Harbor BioSciences, Inc.
Form 10-Q
November 07, 2011
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2011

OR

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

For the transition period from to .

Commission file number: 001-34584

HARBOR BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**13-3697002**
(State or other jurisdiction of incorporation)	**(I.R.S. Employer Identification No.)**
9191 Towne Centre Drive, Suite 409, San Diego, California	**92122**
(Address of principal executive offices)	**(zip code)**

Registrant s telephone number, including area code: (858) 587-9333

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 þ 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x 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 definition of accelerated filer , large accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company þ

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

As of November 4, 2011 there were 35,422,140 shares of registrant s Common Stock, $.01 par value, outstanding.

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HARBOR BIOSCIENCES, INC.

Form 10-Q

FOR THE QUARTER ENDED September 30, 2011

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Part I. Financial Information

Item 1. Financial Statements
Harbor BioSciences, Inc.

(A Development Stage Company)

Balance Sheets

All numbers in thousands	Sept 30, 2011 (Unaudited)	Dec. 31, 2010*
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 2,326	$ 5,923
Prepaid expenses	109	100
Other receivable	75	1
Deposits	14	28
Total current assets	2,524	6,052
Property and equipment, net of accumulated depreciation of $65 and $273, respectively	8	44
Restricted cash	2,825	0
Total assets	$ 5,357	$ 6,096
LIABILITIES AND STOCKHOLDERS EQUITY:		
Current liabilities:		
Accounts payable	$ 77	$ 201
Accrued expenses	455	1,005
Redeemable preferred stock	2,825	0
Other current liabilities	32	29
Total current liabilities	3,389	1,235
Commitments and contingencies	0	0
Stockholders equity:		
Preferred stock, $.01 par value, 10,000 shares authorized; 2,000 and zero shares issued; 2,000 shares outstanding	0	0
Common stock, $.01 par value, 100,000 shares authorized; 35,525 and 35,525 shares issued; 35,466 shares outstanding	355	355
Paid-in capital	263,364	263,281
Cost of treasury stock (59 shares)	-346	-346
Deficit accumulated during development stage	-261,405	-258,429
Total stockholders equity	1,968	4,861
Total liabilities and stockholders equity	$ 5,357	$ 6,096

* Derived from the audited financial statements as of December 31, 2010
The accompanying notes are an integral part of these financial statements.

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Harbor BioSciences, Inc.

(A Development Stage Company)

Statements of Operations

(Unaudited)

All numbers in thousands, except per share amounts	**Three Months ended Sept 30,**		**Nine Months ended Sept 30,**		**Period from Inception (Aug.15,1994) to Sept 30,**
	2011	**2010**	**2011**	**2010**	**2011**
Revenue:					
Contract R&D revenue	$ 73	0	$ 146	0	$ 1,354
Total revenue	73	0	146	0	1,354
Operating expenses:					
Research and development	383	934	1,575	3,518	176,588
General and administrative	485	663	1,567	2,094	95,255
Total operating expenses	868	1,597	3,142	5,612	271,843
Other income (expense):					
Gain/(Loss) on disposal of assets	-7	-49	15	-55	-285
Non-cash amortization of deemed discount and deferred issuance costs on convertible debentures	0	0	0	0	-7,627
Interest income	0	4	5	13	17,384
Interest expense	0	0	0	0	-388
Total other income / (expense), net	-7	-45	20	-42	9,084
Net loss	-802	-1,642	-2,976	-5,654	-261,405
Net loss per share-basic and diluted	-0.02	-0.05	-0.08	-0.18	
Weighted average number of common shares outstanding-basic and diluted	35,466	35,459	35,466	31,915	

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

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Harbor BioSciences, Inc. (A Development Stage Company)

Statements of Cash Flows (Unaudited)

All numbers in thousands	**Nine Months ended Sept 30,**		**Period from Inception (Aug. 15, 1994) to Sept 30,**
	2011	**2010**	**2011**
Cash flows from operating activities:			
Net loss	-2,976	-5,654	-261,405
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1	20	2,244
(Gain)/Loss on disposal of assets	-15	55	285
Compensation expense related to equity awards	85	559	11,369
Amortization of deemed discount on convertible debentures	0	0	6,470
Amortization of deferred issuance cost	0	0	1,157
Common stock issued for the company 401k plan	0	44	1,550
Common stock and options issued as consideration for license fees, milestone payments, interest, note repayment, services and amendments to license / finance agreements	0	0	2,926
Expense related to warrants issued as consideration to consultants	0	0	4,369
Expense related to warrants issued to a director for successful closure of merger	0	0	570
Expense related to stock options issued	0	0	5,718
Expense related to common stock issued for the purchase of technology	0	0	1,848
Common stock issued as consideration for In Process R&D	0	0	2,809
Deferred compensation expense related to options issued	0	0	1,210
Changes in assets and liabilities:			
Prepaid expenses	-9	63	-109
Deposits	14	21	-15
Other receivables	-74	81	-75
Accounts payable	-124	239	769
Accrued expenses	-550	-91	420
Other liabilities	3	0	32
Net cash used in operating activities	-3,645	-4,663	-217,858
Cash flows provided by (used in) investing activities:			
Proceeds from sale of property and equipment	48	26	276
Purchase of property and equipment	0	0	-2,825
Net cash provided by (used in) investing activities	48	26	-2,549
Cash flows from financing activities:			
Contributions from stockholder	0	0	104
Restricted cash	-2,825	34	-2,825
Net proceeds from sale of preferred stock	2,825	0	6,825
Net proceeds from sale of common stock	0	1,789	185,323
Net proceeds from issuance of convertible debentures and warrants	0	0	9,214
Purchase of treasury stock	0	0	-346
Proceeds from issuance of debt	0	0	371

Net proceeds from recapitalization	0	0	6,271
Net proceeds from warrants and options exercised	0	0	17,796
Net cash from financing activities	0	1,823	222,733
Net increase (decrease) in cash	-3,597	-2,814	2,326
Cash and equivalents at beginning of period	5,923	9,738	0
Cash and equivalents at end of period	2,326	6,924	2,326
Supplemental Disclosure of Cash Flow Information:			
Income taxes	0	0	0
Interest paid	0	0	388
Supplemental Disclosure of Non-Cash Financing Activities:			
Conversion of debt to equity	0	0	10,371
Warrants issued to consultants in lieu of cash, no vesting	0	0	559
Warrants issued in lieu of cash, commissions on private placement	0	0	733
Warrants issued in connection with convertible debentures	0	0	371

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

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Harbor BioSciences, Inc.

(A Development Stage Company)

Notes to Financial Statements

(Unaudited)

1. Basis of Presentation

The information at September 30, 2011, and for the three-month and nine-month periods ended September 30, 2011 and 2010, and inception to date is unaudited. In the opinion of management, these financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the results for the interim periods presented. Interim results are not necessarily indicative of results for a full year. These financial statements should be read in conjunction with the Harbor BioSciences, Inc. (Harbor BioSciences , we or the Company) Annual Report on Form 10-K, for the year ended December 31, 2010, which was filed with the United States Securities and Exchange Commission on March 31, 2011.

Our operations to date have consumed substantial capital without generating any revenues other than the amount received under the Cystic Fibrosis Foundation Therapeutics (CFFT) and Michael J. Fox Foundation for Parkinson s Research (MJFF) collaborations. We will continue to require substantial and increasing amounts of funds to conduct necessary research and development and preclinical and clinical testing of our drug candidates, and to market any drug candidates that receive regulatory approval. We do not expect to generate revenue from our biotechnology operations for the foreseeable future, and our ability to meet our cash obligations as they become due and payable will depend for at least the next several years on our ability to complete an acquisition of a profitable company, sell securities, borrow funds or some combination thereof. We expect that it will be very difficult to raise capital to continue our operations and our independent registered public accounting firm has issued an opinion with an explanatory paragraph to the effect that there is substantial doubt about our ability to continue as a going concern.

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Recent Accounting Pronouncements

In January 2010, the FASB issued ASU No. 2010-06, Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements. ASU 2010-06 amends Codification Subtopic 820-10 to add two new disclosures: (1) transfers in and out of Level 1 and 2 measurements and the reasons for the transfers, and (2) a gross presentation of activity within the Level 3 roll forward. The proposal also includes clarifications to existing disclosure requirements on the level of disaggregation and disclosures regarding inputs and valuation techniques. The proposed guidance would apply to all entities required to make disclosures about recurring and nonrecurring fair value measurements. The effective date of the ASU is the first interim or annual reporting period beginning after December 15, 2009, except for the gross presentation of the Level 3 roll forward information, which is required for annual reporting periods beginning after December 15, 2010 and for interim reporting periods within those years. The adoption by the Company has had minimal impact on its financial statements.

Accounts Payable and Accrued Expenses

Accrued expenses as of September 30, 2011 include approximately $0.2 million in accrued vacation expense and $0.3 million in other research and development and general and administrative expenses.

Accrued expenses as of December 31, 2010 include approximately $0.3 million in accrued vacation expense and $0.7 million in other research and development and general and administrative expenses.

Commitments and Contingencies

During July 2011, the proceeds from the sale of preferred stock totaling $2.825 million were placed into an escrow account. These funds are available under certain circumstances to pay certain Company related expenses and to fund the Company s working capital needs beginning in January 2012. The preferred stockholders have the right to put the preferred shares back to the Company in return for the remaining cash held in escrow at the time of the put, upon the occurrence of certain events, The put right expires at the later of July 28, 2012 or 45 days following the 2012 annual stockholders meeting.

2. Other Agreements and Commitments

China State Institute of Pharmaceutical Industry Agreements

In January 2011, the Company announced that it had licensed the research and development and commercialization rights for three of its products, exclusively in the People s Republic of China and Hong Kong, to the China State Institute of Pharmaceutical Industry (CIPI). Harbor BioSciences retains the rights to these products in the U.S. and the rest of the world, and CIPI will make available to the company all pre-clinical and clinical data it generates.

CIPI was recently formed by a merger of the Shanghai Institute of Pharmaceutical Industry and other institutes and companies. CIPI s research and development (R&D) focus has been in the areas of cancer, infectious diseases, cardiovascular, autoimmune disorders, endocrinology and central nervous system (CNS). CIPI is a subsidiary of the China National Pharmaceutical Group Corporation (Sinopharm Group), China s largest pharmaceutical and health industrial group under the state-owned Assets Supervision and Administration Commission of the State Council. Sinopharm Group s core businesses include R&D, manufacturing, distribution and retail sales. Its products are manufactured in more than 10 pharmaceutical and biological production facilities. Sinopharm Group has more than 20 joint ventures with global pharmaceutical companies and through trade and cooperative relations, has a presence in more than 100 countries and regions. Sinopharm Group reported 2010 revenues of approximately $12 billion U.S.

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CIPI is a major supplier of both generic drugs and traditional Chinese medicines in China and Hong Kong. The three license agreements cover Harbor BioSciences compounds HE2000, Apoptone and Triolex for any clinical use in the People s Republic of China and Hong Kong. CIPI plans to develop the Harbor BioSciences compounds for major indications including diabetes, cancer, inflammation and infectious diseases.

The Company believes these are the first drug development agreements between a western pioneer drug company and a government-owned Chinese drug developer for pharmaceutical development to be conducted in the People s Republic of China. CIPI, a low cost drug manufacturer, has agreed to supply the licensed products to Harbor BioSciences for use in clinical studies and sales outside of China and Hong Kong. The Company can also elect to distribute these compounds in countries that accept the State Food and Drug Administration s (SFDA) drug approval process.

Clinical drug development candidates licensed to CIPI include Triolex, which has completed Phase IIa clinical trials in patients with Type 2 diabetes and is in early stage development for ulcerative colitis and rheumatoid arthritis; Apoptone, which has demonstrated activity in Phase I/IIa trials of prostate cancer; and HE2000, which has shown to limit opportunistic infections, including tuberculosis, in humans infected with the HIV-1 virus, to reduce parasite levels in patients with uncomplicated malaria and to attenuate non-productive lung inflammation in animal models.

The Company will receive milestone payments for Triolex, Apoptone and HE2000, excluding infectious diseases, at the completion of Phase II and III clinical studies and upon approval by the SFDA. The Company will also receive royalties based on net profits for the life of each agreement. The term of each agreement runs until the latter of (1) the expiration of the last licensed patent or any Company, CIPI or joint improvement patent and (2) the first documented third party sale of a competing generic product in the licensed territory. In addition, the Company is CIPI s sole agent with commercial development and sales rights to all of CIPI s improvements that are sold outside the licensed territory. Sales of licensed drugs that are covered by CIPI s improvements outside the territory bear a royalty to Harbor BioSciences. No milestones were met during the three and nine months ended September 30, 2011.

The Company announced in June 2011, the signing of an umbrella generic drugs distribution agreement with CIPI. This new agreement provides that Harbor BioSciences and CIPI will select one or more of CIPI s drugs or other products for distribution outside China under separately negotiated sub agreements. The new agreement provides that the Company is to receive commercial development, sales and sublicense rights for products under executed sub agreements. Sales of CIPI s products will bear a royalty to Harbor BioSciences.

3. Equity Transactions

On July 28, 2011, the Company sold an aggregate of 2,000,000 shares of its Series A Preferred Stock (the Preferred Shares) to Amun, LLC, a Delaware limited liability company (the Investor) pursuant to the terms of a Stock Purchase Agreement (the Purchase Agreement) and related Stockholders Agreement (the Stockholders Agreement). The Preferred Shares represent approximately a 28% of the economic interest in the Company and also entitle the Investor to a number of votes equal to 38.28% of the total number of votes entitled to be cast by holders of all shares of the Company s capital stock (including the Common Stock and Series A Preferred Stock) voting together as single class. Under the terms of these and other related agreements between the Company and the Investor, the Investor placed $2.825 million in cash into an escrow account, which amount is available under certain circumstances to pay certain Company related expenses and to fund the Company s working capital needs. Amounts received are included as restricted cash as of September 30, 2011. The Stockholder Agreement provides that the Investor will have the right to put the Preferred Shares acquired pursuant to the Purchase Agreement back to the Company in return for the remaining cash held in escrow at the time of the put, upon the occurrence of certain events.

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No options to purchase shares of common stock were granted in the nine-month periods ended September 30, 2011. There were no options to purchase shares of common stock exercised in the nine-month period ended September 30, 2011. The Company accounts for stock option grants in accordance with Accounting Standards Codification (ASC) Topic 718, Share-Based Payment. Compensation costs related to share-based payments recognized in the Statements of Operations were approximately $42 and $85 thousand for the three-month and nine-month periods ended September 30, 2011, and $99 and $559 thousand for the same periods in 2010. Our outstanding options and warrants are anti-dilutive and are not reflected in the weighted average shares reflected on our income statement basic and diluted. The Company may from time to time extend previous option grants.

4. Fair Value Measurement

We adopted ASC Topic 820, Fair Value Measurement, as of January 1, 2008, for financial instruments measured at fair value on a recurring basis. ASC Topic 820 defines fair value, establishes a framework for measuring fair value in accordance with U.S. GAAP and expands disclosures about fair value measurements.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC Topic 820 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements). These tiers include:

Level 1, defined as observable inputs such as quoted prices for identical instruments in active markets;

Level 2, defined as inputs other than quoted prices in active markets that are directly or indirectly observable such as quoted prices for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active; and

Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions, such as valuations derived from valuation techniques in which one or more significant value drivers are observable.

We measure certain financial instruments at fair value on a recurring basis. Financial assets measured at fair value on a recurring basis are as follows at September 30, 2011:

	Level 1	Level 2	Level 3	Total
		In Thousands		
Money Market funds included in cash and cash equivalents plus restricted cash	$ 3,833	$ 0	$ 0	$ 3,833
Total	$ 3,833	$ 0	$ 0	$ 3,833

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5. Other Matters

The Company recognized $73 thousand of revenue from the Michael J. Fox Foundation (MJFF) during the third quarter and $146 thousand for the nine-month year to date period. Expenses associated with the revenue recognition are contained in research and development expenses for the same periods.

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. While it is not possible to predict accurately or to determine the eventual outcome of these matters, as of the date of this report, we do not believe that we are engaged in any legal proceedings that are expected, individually or in the aggregate, to have a material adverse effect on our business, financial condition or operating results.

The Company s common stock was delisted from the NASDAQ Stock Market at the opening of business on September 23, 2010 at which time the common stock became available for trading on the OTC bulletin board (*OTCBB*) under the symbol HRBR.OB. On August 17, 2011, the Common Stock was delisted from the OTCBB when the Company filed a Form 15 pursuant to Rule 12g-4 and subsequently became available for trading on the pink sheets under the trading symbol HRBR.PK.

The Company has evaluated all subsequent events through November 4, 2011, which represents the filing date of this Form 10-Q with the Securities and Exchange Commission, to ensure that this Form 10-Q includes appropriate disclosure of events both recognized in the financial statements as of September 30, 2011 and events which occurred subsequent to September 30, 2011 but were not recognized in the financial statements.

On October 26, 2011, the stockholders approved several proposals to amend our Amended and Restated Certificate of Incorporation, as amended (the Restated Certificate), to authorize a 1-for-1,000 reverse stock split of the Common Stock, (the Reverse Stock Split), and to then immediately effect a 1,000-for-1 forward stock split of the Common Stock (the inverse ratio of the Reverse Stock Split) immediately following the Reverse Stock Split, (the Forward Stock Split).

On October 26, 2011, we completed the Reverse Stock Split and the Forward Stock Split. As a result, as previously described in the Proxy Statement filed on September 1, 2011, pursuant to Section 3(e) of the Warrants issued to the investors in our June 2010 registered direct offering of Common Stock and Warrants, the holders of the Warrants are eligible to exercise a put right under the Warrants which, if exercised, would entitle them to receive a cash payment in an amount equal to the fair value of the Warrants as determined by reference to a formula set forth in the Warrants. In the event the put right is exercised, we are entitled to disbursement from an escrow account in an amount equal to the amount required to repurchase the Warrants.

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with the financial statements and notes included elsewhere in this report. The following discussion and analysis contains forward-looking statements that involve risks and uncertainties. This discussion represents our current judgment on the future direction of our business and our actual results may differ materially from those discussed here due to risks and factors including the timing, success and cost of preclinical research and clinical studies, the timing, acceptability and review periods for regulatory filings, the ability to obtain regulatory approval of products, our ability to obtain additional funding and the development of competitive products by others as well as the risks and factors set forth below under the caption Risk Factors. Additional factors that could cause or contribute to such differences can be found in the financial statements and the related Management s Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2010, filed on March 31, 2011.

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Overview

Harbor BioSciences, Inc. (Harbor BioSciences , we , the Company), a clinical-stage pharmaceutical company, is engaged in the discovery and development of products for the treatment of diseases related to aging. Our current development efforts are primarily focused on a series of steroid hormone analogs that are derived from the human adrenal metabolome.

We are a development-stage company with two product candidates which recently completed Phase I/IIa clinical trials: Apoptone® (HE3235) in patients with late-stage prostate cancer, and Triolex® (HE3286) in obese type 2 diabetes mellitus patients. Apoptone and Triolex represent two of the lead candidates from Harbor BioSciences small molecule platform based on metabolites or synthetic analogs of endogenous human steroids.

Drawn from our unique and proprietary platform, our research program has identified additional lead candidates active in preclinical models of cancer, metabolic conditions, autoimmune conditions, lung inflammation, bone degeneration and organ regeneration.

We have been unprofitable since our inception in August 1994. As of September 30, 2011, we had an accumulated deficit of approximately $261.4 million. We expect to incur substantial additional operating losses and capital expenditures for the foreseeable future on pre-clinical testing and other activities in support of the development of our drug candidates. In addition, in the future, we may have to meet the substantial new challenge of developing the capability to market products if we are successful in obtaining regulatory approval for any of our current or future drug candidates. Accordingly, our activities to date are not as broad in depth or scope as the activities we may undertake in the future, and our historical operations and financial information are not indicative of the future operating results or financial condition or ability to operate profitably as a commercial enterprise when and if we succeed in bringing any drug candidates to market.

Results of Operations

We have devoted substantially all of our resources to the payment of research and development expenses and general and administrative expenses. From inception through September 30, 2011, we have incurred approximately $176.6 million in research and development expenses and $95.2 million in general and administrative expenses. From inception through September 30, 2011, we have generated approximately $1.4 million in revenues from providing research and development services. Of the $1.4 million in revenue, $0.2 million is under our current funding agreement with MJFF and $1.2 million under our Study Funding Agreement with the CFFT, which expired in December 1999. We have earned $9.1 million in net, other income, as our $17.4 million of interest income has been partly offset by $7.6 million in deemed discount expense, $0.4 million in interest expense and $0.3 million loss on disposal of assets. The combination of these resulted in a net loss of $261.4 million for the period from inception until September 30, 2011.

Research and development expenses were $0.4 and $1.6 million for the three-month and nine-month periods ended September 30, 2011, compared to $0.9 and $3.5 million for the same periods in 2010. The research and development expenses relate primarily to the ongoing development, preclinical testing and clinical trials for our drug candidates. Research and development expenses decreased by $0.5 and $1.9 million for the three-month and nine-month periods ended September 30, 2011 compared to the same periods in 2010. The decrease was primarily due to a reduction in staffing, clinical trial expenses, facilities, and stock option compensation expense.

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General and administrative expenses were $0.5 and $1.6 million for the three-month and nine-month period ended September 30, 2011 compared to $0.7 and $2.1 million for the same period in 2010. General and administrative expenses relate primarily to salaries and benefits, facilities, legal, accounting/auditing, investor relations, consultants, insurance and travel. General and administrative expenses decreased by $0.2 and $0.5 million for the three-month and nine-month periods ended September 30, 2011, compared to the same periods in 2010. The decrease was due mainly to a decrease in staffing, NASDAQ fees and stock option compensation expense.

Other income (expense), net was approximately $(7) and $20 thousand for the three-month and nine-month periods ended September 30, 2011 compared to $(45) and $(42) thousand for the same period in 2010. In 2010, we incurred losses on disposal of assets and a modest gain on disposals during 2011.

Please refer to critical accounting policies included in the Form 10-K filed on March 31, 2011.

CIPI, our Chinese partner, has made progress during 2011. We have delivered to CIPI in excess of 20,000 pages of pre-clinical, non-clinical and chemistry, manufacture and control data for all three projects. These pages have been translated and evaluated by the dedicated project teams, one for each compound. Our historical data has been evaluated against the People s Republic of China s State Food and Drug Administration (SFDA) criteria with their expert advisors.

Late in the second quarter, we met with CIPI in China to review CIPI s project plans for each compound. We have been informed that CIPI intends to commence Phase I clinical trials for Apoptone during the first half of 2012 and for Triolex and HE2000 during the second half of 2012. According to CIPI, they have developed a small-scale synthesis method for each compound and intend to scale-up each synthesis into a larger batch processes that will be used for clinical trials materials. We were told by CIPI that the process will then be scaled-up to manufacture the final active pharmaceutical ingredients in quantities to meet market demands. CIPI also informed us that they are evaluating multiple formulations to identify and use an optimized formulation intended to be the final finished product to initiate their clinical trials. Our agreements with CIPI provide that these products will be made available to us for clinical trials outside of the licensed territory if these activities are successfully completed by CIPI. CIPI further told us that reproductive toxicology and certain other tox studies are planned for the first half of 2012.

During the fourth quarter, we intend to deliver the detailed clinical data from its clinical studies for the licensed compounds for translation and evaluation by CIPI s clinical experts. In cooperation with CIPI s advisors and the SFDA, a detailed clinical development strategy for each project with estimated timelines is expected during the first half of 2012.

The Chinese clinical trial strategy differs from the western world. In the western world, the clinical timelines and scope of the trials become longer and more involved as a compound progresses through the clinical development process. In China, the SFDA has a different clinical trial design than generally practiced in the west. Chinese Phase I safety studies typically are much larger in scope and longer in duration to insure the development program does not become halted for safety concerns during the more expensive downstream stages of a program. For similar reasons, a Phase I study does not commence until all of the safety and toxicology studies required by the SFDA have been completed and evaluated. Consequently, Phase II and Phase III studies are typically smaller in scope and faster than the western world.

Pursuant to our agreements with CIPI, as a matter of course, we are to receive data periodically from CIPI s development efforts to supplement the existing data for each project. We intend to use this data for further partnering discussions in territories outside of China and Hong Kong.

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Liquidity and Capital Resources

A summary of our current contractual obligations as of September 30, 2011 is as follows (in thousands):

		Payments Due by Period			
Contractual Obligations	**Total**	**Less than one year**	**One to three years**	**Three to five years**	**More than five years**
Operating Leases	$ 36	$ 36	$ 0	$ 0	$ 0
Preferred Stock Put Right	2,825	2,825	0	0	0
Total	$ 2,861	$ 2,861	$ 0	$ 0	$ 0

We may also be required to make substantial milestone or royalty payments in cash based on the terms of some of our agreements.

Our operations to date have consumed substantial capital without generating any revenues other than the amount received under the CFFT collaboration. We will continue to require substantial and increasing amounts of funds to conduct necessary research and development and preclinical and clinical testing of our drug candidates, and to market any drug candidates that receive regulatory approval. We do not expect to generate revenue from biotechnology operations for the foreseeable future, and our ability to meet our cash obligations as they become due and payable will depend for at least the next several years on our ability to acquire a profitable company, sell securities, borrow funds or some combination thereof. Based upon our current plans, we believe that our existing capital resources, together with interest thereon, will be sufficient to meet our operating expenses and capital requirements into late 2011. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of such cash before that time. As of September 30, 2011, our unrestricted cash and cash equivalents totaled approximately $2.3 million. In addition, we have $2.8 million of restricted cash that was placed in an escrow account upon the sale of 2,000,000 million preferred shares during July 2011 (see the next three paragraphs for additional information).

Under the terms of the Purchase Agreement, beginning January 1, 2012 and on the first day of each month thereafter, we will be entitled to disbursements from the restricted cash escrow account in the amount of $200 thousand (the Working Capital Amount) for so long as: (x) the Investor has not brought to the board of directors an offer for us to acquire a controlling interest in a profitable entity, which transaction would provide to us at least $5.0 million in cash plus an amount equal to the costs and expenses incurred by us in connection with such transaction (not to exceed $200 thousand), which amounts, together with any operating cash held by us immediately prior to closing such transaction, would be transferable, together with any and all (i) intellectual property and (ii) other assets related to our biotechnology business, to a newly formed subsidiary, which subsidiary will assume all of our liabilities as of immediately prior to such closing (a Qualifying Transaction), and a majority of our disinterested directors fail to recommend and approve the Qualifying Transaction within forty-five calendar days thereafter (a Qualifying Transaction Proposal), (y) for sixty calendar days following the Investor having made a Qualifying Transaction Proposal (provided that the sixty day period will be extended an additional fourteen calendar days in the event the sixty day period includes all or any part of the period from December 15 through December 31, 2011); and (z) in the event that a Qualifying Transaction has been presented and definitive documentation relating to such Qualifying Transaction has been executed, for so long as the Qualifying Transaction has not been consummated (unless the failure to consummate such Qualifying Transaction is due to our breach in any material respect of our obligations under the definitive agreements providing for the Qualifying Transaction, and if and until the Put Right, as described below, is exercised or the right to exercise the Put Right otherwise expires).

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The Stockholders Agreement provides that the Investor will have the right to put the Preferred Shares acquired pursuant to the Purchase Agreement back to us in return for the remaining cash held in escrow at the time of the exercise of the put right, if applicable, upon the occurrence of certain events, including an ownership change as such term is defined by Section 382 of the Internal Revenue Code, or in the event that we fail to take certain actions or the board of directors fails to recommend and approve or consummate a Qualifying Transaction.

Based upon our current plans, we believe that beginning January 1, 2012, if disbursed to us from escrow, $200 thousand per month will be sufficient to meet our operating expenses and capital requirements at that time until such funds are depleted. Further, if the Qualifying Transaction is consummated, we believe that our capital resources, together with interest thereon, would be sufficient to meet our operating expenses and capital requirements into 2013.

The Company s common stock was delisted from the NASDAQ Stock Market at the opening of business on September 23, 2010 at which time the common stock became available for trading on the OTCBB. On August 17, 2011, the Common Stock was delisted from the OTCBB when the Company filed a Form 15 pursuant to Rule 12g-4 and subsequently became available for trading on the Pink Sheets® under the trading symbol HRBR.PK. The Pink Sheets are maintained by Pink Sheets OTC Markets, Inc., a quotation service that collects and publishes market maker quotes for over-the-counter securities. The Pink Sheets is not a stock exchange or a regulated entity. Price quotations are provided by over-the-counter market makers and company information is provided by the over-the-counter companies. The Pink Sheets provide significantly less liquidity than the NASDAQ stock market or any other national securities exchange, which may make it more difficult to raise capital. Further, subject to certain exceptions, for as long as the Investor continues to hold 50% of the Preferred Shares, the Investor is entitled to purchase up to 100% of any securities offered by the Company by giving written notice to the Company within ten days. As a result, we expect that it will be very difficult to raise capital to continue our operations and our independent registered public accounting firm has issued an opinion with an explanatory paragraph to the effect that there is substantial doubt about our ability to continue as a going concern. We do not believe that we could succeed in raising additional capital needed to sustain our operations without the consummation of the Qualifying Transaction or another strategic transaction, such as a partnership or merger. If we are unable to consummate such a transaction, we expect that we would need to cease all operations and wind down. We cannot assure you that any actions that we take would raise or generate sufficient capital to fully address the uncertainties of our financial position. As a result, we may be unable to realize value from our assets and discharge our liabilities in the normal course of business. If we are unable to settle our obligations to our creditors or if we are unable to consummate a strategic transaction, we would likely need to liquidate the Company in a voluntary dissolution under Delaware law or seek protection under the provisions of the U.S. Bankruptcy Code. In that event, we, or a trustee appointed by the court, may be required to liquidate our assets. In either of these events, we might realize significantly less from our assets than the values at which they are carried on our financial statements. The funds resulting from the liquidation of our assets would be used first to satisfy obligations to creditors before any funds would be available to pay our stockholders, and any shortfall in the proceeds would directly reduce the amounts available for distribution, if any, to our creditors and to our stockholders. In the event we are required to liquidate under Delaware law or the federal bankruptcy laws, it is highly unlikely that stockholders would receive any value for their shares.

Cautionary Statement Regarding Forward-Looking Statements

This quarterly report on Form 10-Q contains forward-looking statements that are based on our management s beliefs and assumptions and on information currently available to our management. Forward-looking statements include information concerning our possible or assumed future results of operations, business strategies, financing plans, competitive position, industry environment, potential growth opportunities, the effects of future regulation and the effects of competition. Forward-looking statements include all statements that are not historical facts and can be identified by terms such as anticipates, believes, could, estimates, expects, intends, may, plans, potential, predicts, projects, or similar expressions.

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Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. We discuss these risks in greater detail in the Risk Factors section below and in our other filings with the Securities and Exchange Commission, including our annual report on Form 10-K for the year ended December 31, 2010, filed on March 31, 2011. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

Also, forward-looking statements represent our management s beliefs and assumptions only as of the date of this quarterly report on Form 10-Q. Our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

There have been no material changes to our investment portfolio from December 31, 2010 to the present. At September 30, 2011, our investment portfolio included only cash and money market accounts and did not contain fixed-income securities. There would be no material impact to our investment portfolio, in the short term, associated with any change in interest rates, and any decline in interest rates over time will reduce our interest income, while increases in interest rates over time will increase our interest income.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Based on the evaluation of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act)) required by Rule 13a-15(b) of the Exchange Act, James M. Frincke, our chief executive officer, and Robert W. Weber, our chief financial officer, have concluded that, as of September 30, 2011, our disclosure controls and procedures were effective to ensure that the information required in the reports we file under the Exchange Act is gathered, reported-up, analyzed and disclosed with adequate timeliness, accuracy and completeness.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal controls over financial reporting during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports we file with or submit to the SEC under the Securities and Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer as appropriate, to allow for timely decisions regarding required disclosure. Our management, including our chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls

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can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. The size of our company makes full segregation of duties difficult. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met, and, as set forth above, our chief executive officer and chief financial officer have concluded, based on their evaluation, that our disclosure controls and procedures were effective as of the end of the period covered by this report to provide reasonable assurance that the objectives of our disclosure control system were met.

PART II Other Information

Item 1. Legal Proceedings

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. While it is impossible to predict accurately or to determine the eventual outcome of these matters, as of the date of this report, we do not believe that we are engaged in any legal proceedings that are expected, individually or in the aggregate, to have a material adverse effect on our business, financial condition or operating results.

Item 1A. Risk Factors

In evaluating our business, you should consider the following discussion of risks, in addition to other information contained in this report as well as our other public filings with the Securities and Exchange Commission. The description of risks below includes certain revisions to, and supersedes in its entirety, the description of the risk factors associated with our business previously disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and our subsequent filings with the Securities and Exchange Commission. Any of the following risks could materially adversely affect our business, financial condition, results of operations and prospects and, as a result, the market price of our common stock could decline, and you may lose all or part of the money you paid to buy our common stock.

We are still a development stage company.

We have never had any revenues from sales of products. None of our drug candidates has been approved for commercial sale and we do not expect that any of our present or future drug candidates will be commercially available for a number of years, if at all. We have incurred losses since our inception and we expect to continue to incur significant additional operating losses for the foreseeable future as we fund clinical trials and other expenses in support of regulatory approval of our drug candidates.

We need to raise additional money before we achieve profitability; if we fail to raise additional money, it could be difficult or impossible to continue our business.

As of September 30, 2011, our unrestricted cash and cash equivalents totaled approximately $2.3 million. Based on our current plans, we believe these financial resources, and interest earned thereon, will be sufficient to meet our operating expenses and capital requirements into late 2011. However, changes in our research and development plans or other events affecting our operating expenses may result in the

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expenditure of such cash before that time. Based upon our current plans, we believe that beginning January 1, 2012, if disbursed to us from the restricted cash escrow account, $200 thousand per month will be sufficient to meet our operating expenses and capital requirements at that time until such funds are depleted. Further, if the Qualifying Transaction is consummated, we believe that our capital resources, together with interest thereon, would be sufficient to meet our operating expenses and capital requirements into 2013. We will require substantial additional funds in order to finance our drug discovery and development programs, fund operating expenses, pursue regulatory clearances, develop manufacturing, marketing and sales capabilities, and prosecute and defend our intellectual property rights. We may seek additional funding through public or private financing or through collaborative arrangements with strategic partners.

You should be aware that in the future:

- we may not obtain additional financial resources when necessary or on terms favorable to us, if at all; the escrow funds may not be available to us; the Qualifying Transaction may not be consummated; and
- any available additional financing may not be adequate.

If we cannot raise additional funds when needed, or on acceptable terms, we will not be able to continue to develop our drug candidates.

We may need to liquidate the Company in a voluntary dissolution under Delaware law or seek protection under the provisions of the U.S. Bankruptcy Code, and in either event, it is unlikely that stockholders would receive any value for their shares.

We have not generated any revenues from product sales, and have incurred losses in each year since our inception in 1994. If a Qualifying Transaction is not consummated, we expect that it will be very difficult to raise capital to continue our operations and our independent registered public accounting firm has issued an opinion with an explanatory paragraph to the effect that there is substantial doubt about our ability to continue as a going concern in the annual report for the period ended December 31, 2010. If a Qualifying Transaction is not consummated, we do not believe that we could succeed in raising additional capital needed to sustain our operations without some strategic transaction, such as a partnership or merger. If we are unable to consummate such a transaction, we expect that we would need to cease all operations and wind down. Although we are currently evaluating our strategic alternatives with respect to all aspects of our business, we cannot assure you that any actions that we take would raise or generate sufficient capital to fully address the uncertainties of our financial position. As a result, we may be unable to realize value from our assets and discharge our liabilities in the normal course of business. If we are unable to settle our obligations to our creditors or if we are unable to consummate a strategic transaction, we would likely need to liquidate the Company in a voluntary dissolution under Delaware law or seek protection under the provisions of the U.S. Bankruptcy Code. In that event, we, or a trustee appointed by the court, may be required to liquidate our assets. In either of these events, we might realize significantly less from our assets than the values at which they are carried on our financial statements. The funds resulting from the liquidation of our assets would be used first to satisfy obligations to creditors before any funds would be available to pay our stockholders, and any shortfall in the proceeds would directly reduce the amounts available for distribution, if any, to our creditors and to our stockholders. In the event we are required to liquidate under Delaware law or the federal bankruptcy laws, it is highly unlikely that stockholders would receive any value for their shares. See Liquidity and Capital Resources in Part II, Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations and Note 1 to our financial statements in our Annual Report on Form 10-K.

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We may be unable to obtain a quorum for meetings of our stockholders or obtain necessary stockholder approvals and therefore be unable to take certain actions

Our bylaws require that a quorum, consisting of a majority of the outstanding shares of voting stock, be represented in person or by proxy in order to transact business at a meeting or our stockholders. In addition, amendments to our amended and restated certificate of incorporation, such as an amendment to increase our authorized capital stock, require the approval of a majority of our outstanding shares. Under Rule 452 of the New York Stock Exchange, the U.S. broker-dealer may vote shares absent direction from the beneficial owner on certain matters, such as an amendment to our amended and restated articles of incorporation to increase authorized shares that are to be used for general corporate purposes and the ratification of our auditors. As a result, unless more stockholders elect to be presented in person or by proxy in future annual or special meetings of stockholders, we may be unable to obtain a quorum at such meetings or obtain stockholder approval of proposals when needed.

If we are unable to obtain a quorum at our stockholders meeting and thus fail to get stockholder approval of corporate actions, such failure could have a materially adverse effect on us. In addition, brokers may only vote on those matters for which broker discretionary voting is allowed under Rule 452 of the New York Stock Exchange, and we may not be able to obtain the required number of votes to approve certain proposals that require a majority of all outstanding share to approve the proposal due to our reliance on broker discretionary voting. Therefore, it is possible that even if we are able to obtain a quorum for our meetings of the stockholders we still may not receive enough votes to approve proxy proposals presented at such meeting and, depending on the proposal in question, such failure could have a material adverse effect on us.

If we do not obtain government regulatory approval for our products, we cannot sell our products and we will not generate revenues.

Our principal efforts are currently centered on a proprietary class of small compounds that we believe shows promise for the treatment of several diseases and disorders. However, all drug candidates require approval by the United States Food and Drug Administration (FDA) before they can be commercialized in the United States as well as approval by various foreign government agencies before they can be commercialized in other countries. These regulations change from time to time and new regulations may be adopted. While limited clinical trials of our drug candidates have been conducted to date, significant additional trials are required, and we may not be able to demonstrate that our drug candidates are safe or effective. In addition, success in early development does not mean that later development will be successful because, for example, drug candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy despite having progressed through initial clinical testing. Our clinical experience with our drug candidates is limited, and to date our drug candidates have been tested in less than the number of patients that will likely need to be studied to gain regulatory approval. The data collected from clinical trials with larger patient populations may not demonstrate sufficient safety and efficacy to support regulatory approval of these drug candidates. In addition, we do not know whether early results from any of our ongoing clinical trials will be predictive of final results of any such trial. If we are unable to demonstrate the safety and effectiveness of a particular drug candidate to the satisfaction of regulatory authorities, the drug candidate will not obtain required government approval and we will experience potentially significant delays in, or be required to abandon development of the drug candidate. If we do not receive FDA or foreign approvals for our drug candidates, we will not be able to sell products and will not generate revenues. If we receive regulatory approval of one of our drug candidates, such approval may impose limitations on the indicated uses for which we may market the resulting product, which may limit our ability to generate significant revenues. Further, U.S. or foreign regulatory agencies could change existing, or promulgate new, regulations at any time, which may affect our ability to obtain approval of our drug candidates or require significant additional costs to obtain such approvals. In addition, if regulatory authorities determine that we or a partner conducting research and development activities on our behalf have not complied with regulations in the research and development of one of our drug candidates, then they may not approve the drug candidate and we will not be able to market and sell it. If we were unable to market and sell our drug candidates, our business and results of operations would be materially and adversely affected.

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Recent publicity concerning the safety of certain drug products has resulted in heightened scrutiny by the FDA in the process of approving new drugs, which could delay or limit any regulatory approvals we may obtain for our drug candidates.

In light of widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products after approval. In addition, the Food and Drug Administration Amendments Act of 2007, or FDAAA, grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the new law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. It also significantly expands the federal government s clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials by drug development companies. As a result, the FDA may require us to conduct additional preclinical studies or clinical trials during the clinical development of one or more of our drug candidates as a condition precedent to approval which could potentially delay our development plans, limit the indications for which our drug candidates are ultimately approved, and otherwise adversely impact us.

If we do not successfully commercialize our products, we may never achieve profitability.

We have experienced significant operating losses to date because of the substantial expenses we have incurred to acquire and fund development of our drug candidates. We have never had significant operating revenues and have never commercially introduced a product. Our accumulated deficit was approximately $261.4 million as of September 30, 2011. Our net losses for fiscal years 2010, 2009 and 2008 were approximately $6.6 million, $15.6 million and $21.6 million, respectively. Many of our research and development programs are at an early stage. Potential drug candidates are subject to inherent risks of failure. These risks include the possibilities that no drug candidate will be found safe or effective, meet applicable regulatory standards or receive the necessary regulatory clearances. Even if we were ultimately to receive regulatory approval for one or more of our drug candidates, we may be unable to commercialize them successfully for a variety of reasons. These include, for example, the availability of alternative treatments, lack of cost effectiveness, the cost of manufacturing the product on a commercial scale, the effect of competition with other drugs, or because we may have inadequate financial or other resources to pursue one or more of our drug candidates through commercialization. If we are unable to develop safe, commercially viable drugs, we may never achieve profitability. If we become profitable, we may not remain profitable.

As a result of our intensely competitive industry, we may not gain enough market share to be profitable.

The biotechnology and pharmaceutical industries are intensely competitive. We have numerous competitors in the U.S. and elsewhere. Because we are pursuing potentially large markets, our competitors include major multinational pharmaceutical companies, specialized biotechnology firms as well as academic institutions, government agencies and private and public research institutions. Several of these entities have already successfully marketed and commercialized products that will compete with our drug candidates, assuming that our drug candidates gain regulatory approval. A large number of companies including Merck & Co., Inc., GlaxoSmithKline, Takeda Pharmaceuticals, Amylin Pharmaceuticals, Inc., AstraZeneca,

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Novartis, Novo Nordisk, Pfizer Inc., Sanofi-Aventis and Eli Lilly and Co. are developing and marketing new drugs for the treatment of type 2 diabetes. Similarly, a large number of companies, including Merck & Co., Inc., Pfizer Inc., Johnson & Johnson Inc. and Amgen Inc., are developing and marketing new drugs for the treatment of chronic inflammatory conditions. In addition, there are also a number of other companies with drug candidates in development targeting late-stage prostate cancer, including compounds already in Phase 3 clinical trials. One or more such compounds may be approved before any of our drug candidates could potentially be approved. Many, if not all, of these competing drug development programs are being conducted by pharmaceutical and biotechnology companies with considerably greater financial resources, human resources and experience than ours.

All of these competitors have greater financial and other resources, larger research and development staffs and more effective marketing and manufacturing organizations than we do. In addition, academic and government institutions have become increasingly aware of the commercial value of their research findings. These institutions are now more likely to enter into exclusive licensing agreements with commercial enterprises, including our competitors, to develop and market commercial products.

Our competitors may succeed in developing or licensing technologies and drugs that are more effective, or less costly than any we are developing. Our competitors may succeed in obtaining FDA or other regulatory approvals for drug candidates before we do. If competing drug candidates prove to be more effective or less costly or better-marketed than our drug candidates, our drug candidates, even if approved for sale, may not be able to compete successfully with our competitors existing products or new products under development. Similarly, we cannot predict whether any of our drug candidates, if approved, will have sufficient advantages to cause healthcare professionals to adopt our products over competing products. If we are unable to compete successfully, we may never be able to sell enough products at a price sufficient to permit us to generate profits.

Our common stock has a very limited trading market

Our common stock was recently delisted from the NASDAQ Stock Market and the OTCBB and now trades on the Pink Sheets. The Company s common stock was delisted from the NASDAQ Stock Market at the opening of business on September 23, 2010 at which time the common stock became available for trading on the OTCBB. On August 17, 2011, the Common Stock was delisted from the OTCBB when the Company filed a Form 15 pursuant to Rule 12g-4 and subsequently became available for trading on the Pink Sheets® under the trading symbol HRBR.PK. The Pink Sheets is not a stock exchange or a regulated entity. Price quotations are provided by over-the-counter market makers and company information is provided by the over-the-counter companies. The Pink Sheets provide significantly less liquidity than the NASDAQ stock market or any other national securities exchange. In addition, trading in our common stock has historically been extremely limited. Further, our common stock stock may be subject to manipulation because of the thinness of the market for our stock. This limited trading may adversely affect the liquidity of our common stock, not only in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and reduction in security analysts and the media s coverage of us. As a result, there could be a larger spread between the bid and the ask prices of our common stock and you may not be able to sell shares of our common stock when or at prices you desire.

Substantial sales of our stock may impact the market price of our common stock.

As evidenced by the completion of our registered direct offering completed in June 2010, future sales of substantial amounts of our common stock, including shares that we may issue upon exercise of options and warrants or conversion of convertible securities, could adversely affect the market price of our common stock. Further, if we raise additional funds through the issuance of common stock or securities convertible into or exercisable for common stock, the percentage ownership of our stockholders will be reduced and the price of our common stock may fall.

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Issuing preferred stock with rights senior to those of our common stock could adversely affect holders of common stock.

Our charter documents give our board of directors the authority to issue shares of preferred stock without a vote or action by our stockholders. The board also has the authority to determine the terms of preferred stock, including price, preferences and voting rights. The rights granted to holders of preferred stock may adversely affect the rights of holders of our common stock. For example, a series of preferred stock may be granted the right to receive a liquidation preference a pre-set distribution in the event of liquidation that would reduce the amount available for distribution to holders of common stock. In addition, the issuance of the Series A Preferred Stock makes it more difficult for a third party to acquire a majority of our outstanding voting stock. As a result, common stockholders could be prevented from participating in transactions that would offer an optimal price for their shares.

If we were to lose the services of members of our management team, or fail to attract or retain qualified personnel in the future, our business objectives would be more difficult to implement, adversely affecting our operations.

Our ability to successfully implement our business strategy depends upon the continued services of our management team. If we lose the services of one or more of these individuals, replacement could be difficult and may take an extended period of time and could impede significantly the achievement of our business objectives.

Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn.

Our results of operations could be materially negatively affected by economic conditions generally, both in the U.S. and elsewhere around the world. Continuing concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and a declining residential real estate market in the U.S. have contributed to increased volatility and diminished expectations for the economy and the markets going forward. These factors, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, precipitated an economic recession from which the global economy is in stages of recovery. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a market downturn, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary and our stock price may further decline.

Failure to protect our proprietary technology could impair our competitive position.

We own or have obtained a license to a number of U.S. and foreign patents and patent applications. Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to our ability to commercialize our drug candidates, if approved and our ability to operate our business without infringing the proprietary rights of third parties. We place considerable importance on obtaining patent protection for significant new technologies, products and processes. Legal standards relating to the validity of patents covering pharmaceutical and biotechnology inventions and the scope of claims made under such patents are still developing. In some of the countries in which we intend to market our drug candidates, if approved, pharmaceuticals are either not patentable or have only recently become patentable. Past enforcement of intellectual property rights in many of these countries has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries may be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions. Our domestic patent

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position is also highly uncertain and involves complex legal and factual questions. The applicant or inventors of subject matter covered by patent applications or patents owned by or licensed to us may not have been the first to invent or the first to file patent applications for such inventions. Due to uncertainties regarding patent law and the circumstances surrounding our patent applications, the pending or future patent applications we own or have licensed may not result in the issuance of any patents. Existing or future patents owned by or licensed to us may be challenged, infringed upon, invalidated, found to be unenforceable or circumvented by others. Further, any rights we may have under any issued patents may not provide us with sufficient protection against similar competitive products or technologies that do not infringe our patents or otherwise cover commercially valuable products or processes.

Litigation or other disputes regarding patents and other proprietary rights may be expensive, cause delays in bringing products to market and harm our ability to operate.

The manufacture, use or sale of our drug candidates may infringe on the patent rights of others. If we are unable to avoid infringement of the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming and can preclude, delay or suspend commercialization of our drug candidates. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, or fail to successfully defend an infringement action or have the patents we are alleged to infringe declared invalid, we may:

- incur substantial money damages;
- encounter significant delays in bringing our drug candidates to market;
- be precluded from participating in the manufacture, use or sale of our drug candidates or methods of treatment without first obtaining licenses to do so; and/or
- not be able to obtain any required license on favorable terms, if at all.

In addition, if another party claims the same subject matter or subject matter overlapping with the subject matter that we have claimed in a U.S. patent application or patent, we may decide or be required to participate in interference proceedings in the U.S. Patent and Trademark Office in order to determine the priority of invention. Loss of such an interference proceeding would deprive us of patent protection sought or previously obtained and could prevent us from commercializing our products. Participation in such proceedings could result in substantial costs, whether or not the eventual outcome is favorable. These additional costs could adversely affect our financial results.

Litigation may be expensive and time consuming and may adversely affect our operations.

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. Participation in such proceedings is time consuming and could result in substantial costs, whether or not the eventual outcome is favorable. These additional costs could adversely affect our financial results.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information.

In order to protect our proprietary technology and processes, we also rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

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Existing and/or future pricing regulations and reimbursement limitations may limit our potential profits from the sale of our products.

The requirements governing product licensing, pricing and reimbursement vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after product-licensing approval is granted. As a result, we may obtain regulatory approval for a drug candidate in a particular country, but then be subject to price regulations that reduce our profits from the sale of the product. In some foreign markets pricing of prescription pharmaceuticals is subject to continuing government control even after initial marketing approval. In addition, certain governments may grant third parties a license to manufacture our product without our permission. Such compulsory licenses may be on terms that are less favorable to us and would likely have the effect of reducing our revenues.

Varying price regulation between countries can lead to inconsistent prices and some re-selling by third parties of products from markets where products are sold at lower prices to markets where those products are sold at higher prices. Any practice of exploiting price differences between countries could undermine our sales in markets with higher prices and reduce the sales of our future products, if any.

While we do not have any applications for regulatory approval of our drug candidates currently pending, any decline in the size of the markets in which we may in the future sell commercial products, assuming our receipt of the requisite regulatory approvals, could cause the perceived market value of our business and the price of our common stock to decline.

Our ability to commercialize our drug candidates successfully also will depend in part on the extent to which reimbursement for the cost of our drug candidates and related treatments will be available from government health administration authorities, private health insurers and other organizations. Third-party payers are increasingly challenging the prices charged for medical products and services. If we succeed in bringing any of our drug candidates to the market, such drug candidates may not be considered cost effective and reimbursement may not be available or sufficient to allow us to sell such drug candidates on a profitable or competitive basis.

Delays in the conduct or completion of preclinical or clinical studies or the analysis of the data from preclinical or clinical studies may result in delays in our planned filings for regulatory approvals, or adversely affect our ability to enter into collaborative arrangements.

The current status of our two lead drug candidates is set forth below. We have completed:

Phase I and I/II clinical trials with Triolex in the United States under an IND, for the treatment of metabolic disorders;

Phase IIa clinical trial with Triolex in the United States in type 2 diabetes patients under an IND for the treatment of metabolic disorders;

Phase I/II clinical trial with Triolex in the United States under an IND for the treatment of gastrointestinal inflammatory conditions;

Phase I clinical trial with Triolex in the United States in rheumatoid arthritis patients under an IND for the treatment of inflammatory conditions; and

Phase I/IIa clinical trial with Apoptone in the United States in late-stage prostate cancer patients who have failed hormone therapy and at least one round of chemotherapy treatment or have not received chemotherapy under an IND for the treatment of hormone-sensitive cancers including prostate cancer.

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Any of the following reasons, among others, could delay or suspend the completion of our future studies:

- delays in enrolling volunteers;
- interruptions in the manufacturing of our drug candidates or other delays in the delivery of materials required for the conduct of our studies;
- we may not be able to enter collaborative arrangements besides the CIPI agreements;
- we can not control the uncertainties and lack direct control over the developments of our licensed compounds in China;
- lower than anticipated retention rate of volunteers in a clinical trial;
- unfavorable efficacy results;
- serious side effects experienced by study participants relating to the drug candidate;
- reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;
- failure to conduct a clinical trial in accordance with regulatory requirements or clinical protocols;
- inspection of a clinical trial operations or clinical trial site by regulatory authorities resulting in the imposition of a clinical hold;
- new communications from regulatory agencies about how to conduct these studies; or
- failure to raise additional funds resulting in lack of adequate funding to continue a clinical trial or study.

If the manufacturers of our drug candidates do not comply with current Good Manufacturing Practices regulations, or cannot produce sufficient quantities of our drug candidates to enable us to continue our development, we will fall behind on our business objectives.

Manufacturers producing our drug candidates must follow current Good Manufacturing Practices regulations enforced by the FDA and foreign equivalents. If a manufacturer of our drug candidates does not conform to current Good Manufacturing Practices regulations and cannot be brought up to such a standard, we will be required to find alternative manufacturers that do conform. This may be a long and difficult process, and may delay our ability to receive FDA or foreign regulatory approval of our drug candidates.

We also rely on our manufacturers to supply us with a sufficient quantity of our drug candidates to conduct clinical trials. If we have difficulty in the future with obtaining our required quantity and quality of supply, we could experience significant delays in our development programs and regulatory process.

Our ability to achieve any significant revenue may depend on our ability to establish effective sales and marketing capabilities.

Our efforts to date have focused on the development and evaluation of our drug candidates. As we continue preclinical and clinical studies and seek to commercialize our drug candidates, we may need to build a sales and marketing infrastructure. As a company, we have no experience in the sales and marketing of pharmaceutical products. If we fail to establish a sufficient marketing and sales force or to make alternative arrangements to have our drug candidates marketed and sold by others on attractive terms, it will impair our ability to commercialize our drug candidates and to enter new or existing markets. Our inability to effectively enter these markets would materially and adversely affect our ability to generate significant revenues.

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We may face product liability claims related to the use or misuse of our drug candidates, which may cause us to incur significant losses.

We are currently exposed to the risk of product liability claims due to administration of our drug candidates in clinical trials, since the use or misuse of our drug candidates during a clinical trial could potentially result in injury or death. If we are able to commercialize our products, we will also be subject to the risk of losses in the future due to product liability claims in the event that the use or misuse of our commercial products results in injury or death. We currently maintain liability insurance on a claims-made basis. Because we cannot predict the magnitude or the number of claims that may be brought against us in the future, we do not know whether the insurance policies coverage limits are adequate. The insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms, or at all. Any claims against us, regardless of their merit, could substantially increase our costs and cause us to incur significant losses.

Our securities could be subject to extreme price fluctuations that could adversely affect your investment.

The market prices for securities of life sciences companies are highly volatile particularly those that are not profitable. Publicized events and announcements, most of which we cannot control, may have a significant impact on the market price of our common stock, which has been, and is likely to continue to be, volatile. For example:

- biological or medical discoveries by competitors;
- public concern about the safety of our drug candidates;
- delays in the conduct or analysis of our preclinical or clinical studies;
- unfavorable results from preclinical or clinical studies;
- delays in obtaining or failure to obtain purchase orders of our drug candidates;
- announcements in the scientific and research community;
- changes in the potential commercial markets for our drug candidates;
- unfavorable developments concerning patents or other proprietary rights;
- unfavorable domestic or foreign regulatory or governmental developments or actions;
- broader economic, industry and market trends unrelated to our performance;
- issuances of new equity securities by us, pursuant to our effective shelf registration statement or otherwise;
- discussion of us or our stock price by the financial and scientific press and in online investor communities; or

additions or departures of key personnel

may have the effect of temporarily or permanently driving down the price of our common stock. In addition, the stock market from time to time experiences extreme price and volume fluctuations which particularly affect the market prices for emerging and life sciences companies, such as ours, and which are often unrelated to the operating performance of the affected companies. For example, our stock price has ranged from $0.10 to $0.37 between July 1, 2010 and October 28, 2011.

These broad market fluctuations may adversely affect the ability of a stockholder to dispose of his shares at a price equal to or above the price at which the shares were purchased. In addition, in the past, following periods of volatility in the market price of a company s securities, securities class-action litigation has often been instituted against that company. Any litigation against the Company, including this type of litigation, could result in substantial costs and a diversion of management s attention and resources, which could materially adversely affect our business, financial condition and results of operations.

Item 1B. Unresolved Staff Comments

None.

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

We made no unregistered sales of securities or repurchases of our securities during the quarter ended September 30, 2011.

Item 3. Defaults Upon Senior Securities

None

Item 4. Reserved

Item 5. Other Information

None

Item 6. Exhibits

(a) The following exhibits are included as part of this report:

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Corporation (Reverse Stock Split)
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Corporation (Forward Stock Split)
31.1	Rule 13a-14(a)/15d-14(a) Certification of James M. Frincke.
31.2	Rule 13a-14(a)/15d-14(a) Certification of Robert W. Weber.
32.1	Section 1350 Certifications of James M. Frincke and Robert W. Weber.
101	The following financial statements and footnotes from the Harbor BioSciences Quarterly Report on Form 10-Q for the quarter ended September 30, 2011 formatted in eXtensible Business Reporting Language (XBRL): (i) Balance Sheets; (ii) Statement of Operations; (iii) Statement of Cash Flows; and (iv) Notes to financial Statements, tagged as blocks of text.

* Previously filed

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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.

HARBOR BIOSCIENCES, INC.

Dated: November 4, 2011

/s/ Robert W. Weber
Robert W. Weber
Chief Financial Officer and Secretary
(Principal Financial and Accounting Officer)