaffolding devices for the treatment of spinal cord injuries. The biopolymer devices are designed to protect the damaged spinal cord from further secondary injury and promote neuroplasticity, a process where functional recovery can occur through the rerouting of signaling pathways to the spared healthy tissue.

Since its inception, InVivo has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. Accordingly, InVivo is considered to be in the development stage.

***Reverse Merger***

On October 26, 2010, InVivo completed a reverse merger transaction (the “Merger”) with InVivo Therapeutics Holdings Corporation (formerly Design Source, Inc.) (“ITHC”), a publicly traded company incorporated under the laws of the State of Nevada. InVivo became a wholly owned subsidiary of ITHC, which continues to operate the business of InVivo. As part of the Merger, ITHC issued 31,147,190 shares of its Common Stock to the holders of InVivo common stock on October 26, 2010 in exchange for the 2,261,862 outstanding common shares of InVivo and also issued 500,000 shares to its legal counsel in consideration for legal services provided. All share and per share amounts presented in these consolidated financial statements have been retroactively restated to reflect the 13.7706 exchange ratio of InVivo shares for ITHC shares in the Merger. Immediately prior to the Merger, ITHC had 6,999,981 shares of Common Stock outstanding.

The Merger was accounted for as a “reverse merger,” and InVivo is deemed to be the accounting acquirer. The Merger was recorded as a reverse recapitalization, equivalent to the issuance of common stock by InVivo for the net monetary assets of ITHC accompanied by a recapitalization. At the date of the Merger, the 6,999,981 outstanding ITHC shares were reflected as an issuance of InVivo common stock to the prior shareholders of ITHC. ITHC had no net monetary assets as of the Merger so this issuance was recorded as a reclassification between additional paid-in capital and par value of Common Stock.

The historical consolidated financial statements are those of InVivo as the accounting acquirer. The post-merger combination of ITHC and InVivo is referred to throughout these notes to consolidated financial statements as the “Company.” Subsequent to the Merger, the Company completed three closings as part of a private placement.

On October 26, 2010, in connection with the Merger described above, ITHC transferred all of its operating assets and liabilities to its wholly-owned subsidiary, D Source Split Corp., a company organized under the laws of Nevada (“DSSC”). DSSC was then split-off from ITHC through the sale of all outstanding shares of DSSC (the “Split-Off”). The assets and liabilities of ITHC were transferred to the Split-Off Shareholders in the Split-Off. ITHC executed a split off agreement with the Split-Off Shareholders which obligates the Split-Off Shareholders to assume all prior liabilities associated with Design Source, Inc. and all DSSC liabilities. In conjunction with the Split-Off, certain shareholders of ITHC surrendered for cancellation shares of ITHC common stock for no additional consideration. The purpose of the Split-Off was to make ITHC a shell company with no assets or liabilities in order to facilitate the Merger. Although all transactions related to the Merger occurred simultaneously, the Split-Off, including the cancellation of shares, was considered to have occurred immediately prior to the Merger for accounting purposes. As the accounting acquiree in a reverse merger with a shell company, the historical financial statements of ITHC are not presented and these ITHC transactions are not reflected in the Company’s accompanying consolidated financial statements.

***Basis of Presentation***

The accompanying unaudited consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States (“GAAP”) consistent with those applied in, and should be read in conjunction with, the Company’s audited financial statements and related footnotes for the year ended December 31, 2010 included in the Company’s Annual Report on Form 10-K as filed with the United States Securities and Exchange Commission (“SEC”) on March 24, 2011. The unaudited consolidated financial statements reflect all adjustments, consisting only of normal recurring adjustments, which are, in the opinion of management, necessary for a fair presentation of the Company’s financial position as of March 31, 2011 and its results of operations and cash flows for the interim periods presented and are not necessarily indicative of results for subsequent interim periods or for the full year. The interim financial statements do not include all of

**InVivo Therapeutics Holdings Corp.**  
**(A Development Stage Company)**  
**Notes to Consolidated Financial Statements**  
**Period Ended March 31, 2011 (Unaudited)**

the information and footnotes required by GAAP for complete financial statements as allowed by the relevant SEC rules and regulations; however, the Company believes that its disclosures are adequate to ensure that the information presented is not misleading.

## 2. CASH AND CASH EQUIVALENTS

As of March 31, 2011, the Company held \$6.9 million in cash and cash equivalents. From time to time, the Company may have cash balances in financial institutions in excess of insurance limits. The Company has never experienced any losses related to these balances. All of the Company's non-interest bearing cash balances were fully insured at March 31, 2011 due to a temporary federal program in effect from December 31, 2010 through December 31, 2012. Under the program, there is no limit on the amount of insurance for eligible accounts. Beginning in 2013, insurance coverage will revert to \$250,000 per depositor at each financial institution, and non-interest bearing cash balances may again exceed federally insured limits. The Company's cash equivalents are in money market funds and certificates of deposit. The cash and cash equivalents in excess of interest-bearing accounts and non-interest bearing accounts ineligible under the program amounted to approximately \$6,097,000 as of March 31, 2011. Restricted cash represents a security deposit related to the Company's credit card account.

## 3. FAIR VALUE OF ASSETS AND LIABILITIES

The Company groups its assets and liabilities generally measured at fair value in three levels, based on the markets in which the assets and liabilities are traded and the reliability of the assumptions used to determine fair value.

Level 1 – Valuation is based on quoted prices in active markets for identical assets or liabilities. Level 1 assets and liabilities generally include debt and equity securities that are traded in an active exchange market. Valuations are obtained from readily available pricing sources for market transactions involving identical assets or liabilities.

Level 2 – Valuation is based on observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Valuation is based on unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation.

The Company uses valuation methods and assumptions that consider among other factors the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value for the warrants considered to be derivative instruments.

Assets and liabilities measured at fair value on a recurring basis are summarized below:

	March 31, 2011			Fair Value
	Level 1	Level 2	Level 3	
<b>Liabilities:</b>				
Derivative warrant liability	\$ —	\$10,525,843	—	\$10,525,843
	December 31, 2010			Fair Value
	Level 1	Level 2	Level 3	
<b>Liabilities:</b>				
Derivative warrant liability	\$ —	\$10,647,190	—	\$10,647,190



**InVivo Therapeutics Holdings Corp.**  
**(A Development Stage Company)**  
**Notes to Consolidated Financial Statements**  
**Period Ended March 31, 2011 (Unaudited)**

#### 4. COMMITMENTS

##### *Operating Lease Commitment*

The Company leases approximately 1,200 square feet of laboratory and office space in Medford, Massachusetts under a lease expiring November 14, 2012. Future minimum lease payments under this operating lease are approximately as follows:

	Amount
For the years ending December 31,	
2011	\$35,296
2012	43,139
Total	<u>\$78,435</u>

The Company's rent expense under this lease was approximately \$17,000 and none for the three months ended March 31, 2011 and 2010, respectively. Total rent expense in these periods was approximately \$81,000 and \$88,000, respectively.

##### *Other Commitments*

In February 2011, the Company entered into an agreement with a contract research organization to perform non-human clinical trials. The agreement requires total payments of \$825,000 of which \$425,000 was paid upon execution of the contract. The remaining \$425,000 is expected to be paid in the third quarter of 2011.

##### *Registration Payment Arrangements*

In connection with the Merger (see Note 1), the Company completed a private placement of 13,000,000 Units of its securities. The Company entered into a Registration Rights Agreement with the private placement investors, whereby the Company agreed to register common stock as defined in the agreement. The Company is required to file within 90 days of the date of the final closing (the "Filing Deadline"), a registration statement registering for resale all shares of Common Stock issued in the private placement, including Common Stock (i) included in the Units; and (ii) issuable upon exercise of the Investor Warrants. The Company has agreed to use its reasonable efforts to have the registration statement declared effective within 180 days of filing the registration statement (the "Effectiveness Deadline"). If the Registration Statement is not filed on or before the Filing Deadline or not declared effective on or before the Effectiveness Deadline, the Company shall pay to each holder of registrable securities an amount in cash equal to one-half of one percent (0.5%) of such holder's investment in the Offering or in the Bridge Financing on every thirty (30) day anniversary of such Filing Deadline or Effectiveness Deadline failure until such failure is cured. The payment amount shall be prorated for partial thirty (30) day periods. The maximum aggregate amount of payments to be made by the Company as the result of such failures, whether by reason of a Filing Deadline failure, Effectiveness Deadline failure or any combination thereof, shall be an amount equal to 9% of each Unit holder's investment amount. The Company shall keep the Registration Statement effective for one (1) year from the date it is declared effective by the SEC or until Rule 144 of the Securities Act is available to the investors with respect to all of their shares, whichever is earlier.

At each reporting date, the Company assesses the probability of it transferring consideration under its registration payment arrangements. If at any time it determines that such an event is probable and the amount can be reasonably estimated, the amount of such an obligation is recognized as a liability with a charge to earnings. Future changes in that liability will also be charged (credited) to earnings. At the date the Registration Rights Agreement was entered into and at March 31, 2011, the Company did not conclude that it was probable that they will be obligated to transfer any consideration under the terms of this Registration Rights Agreement.

#### 5. CAPITAL LEASE OBLIGATION

At February 8, 2011, the Company entered into a capital lease agreement under which the Company leased certain laboratory equipment. Capital lease obligation consisted of the following:

	March 31, 2011	December 31, 2010
Capital lease	\$ 88,332	\$ —
Less: current portion	<u>(29,620)</u>	<u>—</u>
	<u>\$ 58,712</u>	<u>\$ —</u>

The total value of the laboratory equipment acquired under this capital lease agreement was \$124,151. The capital lease is payable in monthly installments of \$2,812 payable over thirty six months with the final payment due in January 2014. For the three months ended March 31, 2011, interest expense recorded on the capital lease was \$843 and depreciation expense was \$4,138.

#### 6. COMMON STOCK

The Company has authorized 100,000,000 shares of Common Stock, \$0.00001 par value per share, of which 51,674,712, shares and 51,647,171 shares were issued and outstanding as of March 31, 2011 and December 31, 2010, respectively.

In February 2011, the Company issued 27,541 shares of Common Stock upon the exercise of stock options and received cash proceeds of \$1,999.

**InVivo Therapeutics Holdings Corp.**  
**(A Development Stage Company)**  
**Notes to Consolidated Financial Statements**  
**Period Ended March 31, 2011 (Unaudited)**

**7. DERIVATIVE INSTRUMENTS**

Derivative financial instruments are recognized as a liability on the consolidated balance sheet and measured at fair value.

At March 31, 2011 and December 31, 2010, the Company had outstanding warrants to purchase 18,200,000 shares of its Common Stock. These warrants are considered to be derivative instruments since the agreements contain provisions that include anti-dilution protection and, under certain conditions, grant the right to the holder to request the Company to repurchase the warrant. The Company uses valuation methods and assumptions that consider among other factors the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value for the warrants considered to be derivative instruments. The fair value of these derivative instruments at March 31, 2011 and December 31, 2010 were \$10,525,843 and \$10,647,190, respectively. Changes in fair value of the derivative financial instruments are recognized currently in the Statement of Operations as a derivatives gain or loss. The warrant derivative gain for the three months ended March 31, 2011 was \$121,347 and was included in other income (expense) in the consolidated statement of operations. There was no derivatives gain or loss in the three months ended March 31, 2010.

The primary underlying risk exposure pertaining to the warrants is the change in fair value of the underlying Common Stock for each reporting period.

**8. STOCK OPTIONS**

In 2007, the Company adopted the 2007 Employee, Director and Consultant Stock Plan (the "2007 Plan"). Pursuant to the 2007 Plan, the Company's Board of Directors (or committees and/or executive officers delegated by the Board of Directors) may grant incentive and nonqualified stock options to the Company's employees, officers, directors, consultants and advisors. As of March 31, 2011, there were options to purchase an aggregate of 5,888,016 shares of Common Stock outstanding under the 2007 Plan and no shares available for future grants under the 2007 Plan.

On October 26, 2010, the Company's Board of Directors adopted the 2010 Equity Incentive Plan, subject to shareholder approval (the "2010 Plan"). The 2010 Plan provides for grants of incentive stock options to employees and nonqualified stock options and restricted Common Stock to employees, consultants and non-employee directors of the Company. As of December 31, 2010, the number of shares authorized for issuance under the 2010 Plan was 3,500,000 shares. As of March 31, 2011, there were options to purchase an aggregate of 535,000 shares of Common Stock outstanding under the 2010 Plan and 2,965,000 shares available for future grants under the 2010 Plan. If shareholder approval is not obtained by October 25, 2011, all awards granted under the 2010 Plan will terminate. In addition, no award under the 2010 Plan will become exercisable until shareholder approval has been obtained and a registration statement on Form S-8 has been filed with the SEC.

Options issued under the 2007 Plan and the 2010 Plan (collectively the "Plans") are exercisable for up to 10 years from the date of issuance.

***Share-based compensation***

For stock options issued and outstanding for the three months ended March 31, 2011, the Company recorded non-cash, stock-based compensation expense of \$107,319, net of estimated forfeitures. Included in this amount is approximately (\$34,124) of negative expense related to non-employee options that are being repriced throughout the vesting period.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model that uses the assumptions noted in the following table. Due to its limited operating history and limited number of sales of its Common Stock, the Company estimated its volatility in consideration of a number of factors including the volatility of comparable public companies. The Company uses historical data, as well as subsequent events occurring prior to the issuance of the financial statements, to estimate option exercises and employee terminations within the valuation model. The expected term of options granted under the Plans, all of which qualify as "plain vanilla," is based on the average of the contractual term (generally 10 years) and the vesting period (generally 48 months).

**InVivo Therapeutics Holdings Corp.**  
**(A Development Stage Company)**  
**Notes to Consolidated Financial Statements**  
**Period Ended March 31, 2011 (Unaudited)**

For non-employee options, the expected term is the contractual term. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the option.

The assumptions used principally in determining the fair value of options granted to employees were as follows:

	March 31, 2011
Risk-free interest rate	2.44%
Expected dividend yield	0%
Expected term (employee grants)	6.25
Expected volatility	48.44%

A summary of option activity under the Plans and options granted to officers of the Company outside any plan as of March 31, 2011 and changes during the three months then ended is presented below:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2010	6,195,557	\$ 0.59		
Granted	255,000	\$ 1.21		
Exercised	(27,541)	\$ 0.07		
Outstanding at March 31, 2011	<u>6,423,016</u>	\$ 0.62	<u>—</u>	<u>\$ —</u>
Exercisable at March 31, 2011	<u>2,569,416</u>	\$ 0.19	<u>6.87</u>	<u>\$5,308,494</u>

The weighted average grant-date fair value of options granted during the three months ended March 31, 2011 was \$1.21 per share. The total fair value of options that vested in the three months ended March 31, 2011 was \$103,422. As of March 31, 2011, there was approximately \$1,634,033 of total unrecognized compensation expense, related to non-vested share-based option compensation arrangements. The unrecognized compensation expense is estimated to be recognized over a period of 2.86 years at March 31, 2011.

**InVivo Therapeutics Holdings Corp.**  
**(A Development Stage Company)**  
**Notes to Consolidated Financial Statements**  
**Period Ended March 31, 2011 (Unaudited)**

**9. WARRANTS**

The following presents information about warrants to purchase Common Stock issued and outstanding at March 31, 2011:

<u>Year Issued</u>	<u>Number of Warrants</u>	<u>Exercise Price</u>	<u>Date of Expiration</u>
2010	15,600,000	\$ 1.40	10/26/2015 -12/3/2015
2010	3,200,000	1.00	9/26/2015 -12/3/2015
Total	<u>18,800,000</u>		
Weighted average exercise price		<u>\$ 1.33</u>	
Weighted average life in years			<u>4.5</u>

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

*The following management's discussion and analysis should be read in conjunction with the Company's historical consolidated financial statements and the related notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2010, as amended (the "2010 Annual Report"). The management's discussion and analysis contains forward-looking statements that involve risks and uncertainties, including those we detailed under "Risk Factors" in Item 1A of our 2010 Annual Report, such as statements of our plans, objectives, expectations and intentions. Any statements that are not statements of historical fact are forward-looking statements. When used, the words "believe," "plan," "intend," "anticipate," "target," "estimate," "expect" and the like, and/or future tense or conditional constructions ("will," "may," "could," "should," etc.), or similar expressions, identify certain of these forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements in this quarterly report. The Company's actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors. The Company does not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this quarterly report.*

*The discussion and analysis of the Company's financial condition and results of operations are based on the Company's financial statements, which the Company has prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, the Company evaluates such estimates and judgments, including those described in greater detail below. The Company bases its estimates on historical experience and on various other factors that the Company believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.*

### **Overview**

The Company is developing and commercializing biopolymer scaffolding devices for the treatment of spinal cord injuries. The biopolymer devices are designed to protect the damaged spinal cord from further secondary injury and promote neuroplasticity, a process where functional recovery can occur through the rerouting of signaling pathways to the spared healthy tissue.

Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. Accordingly, the Company is considered to be in the development stage.

### **Critical Accounting Policies and Estimates**

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

On an ongoing basis, we evaluate our estimates and judgments for all assets and liabilities, including those related to stock-based compensation expense and the fair value determined for stock purchase warrants classified as derivative liabilities. We base our estimates and judgments on historical experience, current economic and industry conditions and on various other factors that are believed to be reasonable under the circumstances. This forms the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. There have been no changes in our critical accounting policies and estimates from our 2010 Annual Report.

We believe that full consideration has been given to all relevant circumstances that we may be subject to, and the consolidated financial statements accurately reflect our best estimate of the results of operations, financial position and cash flows for the periods presented.

### **Results of Operations**

Research and development expenses consist primarily of payments to contract research and development companies and payroll. General and administrative expenses consist primarily of payroll, rent and professional services.

***Comparison of the three months ended March 31, 2011 and 2010***

**Research and Development Expenses**

Research and development expenses increased by approximately \$479,000 to approximately \$636,000 for the three months ended March 31, 2011 from approximately \$157,000 for the three months ended March 31, 2010. The increase in expenses is primarily attributable to the hiring of additional personnel and an increase in costs of pre-clinical studies.

**General and Administrative Expenses**

General and administrative expenses increased by approximately \$539,000 to approximately \$764,000 for the three months ended March 31, 2011 from approximately \$225,000 for the three months ended March 31, 2010. The increase in expenses is primarily attributable to an increase in costs associated with operating as a public company and increases in rent, salary and benefit costs.

**Interest expense**

Interest expense decreased by \$70,000 to approximately \$2,000 for the three months ended March 31, 2011 from approximately \$72,000 for the three months ended March 31, 2010. The decrease in interest expense is due to the conversion into common stock of the remaining balance of the convertible notes payable as of March 31, 2010.

**Derivatives Gain (Loss)**

Derivatives gain was approximately \$121,000 for the three months ended March 31, 2011 and reflects the decrease in the fair value of derivative warrant liabilities during the period. We did not have a derivative warrant liability or derivative gain (loss) during the three months ended March 31, 2010.

**Financial Condition, Liquidity and Capital Resources**

Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. Accordingly, the Company is considered to be in the development stage.

Since inception, the Company has experienced negative cash flows from operations. The Company has financed its operations primarily through the sale of equity-related securities. At March 31, 2011, the accumulated deficit was approximately \$15,513,000 and the stockholders' deficit was approximately \$3,021,000.

At March 31, 2011, we had total current assets of approximately \$7,431,000 and current liabilities of approximately \$10,947,000 resulting in a working capital deficit of approximately \$3,516,000. At March 31, 2011, the Company had total assets of approximately \$7,984,000 and total liabilities of approximately \$11,005,000, resulting in a stockholders' deficit of \$3,021,000.

Net cash used by operating activities for the three months ended March 31, 2011 was approximately \$1,943,000. The Company raised approximately \$2,000 from the exercise of stock options. The Company spent approximately \$154,000 for the three months ended March 31, 2011 on the purchase of equipment.

At March 31, 2011, the Company had cash of approximately \$6,864,000 and the Company expects the cash to fund its operations at least through March 31, 2012. The Company will need to raise substantial additional capital to complete its clinical trials, obtain marketing approvals and commercialize its products.

**Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements, including unrecorded derivative instruments that have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources. We have certain warrants and options outstanding but we do not expect to receive sufficient proceeds from the exercise of these instruments unless and until the trading price of our Common Stock is significantly greater than the applicable exercise prices of the options and warrants and mainly following any necessary registering of underlying securities.

**Effect of Inflation and Changes in Prices**

Management does not believe that inflation and changes in price will have a material effect on our operations.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

This information has been omitted as the Company qualifies as a smaller reporting company.

**Item 4. Controls and Procedures.**

**Disclosure Controls and Procedures**

Our management, with the participation of Frank Reynolds, our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that the information required to be disclosed by us in such reports is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

**Internal Control over Financial Reporting**

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the fiscal quarter to which this report relates that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II—OTHER INFORMATION**

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

On February 14, 2011, we issued 27,541 shares of our Common Stock to George Calapai upon his exercise of stock options under our 2007 Stock Option Plan at an exercise price of \$0.0723 per share. The issuance of these shares was effected without registration in reliance on Section 4(2) of the Securities Act of 1933, as amended, as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of these shares.

**Item 5. Other Information.**

During the quarter ended March 31, 2011, we made no material changes to the procedures by which shareholders may recommend nominees to our Board of Directors, as described in our Amendment to Annual Report on Form 10-K/A, filed on April 29, 2011.

**Item 6. Exhibits.**

The Exhibits listed in the Exhibit Index immediately preceding such Exhibits are filed with or incorporated by reference in this report.

**SIGNATURES**

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

**INVIVO THERAPEUTICS HOLDINGS CORP.**

*Date: May 16, 2011*

*By: /s/ Frank M. Reynolds*

*Name: Frank M. Reynolds*

*Title: Chief Executive Officer and Chief Financial Officer (Principal Executive, Financial and Accounting Officer)*



**EXHIBIT INDEX**

- |           |   |
|-----------|---|
| 10.1      | License Agreement dated July 2007 between InVivo Therapeutics Corp. and Children's Medical Center Corporation(1)                            |
| 31.1/31.2 | Certification by the Principal Executive Officer and Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1/32.2 | Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.     |
- 1) Application will be made with the Securities and Exchange Commission to seek confidential treatment of certain provisions. Omitted material for which confidential treatment will be requested will be filed separately with the Securities and Exchange Commission.

Confidential Materials omitted and filed separately with the  
Securities and Exchange Commission. Asterisks denote omissions.

EXCLUSIVE LICENSE AGREEMENT  
BETWEEN  
**CHILDREN'S MEDICAL CENTER CORPORATION**  
AND  
**InVivo Therapeutics Corporation**

TABLE OF CONTENTS

Articles	Page
I.	Definitions
II.	Grant
III.	Due Diligence
IV.	Royalties and Other Payments
V.	Reports and Records
VI.	Patent Prosecution
VII.	Infringement
VIII.	Uniform Indemnification and Insurance Provisions
IX.	Compliance with Laws; Export Controls
X.	Non-Use of Names
XI.	Assignment

---

XII. Dispute Resolution and Arbitration

XIII. Term and Termination

XIV. Payments, Notices and Other Communications

XV. General Provisions

---

## EXCLUSIVE LICENSE AGREEMENT

This Exclusive License Agreement (the “Agreement”) is made and entered into as of July 2, 2007 (the “Effective Date”) by and between CHILDREN’S MEDICAL CENTER CORPORATION, a charitable corporation duly organized and existing under the laws of the Commonwealth of Massachusetts and having its principal office at 300 Longwood Avenue, Boston, Massachusetts, 02115, U.S.A. (hereinafter referred to as “CMCC”), and InVivo Therapeutics Corporation, a business corporation organized and existing under the laws of the State of Delaware and having its principal office at 7 Fort Washington Place, Cambridge, MA (hereinafter referred to as “Licensee”).

WHEREAS, CMCC and the Massachusetts Institute of Technology (hereinafter referred to as “MIT”) are the co-owners of certain Patent Rights (as that term shall be defined hereafter) and have the right to grant exclusive licenses under the Patent Rights;

WHEREAS, CMCC and MIT have entered into an Inter-Institutional Agreement dated June 1, 2006, under which MIT has authorized CMCC to assume the responsibility for the preparation, filing, prosecution, maintenance and defense of the Patent Rights and has appointed CMCC as its sole agent for the licensing of MIT’s interests in the Patent Rights, subject, only to a royalty-free, nonexclusive license granted to the United States Government for those inventions and ensuing patents developed with U.S. Government funding, and certain laws and regulations relating to Federally- funded projects and institutions, if applicable;

WHEREAS, in furtherance of its charitable and research missions and those laws and regulations, CMCC and MIT (hereinafter referred to as “Institutions”) desire to have the Patent Rights utilized to promote the public interest and to further that goal are willing to grant an exclusive license to Licensee on the terms and conditions described herein;

WHEREAS, Licensee plans to engage in the commercial development, production, manufacture, marketing and sale of Licensed Products (as that term shall be defined hereafter) as described in this Agreement; and WHEREAS, Licensee desires to obtain an exclusive license, within a designated territory and for a prescribed field of use, relating to certain licensed products and processes within the scope of the Patent Rights, subject to the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the promises and the mutual covenants contained herein, the parties hereto agree as follows:

## ARTICLE I. DEFINITIONS

For the purpose of this Agreement, the following words and phrases shall have the meanings set forth below:

- A. “Affiliate” shall mean any company or other legal entity actually controlling, controlled by or under common control with Licensee. For purposes of the definition of “Affiliate” the term “control” shall mean: (i) in the case of a corporate entity, the ability to effect the election of directors, or in the case of a for-profit entity direct or indirect ownership of at least a majority of the stock or participating shares entitled to vote for the election of directors of that entity, in any case coupled with active managerial involvement and accountability for directing the business and affairs of that entity; (ii) in the case of a partnership, the power customarily held by a managing partner to direct the management and policies of such partnership, provided that such power is actively exercised; or (iii) in the case of a joint venture, whether in corporate, partnership or other legal form, a prevailing joint economic interest coupled with a managerial role entailing active direction, control and accountability with respect to the business and affairs of the entity.
- B. “Combination Product(s) or Process(es)” shall mean a product or process that includes a Licensed Product sold in combination with another component(s) whose manufacture, use or sale by an unlicensed party would not constitute an infringement of the Patent Rights licensed in this Agreement.
- C. “Confidential Information” shall mean with respect to a party (the “Receiving Party”), all information which is disclosed by the other party (the “Disclosing Party”) to the Receiving Party hereunder or to any of its employees, consultants, Affiliates, licensees or sublicensees, except to the extent that the Receiving Party can demonstrate by written record or other suitable physical evidence that such information, (a) as of the date of disclosure is demonstrably known to the Receiving Party or its Affiliates other than by virtue of a prior confidential disclosure to such Party or its Affiliates; (b) as of the date of disclosure is in, or subsequently enters, the public domain, through no fault or omission of the Receiving Party; (c) is obtained from a Third Party having a lawful right to make such

disclosure free from any obligation of confidentiality to the Disclosing Party; or (d) is independently developed by or for the Receiving Party without reference to or reliance upon any Confidential Information of the Disclosing Party.

- A. "Control" or "Controlled" shall mean with respect to any Patent Rights or Licensed Process, the possession by a party of the power to grant a license or sublicense of such Patent Rights, or Licensed Process as provided for herein without violating the terms of any arrangement or agreements between such party and any third party.
- B. "Distributor" shall mean a person or an entity unaffiliated with the Licensee to whom Licensee has granted an arms length sublicense under this Agreement to re-market, re-distribute and/ or re-sell but not manufacture a Licensed Product. Distributors shall mean dealers, resellers, value added resellers, original equipment manufacturers and other similar purchasers and specifically excludes Manufacturers.
- C. "Field of Use" shall mean treatment of Spinal cord injury (SCI).
- D. "First Commercial Sale" shall mean, with respect to each country: (i) the first sale of any Licensed Product by Licensee or any Sublicensee, following approval of such Licensed Product's marketing by the appropriate governmental agency, if any such approval is necessary, for the country in which the sale is to be made; or (ii) when governmental approval is not required, the first sale in that country of the Licensed Product.
- E. "Improvements" shall mean any enhancement, invention or discovery created or identified during the Term of this Agreement (i) which CMCC owns or is Controlled by CMCC; (ii) deriving from the activities of Dr. Yang Dong Teng or others in his laboratory at CMCC and (ii) that is directed to the subject matter of the claims of the Patent Rights.
- F. "Licensed Product" shall mean any product or part thereof in the Field of Use:

1. The manufacture, use or sale of which would, absent the license granted to Licensee hereunder, infringe any one of the issued, unexpired claim(s) or any one of the pending claim(s) (so long as such pending claims have not been pending for longer than 7 years beginning from the initial examination date by the patent office of that country) contained in the Patent Rights in any country within the Territory. A claim of any issued, unexpired Patent Right shall be presumed to be valid unless and until it has been held to be invalid

by a final judgment of a court of competent jurisdiction from which no appeal can be or is taken; or

1. The manufacture or use of which uses a “Licensed Process” as that term shall be defined hereafter.

- A. “Licensed Process” shall mean any process that would infringe any one of the issued, valid, enforceable, unexpired claim(s) or any one of the pending claim(s) contained in the Patent Rights in any country in the Territory, absent the license granted to Licensee hereunder. A claim of any issued, unexpired Patent Right shall be presumed to be valid unless and until it has been held to be invalid by a final judgment of a court of competent jurisdiction from which no appeal can be or is taken.
- B. “Licensee” shall mean Licensee, and successors and assignees permitted by this Agreement (including Affiliates where they are assignees permitted by this Agreement).
- C. “Manufacturer” shall mean a person or an entity unaffiliated with the Licensee to whom Licensee has granted an arms length sublicense under this Agreement to develop, make/use and sell a Licensed Product. Manufacturer specifically excludes Distributors.
- D. “Net Sales” shall mean the gross invoiced sales price for sales, leases, or other transfers of Licensed Products received by Licensee or its Affiliates for any Licensed Products to a final customer who will be an end user of the Licensed Product and is not an Affiliate or Sublicensee, less (to the extent appropriately documented) the following amounts:
  - (a) credits and allowances for price adjustment, rejection, or return of Licensed Products previously sold;
  - (b) trade, rebates, quantity and cash discounts to purchasers allowed and taken;
  - (c) amounts for third party transportation, insurance, handling, or shipping charges to purchasers;
  - (d) taxes, tariffs, duties and other governmental charges levied on or measured by the sale, transfer, transportation or delivery of Licensed Products (including any tax such as a value added or similar tax or governmental charge), whether



absorbed by Licensee or paid by the purchaser so long as Licensee's price is reduced thereby, but not franchise or income taxes of any kind whatsoever;

- (e) when applicable, for any sale in which the United States government, on the basis of its royalty-free license pursuant to 35 USC Sec. 202(c) to any Patent Right, requires that the gross sales price of any Licensed Product subject to such Patent Right, be reduced by the amount of such royalty owed Licensor, the amount of such royalty.
- (f) Net Sales also includes the fair market value of any non-cash consideration received by Licensee for the sale, lease, or transfer of Licensed Products. Transfer of a Licensed Product within Licensee or between Licensee and an Affiliate for sale by the transferee shall not be considered a Net Sale for purposes of ascertaining royalty charges. In such circumstances, the gross sales price and resulting Net Sales price shall be based upon the sale of the Licensed Product by the transferee.

A. "Patent Rights" shall mean all of the following intellectual property which CMCC owns or has rights to during the Term of this Agreement as hereafter defined:

- 1. The United States and foreign patents and/or patent applications listed in Appendix 1 attached hereto and incorporated herein by reference and divisionals and continuations thereof.
- 2. The United States and foreign patents issued from the applications listed in Appendix 1A and 1B and from divisionals and continuations of those applications.
- 1. Claims of United States and foreign continuation-in-part applications, and of the resulting patents, which are directed to the subject matter specifically described in the United States and foreign patent applications described in Appendix 1A and 1B
- 2. Claims of all later filed foreign patent applications, and of the resulting patents, which are directed to the subject matter specifically described in the United States patent and/or patent applications described in subparagraphs 1, 2 or 3 of this Section.
- 5. Any reissues, divisions, amendments or extensions of the United States or foreign patents described in subparagraphs 1, 2, 3 or 4 of this Section.

- B. “Sublicensee” shall mean a person or entity unaffiliated with Licensee to whom Licensee has granted an arm’s length sublicense under this Agreement. Sublicensee includes Manufacturers and Distributors.
- C. “Territory” shall mean worldwide.
- D. “Term” shall have the meaning stated in paragraph A of Article XIII.
- E. “Know how” shall mean any unpatented manufacturing information, technical information, testing and analytic methods and specifications in the Field of Use which CMCC owns or Controls and which relates to the Patent Rights.

## ARTICLE II. GRANT

A. Subject to the terms of this Agreement, CMCC on its own behalf and on behalf of MIT, hereby grants to Licensee:

1. the worldwide right and sole exclusive license, including the right to grant sublicenses in accordance with this Article II, under the Patent Rights to make, have made, use, lease, offer to lease, sell, offer to sell, have sold, import, have imported the Licensed Products, and to practice the Licensed Processes, in the Territory for the Field of Use to the end of the Term, unless sooner terminated as provided in this Agreement; and

2. for the Term of this Agreement, the worldwide right and non-exclusive license to use the Know how, in connection with Licensee’s research and development of Licensed Products and/or Licensed Processes; provided that such license shall not include the right to sublicense or transfer such Know how except to contractors of Licensee for the purpose of developing, making or selling the Licensed Products, validating the materials or carrying out the Development Plan; and

3. subject to CMCC’s obligations under conflict of interest regulations or guidelines from the federal government or policies of Harvard Medical School (which regulations, guidelines and policies will be provided to Licensee) and any other conflicting legal obligations, including contractual obligations to research sponsors which determination shall reasonably be made in CMCC’s sole discretion, a thirty (30) calendar day exclusive right of first negotiation to Improvements and a non-exclusive right to Know how

associated with such Improvements upon CMCC's written notification to the Licensee that there are no such conflicting obligations. Within such 30-day period, Licensee shall provide a written notice to CMCC indicating Licensee's desire to license such Improvement, together with a written statement explaining development goals and its existing capacity to meet those development goals. Thereafter the parties shall negotiate in good faith the terms, including but not limited to financial terms, for a new license within ninety (90) days of Licensee's written notification. If the Licensee does not timely elect to license the Improvement through such written notice or if the parties are unable to negotiate a new license within ninety (90) days of Licensee's written notification to CMCC regarding Licensee's desire to license the Improvement(s), CMCC shall be free to license such Improvements to a third party.

B. Notwithstanding anything above to the contrary, Institutions shall retain a royalty-free, nonexclusive, right to practice and use, and upon prior written notice to Licensee and furnishment to Licensee of the applicable sublicense to sublicense for a nominal fee (such as shipping and handling charges) to other academic nonprofit research organizations to practice and/or use the Patent Rights and Licensed Processes, for research, educational and clinical purposes only. Any such sublicense shall specifically exclude and prohibit commercialization of the Patent Rights unless the sublicensee enters into an agreement with Licensee on terms consistent with this Agreement but in other respects agreeable to Licensee in Licensee's sole discretion. The Institutions shall use reasonable efforts to enforce the provisions of the sublicense excluding commercialization, through termination of such sublicense, or shall assign their right to enforce this provision to Licensee.

C. Notwithstanding any other provision of this Agreement, if applicable, the license and any sublicense shall be subject to the rights of the United States government, if any, under Public Law 96-517, 97-226, and 98-620, codified at 35 U.S.C. sec. 200-212 and any regulations promulgated thereunder (the "Government Rights Laws"); the obligations of Institutions under applicable laws and regulations; and Licensee's warranty to comply with all applicable laws and regulations.

D. Licensee agrees that, if applicable and if mandated by the Government Rights Laws, Licensed Products leased or sold in the United States shall be manufactured substantially in the United States unless a waiver has been obtained for such requirement as applicable. CMCC shall provide reasonable assistance to Licensee in Licensee's efforts, at Licensee's

election, to obtain such waiver. Upon the First Commercial Sale and thereafter, Licensee's annual report to CMCC shall substantiate Licensee's compliance with this provision. To support exclusivity for Licensee consistent with this Agreement, CMCC hereby agrees that, except as provided in this Agreement, it shall not, without Licensee's prior written consent, grant to any other party a license to make, have made, use, lease and/or sell Licensed Products in the Field of Use, during the period of time in which this Agreement is in effect.

E. The license granted hereunder shall not be construed to confer any rights upon Licensee by implication, estoppel or otherwise as to any inventions, discoveries, know-how, technology or other intellectual property not described in Paragraph A of this Article.

F. Licensee hereby irrevocably covenants and agrees that it will not, directly or indirectly, in any respect, use non-public information it has acquired in the course of prosecution of the Patent Rights from CMCC and/or patent counsel prosecuting the Patent Rights, or non- public information Licensee has provided, or recommendations made by Licensee that have been implemented in whole or in part with respect to prosecution of the Patent Rights, to challenge the Patent Rights or CMCC's ownership of such rights. In addition, Licensee agrees that it will treat such information as CMCC's Confidential Information and shall not disclose it to any third party without CMCC's written permission. To the extent that a Sublicensee wishes to participate in the prosecution of Patent Rights under this Agreement, the Sublicensee shall seek CMCC's permission through a written notification.

G. Except for the restrictions specified herein, nothing in this Agreement shall be construed to limit or constrain CMCC, or any officer, director, employee, member of its medical staff, or of any CMCC Affiliate, from continuing to engage in related research; or from the development of related or unrelated inventions, discoveries, rights or technology, and from practicing, licensing or sublicensing related or unrelated intellectual property rights arising from inventions occurring after the Effective Date of this Agreement; or from academic publication related thereto; or from entering into agreements and other relationships with other persons or organizations related to matters not directly and expressly within the scope of this Agreement; or from exercising any rights whatsoever with respect to the Know how.

H. Licensee shall have the right to enter into sublicensing agreements with respect to any of the rights, privileges, and licenses granted hereunder, subject to the terms and conditions hereof. CMCC agrees that, in the event CMCC terminates this Agreement for any reason provided hereafter, then CMCC shall provide to known Sublicensees, no less than thirty (30)

days prior to the effective date of said termination, written notice of said termination at the address specified by Licensee in the notice provided to CMCC under paragraph I of this Article. If the Sublicensee, during that thirty (30) day period, provides to CMCC authorized and written notice that the Sublicensee: (i) reaffirms the terms and conditions of this Agreement as it relates to the rights the Sublicensee has been granted under the sublicense; (ii) agrees to abide by all of the terms and conditions of this Agreement applicable to Sublicensees and to discharge directly all pertinent obligations of Licensee which Licensee is obligated hereunder to discharge (CMCC agrees in good faith to negotiate with Sublicensee and Licensee and determine what are the "pertinent obligations of Licensee" are as such phrase is used in this subsection); and (iii) acknowledges that CMCC shall have no obligations to the Sublicensee other than its pertinent obligations set forth in this Agreement with regard to Licensee, then, provided that the Sublicensee notice satisfies the foregoing, and Sublicensee is not in breach of its sublicense CMCC shall grant to such Sublicensee license rights and terms equivalent to the sublicense rights and terms which the Licensee shall have previously granted to said Sublicensee, to the extent that those rights were granted by CMCC to the Licensee under this License Agreement. In any event, the Sublicensee shall remain a Sublicensee under this Agreement for a period of at least sixty (60) days following notice by CMCC under this paragraph.

I. In any event, Licensee agrees that any sublicense granted by it shall contain terms substantially similar to those in Articles II (Grant), VII (Infringement), X (Compliance with Laws; Export Controls), XI (Non-Use of Names), XII (Assignment), and XIV (Term and Termination) of this Agreement and identical provisions to those in IX (Insurance and Indemnification) of this Agreement. Licensee shall notify CMCC of a breach of any term of a sublicense that has not been cured within the applicable cure period. Licensee shall use commercially reasonable efforts to enforce the sublicense agreements and Licensee shall be fully liable to CMCC for its failure to comply with this sentence. In addition, every sublicense shall contain within it requirements for commercially reasonable due diligence in developing or exploiting the Patent Rights, or selling Licensed Products, as specifically applicable, shall obligate Licensee to enforce those provisions consistent with achieving Licensee's obligations pursuant to this Agreement. Licensee agrees to provide to CMCC notice of any sublicense granted hereunder and to forward to CMCC a copy of any and all fully executed sublicense agreements within thirty (30) days of execution. Commencing in 2008 and no later than March 1 of each calendar year, Licensee further agrees to forward to

CMCC a copy of any reports received by Licensee from its Sublicensees during the preceding calendar year as shall be pertinent to a royalty accounting under the applicable sublicense.

J. Licensee shall advise CMCC in writing of any consideration received from Sublicensees, and, at CMCC's request provide such information in an electronic format using Microsoft Word or Excel. Licensee shall not accept from any Sublicensee anything of value in lieu of cash payments to discharge sublicensee's payment obligations under any sublicense granted under this Agreement, without the express written permission of CMCC, which permission shall not be unreasonably withheld but may take into account a reasonable valuation for purposes of Licensee's payment obligations to CMCC.

### **ARTICLE III. DUE DILIGENCE AND RELATED MATTERS**

- A. Licensee, upon execution of this Agreement, shall use diligent efforts in good faith to bring one or more Licensed Products to market as soon as practicable, consistent with sound and legal business practices and judgment, through a vigorous and diligent program for exploitation of the Patent Rights taking into account the competitiveness of the marketplace, the proprietary position of the Licensed Product, the relative potential safety and efficacy of the Licensed Product, the cost of goods and availability of capacity to manufacture and supply the Licensed Product at commercial scale, the profitability of the applicable Licensed Product, and other relevant factors including, without limitation, technical, legal, scientific or medical factors. Licensee shall use diligent efforts to obtain all necessary government approvals for the manufacture, use, sale and distribution of Licensed Products. Thereafter, Licensee agrees that until expiration or termination of this Agreement, Licensee shall use commercially reasonable to continue active and diligent efforts to keep Licensed Products reasonably available to the public. In the event Licensee decides not to exploit a licensed Patent Right, or Field of Use, in a given portion of the Territory, it shall promptly inform CMCC in writing and shall surrender to CMCC its license to that Patent Right or Field of Use in that Territory.
- B. The parties acknowledge that Licensee has provided to CMCC prior to the date of execution of this Agreement a written development plan ("Development Plan") setting forth for a period of five (5) years beginning the Effective Date, projections for the initial

indications and markets for Licensed Products and Licensed Processes for the subfield of SCI in the Field of Use, including (i) time-delimited targets for pre-clinical development, clinical trials, regulatory approval, manufacturing and marketing that represent reasonable efforts, consistent with industry norms for similar technology and applications, to bring Licensed Products to the marketplace; and (ii) actual or projected financial resources and/or strategic alliances that will be required to implement the Development Plan and (iii) identified project management structure calculated to meet the objectives and commitments in the Development Plan. The Development Plan is attached hereto as Appendix 2 and is hereby incorporated herein by reference. In addition, prior to submission of the first regulatory filing relating to the first Licensed Product, but in any event no later than five years from the Effective Date, Licensee shall submit a commercialization plan ("Commercialization Plan") setting forth projected (i) time delimited commercialization milestones for bringing Licensed Products to the marketplace and (ii) strategic alliances (including but not limited to alliances with Distributors) required to achieve the goals outlined in the Commercialization Plan. The Commercialization Plan shall be attached to this Agreement as Appendix 3.

- C. Licensee shall use good faith and diligent efforts to accomplish the milestones set forth in the Development Plan and to manufacture and distribute Licensed Products.
- D. Licensee shall be deemed to be using diligent efforts during the one (1) year period after the Effective Date if Licensee has raised and allocated for expenditure for carrying out the Development Plan during the period commencing on September 26, 2006 and ending on the one (1) year anniversary date of the Effective Date a cumulative total of investment capital and/or research and development funds of at least \$[\*\*\*\*]. In addition, the Licensee shall be deemed to be using diligent efforts during the three (3) year period after the Effective Date, if the Licensee has expended at least \$[\*\*\*\*] reasonably allocated during that period to implement the Development Plan.
- E. From and after the Effective Date, Licensee shall have full control and authority over the development and commercialization of Licensed Products in the Field of Use in the Territory, including without limitation, (a) all activities related to human clinical trials (including all clinical studies), (b) all activities relating to manufacture and supply of all Licensed Products (including all required process development and scale up work with respect thereto), (c) all marketing, promotion, sales, distribution, import and export

activities relating to any Licensed Product, and (d) all activities relating to any regulatory filings, registrations, applications and regulatory approvals relating to any of the foregoing. Licensee shall own all data, results and all other information arising from any such activities performed solely by Licensee under this Agreement, and all of the foregoing information, documentation and materials shall be considered Confidential Information and technology solely owned by Licensee.

- F. Notwithstanding anything above to the contrary, CMCC shall not unreasonably withhold its consent to any revision of the objective(s) set forth in the Development Plan when requested in writing in advance by Licensee and the request is supported by evidence reasonably acceptable to CMCC: (i) of technical difficulties or delays in the clinical studies or regulatory process that Licensee could not reasonably have been avoided; (ii) Licensee is proposing and will implement satisfactory and effective means of addressing such difficulties or delays, including sufficient financial and technical resources; and (iii) that Licensee, its Affiliates and/or sublicensees have in good faith made diligent efforts and expended adequate resources to meet said objective and will continue to do so.
- G. In the event Licensee fails to meet the objective(s) set forth in the Development Plan in a timely manner, CMCC shall notify Licensee thereof in writing, and Licensee shall have sixty (60) days following such notification to establish to the reasonable satisfaction of CMCC that (i) it has met such objective(s); or (ii) a revision to the Development Plan is necessary and appropriate as contemplated above. In the event Licensee fails to establish the same within the 60-day cure period, to CMCC's reasonable satisfaction, CMCC shall have the right in its sole discretion to terminate in whole or in part the license granted to Licensee under this Agreement effective immediately.
- H. If, during the course of this Agreement, Licensee makes any discovery or invention that is not within the scope of the Patent Rights but would not have been made but for the Patent Rights, Licensed Products or Licensed Processes licensed hereunder, Licensee shall, as a condition of this License, confidentially disclose such discovery or invention to CMCC, on usual and customary terms necessary to protect its patentability or its confidentiality as a trade secret. Recognizing that CMCC enters into this Agreement in furtherance of its charitable academic research mission, Licensee shall enter into with CMCC a non-exclusive license or permit, as applicable, including no more than a nominal fee, to practice such discovery or invention, whether or not patented, solely for



CMCC internal and academic research purposes. Any such license shall specifically exclude and prohibit commercialization of such discoveries or inventions. CMCC on its own behalf, grants Licensee a thirty (30) calendar day exclusive right of first negotiation to license any rights resulting from such discoveries or inventions.

#### ARTICLE IV. ROYALTIES AND OTHER PAYMENTS

- A. For the rights, privileges and exclusive license granted hereunder, Licensee shall pay to CMCC the following amounts in the manner hereinafter provided. Unless expressly stated otherwise in this Agreement, periodic payment obligations listed below shall endure through the Term of this Agreement, unless this Agreement shall be sooner terminated as hereinafter provided:
14. A license issue fee of \$[\*\*\*\*] (subject to the adjustment provided herein), which license issue fee shall be deemed earned and due immediately upon the execution of this Agreement. The parties acknowledge and agree that Licensee has paid to CMCC a total of \$[\*\*\*\*] under the Option Agreement between CMCC and Licensee dated September 26, 2006 (the "Option Agreement") and pursuant to the terms of the Option Agreement such amount will be credited against this license issue fee. Accordingly, the license issue due upon the execution of this Agreement is \$[\*\*\*\*].
  15. Payments for accrued and continuing patent prosecution costs as stated in Article VI hereof.
  16. Licensee shall make the following payments to CMCC upon the occurrence of the following events ("Milestones") for the first Licensed Product in the Field of Use:
    - (a) \$[\*\*\*\*] upon the filing with the United States Food and Drug Administration ("FDA") of the first Investigational New Drug ("IND") application, Investigational Device Exemption ("IDE") application, or comparable application;
    - (b) \$[\*\*\*\*] upon the enrollment of the first patient in Phase II testing;
    - (a) \$[\*\*\*\*] upon the enrollment of the first patient in Phase III testing;

- (b) \$[\*\*\*\*] upon filing with the FDA of the first New Drug Application (“NDA”), 510(k) application, Pre-Market Approval (“PMA”) application or PMA Supplement, or BLA, or comparable application;
- (c) \$[\*\*\*\*] upon approval by the FDA of the first NDA, 510(k), PMA or PMA Supplement, BLA, or comparable application within the United States with respect to any Licensed Product;
- (d) \$[\*\*\*\*] upon first marketing approval in any country outside of the United States; and
- (e) Running royalties in an amount equal to [\*\*\*\*] percent ([\*\*\*\*]%) of Net Sales of Licensed Products used, leased or sold by and/or for Licensee (including its Affiliates).

17. In each year prior to which the Licensed Product is released for sale, a License Maintenance Fee of \$[\*\*\*\*], which shall be payable on the first anniversary of the Effective Date and each subsequent anniversary thereafter. For the year in which the first Licensed Product is released for sale, the License Maintenance Fee due shall be pro-rated so that Licensee shall owe to CMCC only the amount due up to the date of the First Commercial Sale of the first Licensed Product. In order for Licensee to be able to accurately determine such pro-rated amount owed, in the year Licensee anticipates the First Commercial Sale of the first Licensed Product, Licensee can withhold the License Maintenance Fee until the end of that year at which time the Licensee will pay to CMCC either the pro-rated amount or the entire License Maintenance Fee as applicable.

5. In the event Licensee has granted a Manufacturer a sublicense to manufacture and sell Licensed Products under this Agreement, Licensee shall pay the following percentages of any and all payments received by Licensee from each said Manufacturer in consideration of permitting the Manufacturer to practice the Patent Rights, including but not limited to the Manufacturer sublicense issue fees, any lump sum payments, milestone payments, technology transfer payments or other similar fees (“Manufacturer Sublicense Revenue”):

- a. [\*\*\*\*]% of all Manufacturer Sublicense Revenue excluding royalties if the Licensee sublicenses the Licensed Product to the said Manufacturer prior to the Licensee

having raised and invested \$[\*\*\*\*] or more in the development of Licensed Products.

b. [\*\*\*\*]% of all Manufacturer Sublicense Revenue excluding royalties if the Licensee Sublicenses the Licensed Product to the said Manufacturer at the time that the Licensee has raised and invested \$[\*\*\*\*] or more but less than \$[\*\*\*\*] in the development of Licensed Products.

c. [\*\*\*\*]% of all Manufacturer Sublicense Revenue excluding royalties if the Licensee Sublicenses the Licensed Product to the said Manufacturer at any time after the Licensee has raised and invested \$[\*\*\*\*] or more in the development of Licensed Products.

Notwithstanding the foregoing, Manufacturer Sublicense Revenue specifically excludes (i) equity investments at fair market value made by the Manufacturer in the Licensee, (ii) payment by Manufacturer to the Licensee for payment or reimbursement of patent and/or other expenses, or (iii) payments by Manufacturer to the Licensee for research, development, and pre-clinical and clinical studies undertaken by the Licensee on behalf of the Manufacturer or financing of research and development at the Licensee (including FTEs).

With respect to running royalties in connection with a Manufacturer's sales of Licensed Products, Licensee shall pay to CMCC hereunder an amount equal to the royalty CMCC would have received from Licensee if such sales had been made by Licensee to a final customer who will be an end user of the Licensed Product.

6. In the event Licensee has granted a Distributor a sublicense to sell or resell Licensed Products, Licensee shall pay to CMCC [\*\*\*\*] percent ([\*\*\*\*]%) of all payments received by the Licensee for the license by the Licensee to the Distributor to sell or resell the Licensed Product excluding royalties in consideration of permitting the Distributor to sell or resell Licensed Products. With respect to running royalties in connection with Licensee's sales of Licensed Products to a Distributor for the purpose of sale and resale, Licensee shall pay to CMCC running Royalties in an amount equal to [\*\*\*\*] percent ([\*\*\*\*]%) of Net Sales of Licensed Products where the Distributor is considered the end user.

- A. Licensee shall not be required to pay to CMCC multiple royalties hereunder if any Licensed Product, its manufacture, use, lease or sale are or shall be covered by more than one Patent Rights patent application or Patent Rights patent licensed under this Agreement.
- B. To the extent that Licensee is necessarily required to obtain, subsequent to the date of this Agreement, licenses to third party patents or other intellectual property that dominates or is dominated by the Patent Rights in order to practice the Patent Rights or to produce or sell Licensed Products in a particular country and avoid infringing such third-party intellectual property, Licensee may deduct from the running royalty due to CMCC for that country [\*\*\*\*] percent ([\*\*\*\*]%) of the royalties due on such third party patents or intellectual property up to an amount equal to [\*\*\*\*] percent ([\*\*\*\*]%) of royalties due hereunder, provided that such deduction reflects a pro rata or other fair apportionment among Licensee and other royalty obligations of Licensee for required licenses and other intellectual property of Licensee, as documented by Licensee to CMCC's reasonable satisfaction in royalty reports to CMCC.
- C. For purposes of calculating royalties, in the event that a Licensed Product includes both component(s) covered by a claim of a Patent Right ("Patented Component") and a component which is therapeutically active alone or in a combination, and such component is not covered by a claim of a Patent Right ("Unpatented Component"), then Net Sales of the Combination Product or Combination Process shall be calculated using one of the following methods:
  - 1. By multiplying the Net Sales of the Combination Product or Combination Process during the applicable royalty accounting period ("accounting period") by a fraction, the numerator of which is the aggregate gross selling price of the Patented Component(s) contained in the Combination Product or Combination Process if sold separately, and the denominator of which is the sum of the gross selling price of both the Patented Component(s) and the Unpatented Component(s) contained in the Combination Product or Combination Process if sold separately; or
  - 2. In the event that no such separate sales are made of the Patented Component(s) or the Unpatented Components during the applicable accounting period, Net Sales for purposes of determining royalties payable hereunder shall

be calculated by multiplying the Net Sales of the Combination Product or Combination Process by a fraction, the numerator of which is the fully allocated production cost of the Patented Component(s) and the denominator of which is the sum of the fully allocated production costs of the Patented Component(s) and the Unpatented Component(s) contained in the Combination Product or Combination Process. Such fully allocated costs shall be determined by using Licensee's standard accounting procedures, which procedures must conform to standard cost accounting procedures.

- D. All payments, including royalty payments shall be paid in United States dollars in Boston, Massachusetts, or at such other place in the United States as CMCC may reasonably designate consistent with the laws and regulations controlling in any foreign country. If the currency conversion shall be required in connection with the payments of royalties or other amounts hereunder, the conversion shall be made by using the exchange rate prevailing as reported in *The Wall Street Journal* on the last business day of the calendar quarterly reporting period to which such royalty payments relate.
- E. Payment of royalties specified in this Article shall be made by Licensee to CMCC within forty-five (45) days after March 31, June 30, September 30 and December 31 each year during the Term of this Agreement covering the quantity of Licensed Products sold by Licensee during the preceding calendar quarter. The last such payment shall be made within forty-five (45) days after termination of this Agreement. The royalty payments set forth in this Agreement shall, if overdue, bear interest until payment at a per annum rate of four percent (4%) above the prime rate in effect at Bank of America, Boston, on the due date, provided that in no event shall said annual rate exceed the maximum interest rate permitted by law in regard to such payments. The payment of such interest shall not foreclose CMCC from exercising any other rights it may have as a consequence of the lateness of any payment.

## **ARTICLE V. REPORTS, RECORDS AND RELATED MATTERS**

- A. Licensee shall keep, and shall require its Affiliates and use commercially reasonable efforts to require its Sublicensees to keep, full, true and accurate books and records, including books of account in accordance with reasonable customary professional accounting practices in sufficient detail to enable CMCC to determine Licensee's

compliance with this Agreement, including diligence with respect to development, and the royalty and other amounts payable to CMCC under this Agreement. Said books and records, including books of account, shall be kept at Licensee's principal place of business or the principal place of business of the appropriate division of Licensee to which this Agreement relates. Said books and the supporting data shall be retained for at least six (6) years following the end of the calendar year to which they pertain.

- B. In the event of a suspected breach by the Licensee of its payment obligations hereunder or its obligations pertaining to sublicenses, CMCC shall send a letter to Licensee indicating that it reasonably believes a breach may have occurred and indicating the breach and then Licensee shall have thirty (30) days from the date of its receipt of such letter to respond to such letter. If Licensee has not responded to the letter in such 30- day period to CMCC's satisfaction, then CMCC shall have the right to inspect, copy and audit, on fifteen (15) days prior written notice, at CMCC's expense, the books described above from time to time to verify the reports provided for herein or compliance in other respects with this Agreement. Any person(s) conducting such audit on behalf of CMCC shall be a Certified Public Accountant. In every case the accountant must have previously entered into a confidentiality agreement reasonably satisfactory to Licensee to protect Licensee's confidential information and limiting the disclosure and use of such information by such accountant to authorized representatives of the parties and the purposes germane to this paragraph. Licensee shall be a third party beneficiary of the confidentiality agreement between CMCC and the Certified Public Accountant. Such accountant shall perform such inspection, copying and auditing at CMCC's expense during Licensee's regular business hours. Each party agrees to treat the results of any such accountant's review of the other party's records under this paragraph as Confidential Information of the other party hereunder.
- C. Until the later of First Commercial Sale of each Licensed Product or the last development milestone, Licensee shall provide to CMCC, at least annually, reasonable detail regarding the activities of Licensee and Licensee's Affiliates and Sublicensees relative to achieving the objectives set forth in the Development Plan in a timely manner, including but not limited to, reports of financial expenditures to achieve said objectives; research and development activities; names, addresses and actions of all Sublicensees and affiliates; the progress of obtaining regulatory approvals, with appropriate documentation (including, without limitation, applications, reports, and planning

documents submitted to the Food and Drug Administration); strategic alliances and manufacturing, sublicensing and marketing efforts. Licensee shall also report more frequently, but no more than quarterly, at CMCC's written request.

- D. After First Commercial Sale, within forty-five days (45) after the end of each calendar quarter, Licensee shall deliver to CMCC, at Licensee's expense, true and accurate reports for the said preceding quarter, giving such particulars of the business conducted by Licensee, its Affiliates and its Sublicensees during the preceding three-month period under this Agreement as shall be pertinent to CMCC determining compliance with this Agreement, including a royalty accounting hereunder and to verify Licensee's activities with respect to achieving the objectives of the Development Plan described in Article III above. These reports shall, at CMCC's request, be provided by Licensee in an electronic format using Microsoft Word or Excel. Reports shall include at least the following:
1. Number of Licensed Products manufactured and sold.
  2. Total Net Sales for Licensed Products sold, by country.
  3. Accounting for all Licensed Products sold.
  4. Applicable deductions.
  5. Total royalties payable to CMCC.
  6. Names and addresses of all Sublicensees.
  7. Payments received by Licensee from Affiliates and Sublicensees.
  8. When applicable, Licensed Products manufactured and sold to the U.S. Government, segregating those sold at a profit from those sold at cost in light of any royalty-free, nonexclusive license that may heretofore have been granted to the U.S. Government.
  9. Royalties and Fees received from Sublicensees.
- D. On the later of (i) on or before the ninetieth (90<sup>th</sup>) day following the close of Licensee's fiscal year and (ii) that date that such statements are available, during the period prior to which Licensee makes a royalty payment hereunder Licensee shall provide CMCC with Licensee's financial statements for the preceding fiscal year, including without limitation

all statements reflecting profits and losses from operations, cash balances, and any management letter. Any information furnished under this paragraph shall be deemed Confidential Information of Licensee.

- F. Licensee acknowledges that policies of INSTITUTIONS, Harvard Medical School and affiliated organizations, relating to, *inter alia*, conflicts of interest and intellectual property, may affect certain direct and indirect arrangements between inventors and Licensee or related organizations. During the Term of this Agreement if Licensee knows that it, or any Affiliate of Licensee, or any officer or director of Licensee acting on behalf of Licensee is intending on entering into any agreement other than this Agreement with or involving the inventor(s) of the Patent Rights, or their family, relatives or members or staff of their laboratories, whether relating to sponsored research, consulting, board membership, securities, or otherwise, then Licensee shall notify CMCC in writing at least 30 days before the date of such agreement. Licensee's notice to CMCC shall include a detailed description of all proposed terms and conditions. Licensee shall not knowingly enter into such an agreement if it would violate such policies unless the terms and conditions of the agreement have been duly approved by CMCC pursuant to such policies. Notwithstanding the foregoing, the provisions of this Section (F) of Article V shall apply only to CMCC inventors and only while they are officially a member of the CMCC staff or an employee of CMCC.

## **ARTICLE VI. PATENT PROSECUTION**

- A. CMCC shall apply for, seek prompt issuance in all relevant major market countries designated by Licensee of, and maintain during the term of this Agreement the Patent Rights set forth in Appendix 1. CMCC reserves the sole right to make all final decisions with respect to the preparation, filing, prosecution and maintenance of such patent applications and patents. Although CMCC shall be the client in the attorney-client relationship with patent counsel, Licensee shall have day-to-day responsibility for interaction with such patent counsel relating to prosecution of the Patent Rights, and may provide recommendations to such patent counsel regarding the scope and content of patent applications to be filed and prosecuted to assure that the Patent Rights cover all items of commercial interest to Licensee. Licensee and CMCC each shall receive copies of all correspondence with respect to such preparation, filing, prosecution and



maintenance of the Patent Rights in sufficient time to review and provide comments and with file copies after the action is completed, and each shall receive a copy of invoices.

- B. Licensee shall reimburse CMCC for all patent costs, past, present and future incurred by CMCC for the preparation, filing, prosecution and maintenance of patents underlying the Patent Rights, provided that Licensee shall be notified prior to such costs exceeding \$20,000. Past patent costs are the full amount of \$2,265 for patents in Appendix 1B and capped at a maximum of no more than \$20,000 for the patent applications in Appendix 1 A. Licensee shall pay such costs for the patents and applications in Appendix 1A and Appendix 1B within thirty (30) days after receipt of an invoice covering such costs. Upon request of CMCC, and only upon such CMCC request, Licensee agrees to have CMCC's patent counsel directly bill Licensee and Licensee shall directly pay such invoices in compliance with such counsel's customary business terms, but in any event not greater than thirty (30) days from receipt of invoice which is not disputed in good faith. If Licensee elects to no longer pay the expenses of a patent application or patent included within Patent Rights, Licensed Products or Licensed Processes, Licensee shall notify CMCC not less than sixty (60) days prior to such action and shall thereby surrender its rights under such patent or patent application. Such notice shall not relieve Licensee from responsibility to reimburse CMCC for patent-related expenses incurred prior to the expiration of the (60)-day notice period (or such longer period specified in Licensee's notice). CMCC shall then be free to license its rights to that patent or patent application to any other party on any other terms.
- C. In the event CMCC elects, in its sole discretion, not to pursue, maintain or retain a particular Patent Right licensed to Licensee hereunder, then CMCC shall so notify Licensee and, subject to the rights of the United States government and any other contractual obligations to research sponsors when applicable, CMCC shall, provided that the Licensee is not in breach of this Agreement and hasn't cured such breach during any applicable cure period, authorize Licensee to assume the filing, prosecution and/or maintenance of such application or patent at Licensee's expense. The parties agree in good faith to discuss and address any issues that resulted in CMCC's election not to pursue such Patent Rights. In such event, CMCC shall provide to Licensee reasonable assistance in the filing, prosecution and/or maintenance of such application or patent and any authorization necessary to permit Licensee to pursue and/or maintain such Patent Right, on such economic and other terms as the parties shall mutually agree.

- D. The maintenance of Patent Rights in Appendix 1B are and shall remain under the administration of MIT. MIT shall directly submit invoices for payment to Licensee. Licensee shall be responsible for a twenty five percent (25%) share of past costs and future patent costs going forward. In the event that the third party abandons their rights to the patents in Appendix 1 B, CMCC and MIT shall not be required to subsidize the seventy five percent (75%) share of costs paid by the third party to maintain Licensee's share of costs at twenty-five percent (25%). CMCC and Licensee shall negotiate a reasonable expansion in the Field of Use for any of these Patent Rights which Licensee also agrees to pay some or all of the 75% share of patent costs. Licensee will then be notified to either pay the new share of costs going forward for the patents in Appendix 1B or give up those rights.

## **ARTICLE VII. INFRINGEMENT**

- A. Licensee and CMCC shall each inform the other promptly in writing and shall provide such other party with available evidence of any actual, alleged or threatened infringement by a third party of the Patent Rights in the Field of Use within the scope of this Agreement and of any available evidence thereof.
- B. During the Term of this Agreement, CMCC shall have the first right, but shall not be obligated, to prosecute at its own expense any infringement of the Patent Rights and, in furtherance of such right, Licensee hereby agrees that CMCC may include Licensee as a party plaintiff in any such suit, without expense to Licensee. Licensee shall have the right, at its own expense, to be represented in any such action by counsel of Licensee's own choice; provided, however, that under no circumstances shall the foregoing affect the right of CMCC to control the suit as described in the first sentence of this Section. The total cost of any such infringement action commenced or defended solely by CMCC shall be borne by CMCC. Any recovery of damages, monetary awards or other amounts recovered, whether by judgment or settlement (collectively the "Recovery Amounts"), by CMCC for each such suit, proceeding or other legal action taken under this paragraph shall be applied as specified in paragraph E of this Article VII. No settlement, consent judgment or other voluntary final disposition of the suit involving the Patent Rights may be entered into without the consent of Licensee, which consent shall not be unreasonably withheld, delayed or conditioned.

- C. If within three (3) months after having been notified of any alleged infringement, CMCC shall have been unsuccessful in persuading the alleged infringer to desist and shall not have brought and shall not be diligently prosecuting an infringement action, or if CMCC shall notify Licensee of its intention not to bring suit against any alleged infringer then, Licensee shall have the right, but shall not be obligated, to prosecute at its own expense any infringement of the Patent Rights, provided, however, that such right to bring such an infringement action shall remain in effect only for so long as the license granted hereunder remains exclusive. No settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the consent of CMCC, which consent shall not be unreasonably withheld, delayed or conditioned. Licensee shall indemnify CMCC against any order for costs that may be made against CMCC in such proceedings.
- A. In the event Licensee shall undertake the enforcement and/or defense of the Patent Rights by litigation pursuant to paragraph C of this Article, Licensee may withhold up to fifty percent (50%) of the payments otherwise thereafter due to CMCC under Article IV above and apply the same toward reimbursement of up to fifty percent (50%) of Licensee's expenses, including reasonable attorney's fees, in connection therewith.
- B. Any recovery of Recovery Amounts under paragraphs B or C of this Article shall be applied first in satisfaction of any un-reimbursed expenses and legal fees of CMCC and Licensee incurred in prosecuting such enforcement action relating to such suit and next toward payment to CMCC for any payments under Article IV past due. The balance remaining from any such Recovery Amounts shall be for distribution purposes, treated as if it were sublicensing revenue and divided accordingly between Licensee and CMCC with 75% to Licensee and 25% to CMCC.
- F. In the event that a declaratory judgment action alleging invalidity or infringement of any of the Patent Rights shall be brought against Licensee, CMCC, at its option, shall have the right, within thirty (30) days after commencement of such action, to intervene and participate in the defense of the action at its own expense.
- G. In any infringement suit which either party may institute to enforce the Patent Rights pursuant to this Agreement, the other party hereto shall cooperate in all reasonable respects and , to the extent reasonably possible, have its employees testify when

---

requested and make available relevant records, papers, information, samples, specimens, and the like.

- H. Licensee shall during the exclusive period of this Agreement have the sole right subject to the terms and conditions hereof to sublicense any alleged infringer for future use of the Patent Rights to the extent licensed by this Agreement. Any upfront fees paid to Licensee as part of such a sublicense shall be subject to the payment obligations hereunder as if they were Sublicensing revenues under this Agreement.

## ARTICLE VIII: WARRANTY

- A. CMCC represents and warrants to Licensee that:

- (i) the execution and delivery of this Agreement and the performance of the transactions contemplated hereby have been duly authorized by all appropriate CMCC corporate action;
- (ii) this Agreement is a legal and valid obligation binding upon CMCC and enforceable in accordance with its terms, and, to the best knowledge of CMCC's Intellectual Property Office, the execution, delivery and performance of this Agreement by the parties does not conflict with any agreement, instrument or understanding to which CMCC is a party or by which it is bound;
- (iii) CMCC has the full right, power and legal capacity to enter into this Agreement and grant the rights granted to Licensee hereunder;
- (iv) To the best knowledge of CMCC's Intellectual Property Office, Patent Rights have been properly filed and prosecuted and CMCC and MIT are the sole owners of the Patent Rights; and
- (v) To the best knowledge of CMCC's Intellectual Property Office, CMCC is not aware of any third party patent, patent application or other intellectual property rights that would be infringed by making, using, offering for sale, selling or importing Licensed Products.

B. Licensee represents and warrants to CMCC that:

- (i) the execution and delivery of this Agreement and the performance of the transactions contemplated hereby have been duly authorized by all appropriate Licensee corporate action; and
- (ii) this Agreement is a legal and valid obligation binding upon Licensee and enforceable in accordance with its terms, and the execution, delivery and performance of this Agreement by the parties does not conflict with any agreement, instrument or understanding to which Licensee is a party of or by which it is bound.

## **ARTICLE IX. UNIFORM INDEMNIFICATION AND INSURANCE PROVISIONS**

- A. Licensee shall indemnify, defend and hold harmless CMCC, its corporate affiliates, current or future directors, trustees, officers, faculty, medical and professional staff, employees, students and agents and their respective successors, heirs and assigns (the “Indemnitees”), against any claim, liability, cost, damage, deficiency, loss, expense or obligation of any kind or nature (including without limitation reasonable attorneys’ fees and other costs and expenses of litigation) incurred by or imposed upon the Indemnitees or any one of them in connection with any third party claims, suits, actions, demands or judgments arising out of any theory of product liability (including, but not limited to, actions in the form of tort, warranty, or strict liability) to the extent concerning any product, process or service made, used or sold pursuant to any right or license granted under this Agreement.
- B. Licensee’s indemnification under Article VIII, Paragraph A above shall not apply to any liability, damage, loss or expense to the extent that it is directly attributable to the negligent activities, reckless misconduct or intentional misconduct of the Indemnitees.
- C. Licensee agrees, at it’s own expense, to provide attorneys reasonably acceptable to CMCC to defend against any actions brought or filed against any party indemnified hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought.
- D. Beginning at the time as any such product, process or service is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by Licensee or by a sublicensee, Affiliate or agent of Licensee, Licensee shall, at its sole cost and expense, procure and maintain commercial general liability insurance in amounts not less than \$2,000,000 per incident and \$2,000,000 annual aggregate and naming the Indemnitees as additional insureds. Such commercial general liability insurance shall provide (i) product liability coverage and (ii) contractual liability coverage for Licensee’s indemnification under Article VIII, Paragraphs A through C of this Agreement. If Licensee elects to self-insure all or part of the limits described above (including deductibles or retentions which are in excess of \$250,000 annual aggregate), such self-insurance program must be acceptable to CMCC and the Risk Management Foundation of the Harvard Medical Institutions, Inc. The minimum amount of insurance coverage required under this Article VIII, Paragraph D, shall not be construed to create a

limit of Licensee's liability with respect to its indemnification under Article VIII, Paragraphs A through C of this Agreement.

- E. Licensee shall provide CMCC with written evidence of such insurance upon request of CMCC. Licensee shall provide CMCC with written notice at least fifteen (15) days prior to the cancellation, non-renewal or material change in such insurance. Notwithstanding any other term of this Agreement, if Licensee does not obtain replacement insurance providing comparable coverage within such fifteen (15) day period, CMCC shall have the right to terminate this Agreement effective at the end of such fifteen (15) day period without notice of any additional waiting periods.
- F. Licensee shall maintain such commercial general liability insurance during (i) the period that any such product, process or service is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by Licensee or by a sublicensee, Affiliate or agent of Licensee and (ii) a reasonable period after the period referred to above, which in no event shall be less than fifteen (15) years.
- G. The provisions of this Article VIII shall survive expiration or termination of this Agreement.
- H. EXCEPT AS PROVIDED IN ARTICLE VIII NEITHER PARTY MAKES ANY WARRANTY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR ANY EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE, OR WARRANTY OF NON-INFRINGEMENT, WITH RESPECT TO ANY MATTER WITHIN THE SCOPE OF THIS AGREEMENT, INCLUDING WITHOUT LIMITATION ANY WARRANTY WITH RESPECT TO THE PATENT RIGHTS, LICENSED PRODUCTS, OR ANY PATENT, TRADEMARK, SOFTWARE, TRADE SECRET, TANGIBLE RESEARCH PROPERTY, INFORMATION OR DATA LICENSED OR OTHERWISE PROVIDED TO THE OTHER PARTY HEREUNDER, AND HEREBY DISCLAIMS THE SAME.

## **ARTICLE X. COMPLIANCE WITH LAWS; EXPORT CONTROLS**

Licensee shall comply with all applicable laws and regulations, including, without limitation, statutes and regulations affecting drug testing, development, marketing and distribution; laws

and implementing regulations of the Department of Commerce governing intellectual property in federally-funded inventions when applicable; and Export Administration Regulations of the United States Department of Commerce issued pursuant to the Export Administration Act of 1979 (50 App. U.S.C. §2401 et. seq.). Licensee understands and acknowledges that transfer of certain technical data, computer software, laboratory prototypes and other commodities is subject to United States laws and regulations controlling their export, some of which prohibit or require a license for the export of certain types of technical data, to certain specified countries. CMCC neither represents that a license shall not be required, nor that if required, it shall be issued. Licensee hereby agrees and gives written assurance that it will comply with all United States laws and regulations, and any applicable similar laws and regulations of any other country, controlling the export of commodities and technical data, that it will be solely responsible for any violation of such by Licensee and/or its Affiliates and/or sublicensees, and that it will defend and hold CMCC, its affiliates and their officers, directors, employees, agents, and medical staff harmless in the event of any legal action of any nature occasioned by such violation, and any action by any governmental agency or authority, or any other party, relating to any asserted illegality or regulatory violation in the development, production, approval, marketing, sale, storage, manufacture, distribution, export or commercialization of Licensed Products.

## **ARTICLE XI. NON-USE OF NAMES**

Licensee represents and agrees that it will not use the name, names, logos or trademarks of the CMCC or any of its corporate affiliates, nor the name or photograph or other depiction of any employee or member of the staff of CMCC or such affiliates, nor any adaptation of any of the foregoing, in any advertising, promotional, or sales literature without, in each case, prior written consent from CMCC and from the individual staff member, employee, or student if such individual's name, photograph or depiction is used. Notwithstanding the above, Licensee may state that the intellectual property rights underlying the Licensed Products are licensed from CMCC under one or more patents and/or applications consistent with this Agreement, and Licensee may comply with disclosure requirements of all applicable laws relating to its business, including United States and state security laws. In addition, Licensee may refer to publications by employees, research staff or medical staff of CMCC in the scientific literature. Notwithstanding the foregoing, Licensee shall be permitted to disclose the terms and conditions



of this Agreement and CMCC and/or any of its affiliates involvement in connection therewith solely on a need-to-know basis and solely in conjunction with Licensee's fund raising activities.

## **ARTICLE XII. ASSIGNMENT**

Except as specified herein, neither party may assign this Agreement at any time without the prior consent of the other. Except as otherwise provided herein, this Agreement is not assignable or delegable, in whole or in part, by Licensee without the prior written consent of CMCC acting through an authorized designee, and any purported assignment otherwise shall be void and of no effect. Notwithstanding the foregoing, upon prior written notice to Licensee CMCC may assign this Agreement in whole to an Affiliate of CMCC. Notwithstanding the foregoing, in the event Licensee merges with another entity, is acquired by another entity, or sells all or substantially all of its assets to another entity, Licensee may assign its rights and obligations hereunder to the surviving or acquiring entity if:

(i) Licensee is not then in breach of this Agreement; (ii) the proposed assignee has a net worth at least equivalent to the net worth Licensee had as of the date of this Agreement; (iii) the proposed assignee has or will have sufficient available resources, including liquid financial resources, management experience, and sufficient scientific, business and other expertise comparable or superior to Licensee, that will be committed in order to satisfy its obligations hereunder; (iv) Licensee provides written notice of the assignment to CMCC, together with documentation reasonably satisfactory to CMCC sufficient to demonstrate the requirements set forth in subparagraphs (i) through (iii) above, at least thirty (30) days prior to the effective date of the assignment; and (v) CMCC receives from the assignee, in writing, at least fifteen (15) days prior to the effective date of the assignment: (a) reaffirmation of the terms of this Agreement; (b) an agreement to be bound by the terms of this Agreement; (c) an agreement to perform the obligations of Licensee under this Agreement, and (d) details reasonably satisfactory to CMCC concerning subparagraphs (ii) and (iii) of this paragraph. Such consent to such assignment shall not be unreasonably withheld, delayed or conditioned by CMCC.

## **ARTICLE XIII. DISPUTE RESOLUTION AND ARBITRATION**

- A. Any and all claims, disputes or controversies arising under, out of, or in connection with this Agreement, which have not been resolved by good faith negotiations between the

parties shall be resolved by final and binding arbitration in Boston, Massachusetts, in accordance with the rules then obtaining applicable to the appointment of a single arbitrator of the American Health Lawyers Association, or in the event such arbitration is not then available under those rules, the rules of the American Arbitration Association (“AAA”). All expenses and costs of the arbitrators and the arbitration in connection therewith will be shared equally, except that each party will bear the costs of its prosecution and defense, including without limitation attorneys fees and the production of witnesses and other evidence. Any award rendered in such arbitration shall be final and may be enforced by either party.

- B. Notwithstanding the foregoing, nothing in this Agreement shall be construed to waive any rights or timely performance of any obligations existing under this Agreement, including without limitation Licensee’s obligations to make royalty and other payments, and also, unless CMCC has terminated the License, Licensee’s obligation to continue due diligence and development obligations. Notwithstanding any other provision of this Agreement, each party agrees that it shall not withhold or offset such payments, and agrees that, except as provided in Article XIV of this Agreement, each party’s sole remedy for alleged breaches by the other party is pursuant to this Article XIII.

#### **ARTICLE XIV. TERM AND TERMINATION**

- A. The term of this Agreement shall be fifteen (15) years or the life of the last expiring Patent Right, whichever period is the longer term (the “Term”). Upon the expiration of the Term of this Agreement, Licensee shall have a fully paid-up, irrevocable, freely transferable and sublicensable license in the Territory under the Patent Rights to develop, have developed, make, have made, use, have used, sell, have sold, offer for sale, import and have imported any and all Licensed Products in the Territory.
- B. Notwithstanding Article XIII of this Agreement, CMCC may terminate this Agreement immediately upon the bankruptcy, liquidation, dissolution or cessation of operations of Licensee; or the filing of any voluntary petition for bankruptcy, dissolution, liquidation or winding-up of the affairs of Licensee; or any assignment by Licensee for the benefit of creditors; or the filing of any involuntary petition for bankruptcy, dissolution, liquidation or winding-up of the affairs of Licensee which is not dismissed within ninety (90) days of the date on which it is filed or commenced. Upon any final judicial or administrative

determination that this Agreement violates, or if continued would violate, in a substantial manner, any provision of the Federal Internal Revenue Code, applicable rights of the United States or obligations of CMCC under Title 15 of the United States Code, or other Federal or State laws applicable to CMCC, the parties agree to negotiate in good faith revising this Agreement as necessary so that the Agreement shall be valid and enforceable to the extent permitted by applicable law. In such event the parties shall use their best efforts to replace the invalid or unenforceable provision by a provision that, to the extent permitted by applicable law, achieves the purposes intended under the invalid or unenforceable provision.

C. Either party may terminate this Agreement as a result of a material breach by the other party of any material obligations or conditions hereunder, effective upon thirty (30) days after giving prior written notice to the breaching party of such termination in the case of a payment breach and sixty (60) days after giving written notice to the breaching party of such termination in the case of any other breach and if such breach is not cured within such period. Notwithstanding Article XIII of this Agreement, upon the expiration of the thirty (30) day period, if Licensee shall not have made all such payments to CMCC the rights, privileges and licenses granted hereunder shall terminate without further action by CMCC provided, however, that CMCC shall not terminate this Agreement during the course of a good faith arbitration over the amount due, initiated within said thirty (30) day period, and pursued in accordance with Article XIII of this Agreement, if during the course of said arbitration, within fifteen (15) days after written demand from CMCC, Licensee shall have timely paid the disputed amount into an escrow agent, with irrevocable instructions to dispose of the escrowed funds according to the final order resulting from the arbitration or any judicial proceeding thereon.

D. Licensee shall have the right to terminate this Agreement at any time upon three (3) months' prior written notice to CMCC, upon payment by Licensee of all amounts due CMCC through the effective date of termination.

E. Upon termination of this Agreement for any reason, nothing herein shall be construed to release either party from any obligation that matured prior to the effective date of such termination.

- F. If Licensee terminates this Agreement due to adverse results in clinical or other testing of Licensed Products or Licensed Processes, Licensee shall make available to CMCC, for purposes of its evaluation of the future viability of the technology, a summary of such results together with copies of any government-mandated reports, such as FDA safety reports, made in connection with the decision to terminate development.

## **ARTICLE XV. PAYMENTS, NOTICES, AND OTHER COMMUNICATIONS**

All notices, reports and/or other communications made in accordance with this Agreement shall be sufficiently made or given if delivered by hand, delivered by facsimile (with mechanical confirmation of transmission), or sent by overnight receipted mail, postage prepaid, or by reasonable, customary and reliable commercial overnight carrier in general usage, and addressed as follows:

In the case of CMCC:

Chief Intellectual Property Officer  
Intellectual Property Office  
Children's Hospital Boston  
300 Longwood Avenue  
Boston, MA 02115

Payments shall be transmitted by reliable means to the same addressee, payable to Children's Hospital Boston.

In the case of Licensee:

Chief Executive Officer  
InVivo Therapeutics Corporation  
7 Fort Washington Place  
Cambridge, MA 02139

With a copy to:

Frank Reynolds  
4116 Barberry Drive  
Lafayette Hill, PA 19444

## ARTICLE XVI. GENERAL PROVISIONS

- A. All rights and remedies hereunder will be cumulative and not alternative. This Agreement shall be construed and governed by the laws of the Commonwealth of Massachusetts.
- B. This Agreement may be amended only by written agreement signed by the parties.
- C. It is expressly agreed by the parties hereto that CMCC and Licensee are independent contractors and nothing in this Agreement is intended to create an employer relationship, joint venture, or partnership between the parties. No party has the authority to bind the other.
- D. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all proposals, representations, negotiations, agreements and other communications between the parties, whether written or oral, with respect to the subject matter hereof. Where inconsistent with the terms of any contemporaneous related agreements (such as sponsored research agreements), terms in this Agreement shall control.
- E. If any provisions of this Agreement shall be held to be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions of this Agreement shall not be impaired thereby.
- F. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original as against the party whose signature appears thereon, but all of which taken together shall constitute but one and the same instrument.
- G. The failure of either party to assert a right to which it is entitled, or to insist upon compliance with any term or condition of this Agreement, shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other party.

- H. Licensee agrees to mark any Licensed Products sold in the United States with all applicable United States patent numbers. All Licensed Products shipped to or sold in other countries shall be marked in such a manner as to conform with the patent laws and practices of the country of manufacture or sale.
- I. Each party hereto agrees to execute, acknowledge and deliver such further instruments as may be necessary or appropriate to carry out the purposes and intent of this Agreement.
- B. The paragraph headings contained in this Agreement are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.
- C. The signatories below each warrant that he or she is duly authorized to execute this Agreement.
- D. CMCC and Licensee each recognize that the other party's Confidential Information constitutes highly valuable and proprietary confidential information. CMCC and Licensee each agree that it will keep confidential, and will cause its employees, consultants, Affiliates and sublicensees to keep confidential, all Confidential Information of the other party. Neither CMCC nor Licensee nor any of their respective employees, consultants, Affiliates or sublicensees shall use Confidential Information of the other party for any purpose whatsoever other than exercising any rights granted to it or reserved by it hereunder. Without limiting the foregoing, each party may disclose information to the extent such disclosure is reasonably necessary to (a) file and prosecute patent applications and/or maintain patents which are filed or prosecuted in accordance with the provisions of this Agreement, or (b) file, prosecute or defend litigation in accordance with the provisions of this Agreement or (c) comply with applicable laws, regulations or court orders; provided, however, that if a party is required to make any such disclosure of the other party's Confidential Information in connection with any of the foregoing, it will give reasonable advance notice to the other party of such disclosure requirement and will use reasonable efforts to assist such other party in efforts to secure confidential treatment of such information required to be disclosed.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date last written below.

**CHILDREN'S MEDICAL CENTER CORPORATION**

**INVIVO THERAPEUTICS CORPORATION**

By:



Name: Brenda Manning

Title: Director of Licensing

Date: July 2, 2007

---

By:



Name: Frank Reynolds

Title: President & CEO

Date: 7/2/07

---

US Provisional Application 60/794,986 based on CMCC cases 1455 and 1456

US Utility Application 11/789,538

PCT Application PCT/US07/67403



## US Patents and their parent CMCC and MIT cases

5514378	(CMCC 25, MIT 5573)	5759830	(CMCC 30, MIT 4279)
5804178	(CMCC 23, MIT 4973)	5770417	(CMCC 30, MIT 4279)
6095148	(CMCC 505, MIT 7138)	5770193	(CMCC 30, MIT 4279)
6689608	(CMCC 389, MIT 6560)	6281015	(CMCC 415, MIT 6798)
6309635	(CMCC 26, MIT 5729)	5654381	(MIT 6984)

## International Patents

**(based on US Patent 5759830)**

Japan 2067741

Canada 1340581

Netherlands 299010

**(based on US Patent 5804178)**

Austria 422209

Australia 636346

Belgium 42209

Canada 2031532

Japan 3073766

Switzerland 422209

Germany 69017820

Spain 422209

France 422209

United Kingdom 422209

Italy 422209

Sweden 422209

Netherlands 422209

European Patent Convention 422209

**(based on US Patent 5770417)**

Japan 2067741

Canada 1340581

Netherlands 299010

Austria E139432

Belgium 299010

European Patent Convention 0299010

France 0299010

Germany P3751843

Italy 0299010

Luxembourg 0299010

Sweden 0299010

Switzerland 0299010

United Kingdom 0299010

---

**(based on US Patent 6309635)**

Japan 3524919  
Austria 610423  
Netherlands 610423  
Belgium 610423  
France 610423  
Germany 69219613  
Italy 610423  
Luxembourg 610423  
Sweden 610423  
United Kingdom 610423  
Canada 2121040

**(based on US Patent 5770193)**

Japan 2067741  
Canada 1340581  
Netherlands 299010

**(based on US Patent 6281015)**

European Patent Convention 794790  
Austria 794790  
Belgium 794790  
Switzerland 794790  
Canada 794790  
Denmark 794790  
Germany 794790  
Spain 794790  
France 794790  
United Kingdom 4794790  
Greece 794790  
Italy 794790  
Ireland 794790  
Sweden 794790  
Luxembourg 794790  
Netherlands 794790  
Portugal 794790

**(based on US Patent 6095148)**

Australia 720275  
Canada 2236749  
Japan 9-517608  
New Zealand 321886  
European Patent Convention 96937894.2  
Korean 98-703320

Appendix 2: Development Plan

[\*\*\*\*]

[\*\*\*]

[\*\*\*]

To be submitted no later than July 2, 2012.

**SARBANES-OXLEY SECTION 302(a) CERTIFICATION**

I, Frank M. Reynolds, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of InVivo Therapeutics Holdings Corp.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 16, 2011

/s/ Frank M. Reynolds

Frank M. Reynolds, Principal Executive Officer and  
Principal Financial Officer

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of InVivo Therapeutics Holdings Corp. (the “Company”) on Form 10-Q for the quarter ended March 31, 2011 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Frank M. Reynolds, Chief Executive Officer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: May 16, 2011

/s/ Frank M. Reynolds

---

Frank M. Reynolds, Chief Executive Officer and  
Chief Financial Officer