

EXACT SCIENCES CORP  
Form 10-Q  
November 02, 2012  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

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

For the quarterly period ended September 30, 2012

OR

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

Commission File Number: 000-32179

**EXACT SCIENCES CORPORATION**

(Exact name of registrant as specified in its charter)

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

**02-0478229**  
(I.R.S. Employer  
Identification Number)

**441 Charmany Drive, Madison WI**  
(Address of principal executive offices)

**53719**  
(Zip Code)

**(608) 284-5700** (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

Accelerated filer

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

Smaller reporting company

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

As of October 30, 2012, the registrant had 63,767,680 shares of common stock outstanding.

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EXACT SCIENCES CORPORATION

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Part I Financial Information

Table of Contents**EXACT SCIENCES CORPORATION****Condensed Balance Sheets****(Amounts in thousands, except share data - unaudited)**

	September 30, 2012	December 31, 2011
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 12,660	\$ 35,781
Marketable securities	105,912	57,580
Prepaid expenses and other current assets	1,252	1,034
Total current assets	119,824	94,395
Property and Equipment, at cost:		
Laboratory equipment	3,955	2,314
Office and computer equipment	825	729
Leasehold improvements	283	288
Furniture and fixtures	28	23
	5,091	3,354
Less Accumulated depreciation	(1,462)	(796)
	3,629	2,558
	\$ 123,453	\$ 96,953
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 1,030	\$ 765
Accrued expenses	4,084	3,069
Capital lease obligation, current portion	355	
Deferred license fees, current portion	4,143	4,143
Total current liabilities	9,612	7,977
Long-term debt	1,000	1,000
Long-term accrued interest	57	42
Capital lease obligation, less current portion	796	
Deferred license fees, less current portion	1,331	4,439
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, \$0.01 par value		
Authorized 5,000,000 shares		
Issued and outstanding no shares at September 30, 2012 and December 31, 2011		
Common stock, \$0.01 par value		
Authorized 100,000,000 shares		
Issued and outstanding 63,753,363 and 56,624,763 shares at September 30, 2012 and December 31, 2011	638	566
Additional paid-in capital	370,184	304,767
Other comprehensive income (loss)	92	(14)
Accumulated deficit	(260,257)	(221,824)
Total stockholders' equity	110,657	83,495
	\$ 123,453	\$ 96,953

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

Table of Contents**EXACT SCIENCES CORPORATION****Condensed Statements of Operations****(Amounts in thousands, except per share data - unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,					
	2012	2011	2012	2011				
<b>Revenue:</b>								
Product royalty fees	\$	\$	4	\$	14			
License fees		1,036	1,035	3,108	3,107			
		1,036	1,039	3,108	3,121			
<b>Cost of revenue:</b>								
Product royalty fees			6		18			
Gross profit		1,036	1,033	3,108	3,103			
<b>Operating expenses:</b>								
Research and development		10,491	6,110	31,692	14,296			
General and administrative		2,547	1,951	7,085	5,931			
Sales and marketing		1,006	815	2,931	1,763			
		14,044	8,876	41,708	21,990			
Loss from operations		(13,008)	(7,843)	(38,600)	(18,887)			
Investment income		67	75	188	131			
Interest expense		(11)	(5)	(21)	(15)			
Net loss	\$	(12,952)	\$	(7,773)	\$	(38,433)	\$	(18,771)
Net loss per share basic and diluted	\$	(0.21)	\$	(0.15)	\$	(0.66)	\$	(0.36)
Weighted average common shares outstanding basic and diluted		60,531	52,443	58,104	52,129			

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

Table of Contents**EXACT SCIENCES CORPORATION****Condensed Statements of Comprehensive Loss**

(Amounts in thousands - unaudited)

	Three Months September 30,		Nine Months September 30,	
	2012	2011	2012	2011
Net loss	\$ (12,952)	\$ (7,773)	\$ (38,433)	\$ (18,771)
Other comprehensive income (loss), net of tax:				
Unrealized gain (loss) on securities:				
Unrealized holding gain (loss) on marketable securities	39	(38)	106	(51)
Comprehensive loss	\$ (12,913)	\$ (7,811)	\$ (38,327)	\$ (18,822)

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



Table of Contents**EXACT SCIENCES CORPORATION****Condensed Statements of Cash Flows****(Amounts in thousands, except share data - unaudited)**

	<b>Nine Months Ended September 30,</b>	
	<b>2012</b>	<b>2011</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (38,433)	\$ (18,771)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	666	262
Stock-based compensation	4,024	2,707
Amortization of deferred license fees	(3,108)	(3,107)
Warrant licensing expense	152	80
Restricted stock licensing expense	1,000	
Amortization of premium on short-term investments	359	250
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(218)	(621)
Accounts payable	265	(51)
Accrued expenses	1,483	596
Accrued interest	15	15
Net cash used in operating activities	(33,795)	(18,640)
<b>Cash flows from investing activities:</b>		
Purchases of marketable securities	(90,408)	(71,202)
Maturities of marketable securities	41,823	17,128
Purchases of property and equipment	(586)	(1,599)
Net cash used in investing activities	(49,171)	(55,673)
<b>Cash flows from financing activities:</b>		
Proceeds from exercise of common stock options and stock purchase plan	2,090	556
Proceeds from sale of common stock, net of issuance costs	57,755	
Net cash provided by financing activities	59,845	556
Net decrease in cash and cash equivalents	(23,121)	(73,757)
Cash and cash equivalents, beginning of period	35,781	78,752
Cash and cash equivalents, end of period	\$ 12,660	\$ 4,995
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Unrealized gain (loss) on available-for-sale investments	\$ 106	\$ (51)
Issuance of 32,872 and 27,872 shares of common stock to fund the Company's 401(k) matching contribution for 2011 and 2010, respectively	\$ 274	\$ 169
Conversion of accrued expenses into 34,336 and 27,110 shares of common stock in connection with the Company's Employee Stock Purchase Plan for 2012 and 2011, respectively	\$ 194	\$ 148
Laboratory equipment acquired with a capital lease	\$ 1,151	\$

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



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**EXACT SCIENCES CORPORATION**

**Notes to Condensed Financial Statements**

**(Unaudited)**

**(1) ORGANIZATION AND BASIS OF PRESENTATION**

**Organization**

Exact Sciences Corporation ( Exact, we, us or the Company ) was incorporated in February 1995. Exact is a molecular diagnostics company focused on the early detection and prevention of colorectal cancer. The Company's non-invasive stool-based DNA (sDNA) screening technology includes proprietary and patented methods that isolate and analyze human DNA present in stool to screen for the presence of colorectal pre-cancer and cancer.

**Basis of Presentation**

The accompanying condensed financial statements of the Company are unaudited and have been prepared on a basis substantially consistent with the Company's audited financial statements and notes as of and for the year ended December 31, 2011 included in the Company's Annual Report on Form 10-K (the 2011 Form 10-K ). These condensed financial statements are prepared in conformity with accounting principles generally accepted in the United States of America ( GAAP ) and follow the requirements of the Securities and Exchange Commission ( SEC ) for interim reporting. In the opinion of management, all adjustments (consisting only of adjustments of a normal and recurring nature) considered necessary for a fair presentation of the results of operations have been included. The results of the Company's operations for any interim period are not necessarily indicative of the results of the Company's operations for any other interim period or for a full fiscal year. The statements should be read in conjunction with the audited financial statements and related notes included in the 2011 Form 10-K. Management has evaluated subsequent events for disclosure or recognition in the accompanying financial statements up to the filing of this report.

**(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Use of Estimates**

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and 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. Actual results could differ from those estimates.

### **Cash and Cash Equivalents**

The Company considers cash on hand, demand deposits in bank, money market funds, and all highly liquid investments with an original maturity of 90 days or less to be cash and cash equivalents.

### **Marketable Securities**

Management determines the appropriate classification of debt securities at the time of purchase and re-evaluates such designation as of each balance sheet date. Debt securities carried at amortized cost are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Marketable equity securities and debt securities not classified as held-to-maturity are classified as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses, net of tax, reported in other comprehensive income. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity computed under the straight-line method. Such amortization is included in investment income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in investment income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in investment income.

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At September 30, 2012 and December 31, 2011, the Company's investments were comprised of fixed income investments and all were deemed available-for-sale. The objectives of the Company's investment strategy are to provide liquidity and safety of principal while striving to achieve the highest rate of return consistent with these two objectives. The Company's investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer. All of the Company's investments are considered current. There were no realized losses for the nine months ended September 30, 2012. Realized losses for the nine months ended September 30, 2011 were \$477. Realized gains for the nine months ended September 30, 2012 were \$4,168. There were no realized gains for the nine months ended September 30, 2011. Unrealized gains or losses on investments are recorded in other comprehensive income.

Available-for-sale securities at September 30, 2012 consist of the following:

(In thousands)	Amortized Cost	September 30, 2012		Estimated Fair Value
		Gains in Accumulated Other Comprehensive Income	Losses in Accumulated Other Comprehensive Income	
U.S. government agency securities	\$ 43,414	\$ 33	\$	\$ 43,447
Corporate bonds	51,630	41		51,671
Certificates of deposit	9,179	18		9,197
Commercial paper	1,597			1,597
Total available-for-sale securities	\$ 105,820	\$ 92	\$	\$ 105,912

Available-for-sale securities at December 31, 2011 consist of the following:

(In thousands)	Amortized Cost	December 31, 2011		Estimated Fair Value
		Gains in Accumulated Other Comprehensive Income	Losses in Accumulated Other Comprehensive Income	
U.S. government agency securities	\$ 28,004	\$	\$ (10)	\$ 27,994
Corporate bonds	19,124		(2)	19,122
Certificates of deposit	9,467		(2)	9,465
Commercial paper	999			999
Total available-for-sale securities	\$ 57,594	\$	\$ (14)	\$ 57,580

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Basic net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted average common shares outstanding during the period. Basic and diluted net loss per share are the same because all outstanding common stock equivalents have been excluded, as they are anti-dilutive due to the Company's losses.

The following potentially issuable common shares were not included in the computation of diluted net loss per share because they would have an anti-dilutive effect due to net losses for each period:

(In thousands)	2012	September 30, 2011
Shares issuable upon exercise of stock options	6,282	6,678
Shares issuable upon exercise of outstanding warrants (1)	325	325
Shares of restricted stock awards outstanding	945	504
Shares issuable upon the vesting of restricted stock awards related to a licensing agreement	73	
	7,625	7,507

(1) At September 30, 2012 and September 30, 2011, represents warrants to purchase 250,000 shares of common stock issued under a licensing agreement and warrants to purchase 75,000 shares of common stock issued under a consulting agreement.

**Revenue Recognition**

**License fees.** License fees for the licensing of product rights are recorded as deferred revenue upon receipt of cash and recognized as revenue on a straight-line basis over the license period. As more fully described in the 2011 Form 10-K, in connection with our January 2009 strategic transaction with Genzyme Corporation, Genzyme agreed to pay us a total of \$18.5 million, of which \$16.65 million was paid on January 27, 2009 and \$1.85 million was subject to a holdback by Genzyme to satisfy certain potential indemnification obligations in exchange for the assignment and licensing of certain intellectual property to Genzyme. The Company's on-going performance obligations to Genzyme under the Collaboration, License and Purchase Agreement (the "CLP Agreement"), as described below, including its obligation to deliver through licenses certain intellectual property improvements to Genzyme, if improvements are made during the initial five-year collaboration period, were deemed to be undelivered elements of the CLP Agreement on the date of closing. Accordingly, the Company deferred the initial \$16.65 million in cash received at closing and is amortizing that up-front payment on a straight-line basis into revenue over the initial five-year collaboration period ending in January 2014. The Company received the first holdback amount of \$962,000, which included accrued interest due, from Genzyme during the first quarter of 2010. The Company received the second holdback amount of \$934,250, which included accrued interest due, from Genzyme during the third quarter of 2010. The amounts were deferred and are being amortized on a straight-line basis into revenue over the remaining term of the collaboration at the time of receipt.

In addition, Genzyme purchased 3,000,000 shares of common stock on January 27, 2009 for \$2.00 per share, representing a premium of \$0.51 per share above the closing price of the Company's common stock on that date of \$1.49 per share. The aggregate premium paid by Genzyme over the closing price of the Company's common stock on the date of the transaction of \$1.53 million is deemed to be a part of the total consideration

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for the CLP Agreement. Accordingly, the Company deferred the aggregate \$1.53 million premium and is amortizing that amount on a straight-line basis into revenue over the initial five-year collaboration period ending in January 2014.

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The Company recognized approximately \$1.0 million in license fee revenue in connection with the amortization of the up-front payments from Genzyme, during each of the three months ended September 30, 2012 and September 30, 2011. The Company recognized approximately \$3.1 million in license fee revenue in connection with the amortization of up-front payments from Genzyme during each of the nine months ended September 30, 2012 and September 30, 2011.

**Reclassifications**

Certain prior year amounts have been reclassified to conform to the current year presentation.

**(3) MAYO LICENSE AGREEMENT**

**Overview**

On June 11, 2009, the Company entered into a license agreement (the License Agreement ) with MAYO Foundation for Medical Education and Research ( MAYO ). Under the License Agreement, MAYO granted the Company an exclusive, worldwide license within the field (the Field ) of stool or blood based cancer diagnostics and screening (excluding a specified proteomic target) with regard to certain MAYO patents, and a non-exclusive worldwide license within the Field with regard to certain MAYO know-how. The licensed patents cover advances in sample processing, analytical testing and data analysis associated with non-invasive, stool-based DNA screening for colorectal cancer. Under the License Agreement, the Company assumes the obligation and expense of prosecuting and maintaining the licensed patents and is obligated to make commercially reasonable efforts to bring products covered by the license to market. Pursuant to the License Agreement, the Company granted MAYO two common stock purchase warrants with an exercise price of \$1.90 per share covering 1,000,000 and 250,000 shares of common stock, respectively. The Company is also required to make payments to MAYO for up-front fees, fees once certain milestones are reached by the Company, and other payments as outlined in the License Agreement. In addition to the license to intellectual property owned by MAYO, the Company receives product development and research and development efforts from MAYO personnel. The Company determined that the payments made for intellectual property should not be capitalized as the future economic benefit derived from the transactions is uncertain. The Company is also obligated to make royalty payments to MAYO on potential future net sales of any products developed from the licensed technology.

**Warrants**

The warrants granted to MAYO were valued based on a Black-Scholes pricing model at the date of the grant. The warrants were granted with an exercise price of \$1.90 per share of common stock. The grant to purchase 1,000,000 shares was immediately exercisable and the grant to purchase 250,000 shares vests and becomes exercisable over a four year period.

In March of 2010, MAYO partially exercised its warrant covering 1,000,000 shares by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 200,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its rights with respect to 86,596 shares leaving it with a net amount of 113,404 shares.



In September of 2010, MAYO partially exercised this warrant by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 300,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its rights with respect to 97,853 shares leaving it with a net amount of 202,147 shares.

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In June of 2011, MAYO partially exercised this warrant by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 250,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its rights with respect to 60,246 shares leaving it with a net amount of 189,754 shares.

In September of 2011, MAYO partially exercised this warrant by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 250,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its right with respect to 56,641 shares leaving it with a net amount of 193,359 shares. Following this exercise, the warrant covering 1,000,000 shares was fully exercised.

**Royalty Payments**

The Company is required to make royalty payments to MAYO based on a percentage of net sales of products developed from the licensed technology. Minimum royalty payments are \$10,000 in 2012 and \$25,000 per year thereafter through 2029, the year the last patent expires.

**Other Payments**

Other payments under the MAYO agreement include an upfront payment of \$80,000, a milestone payment of \$250,000 on the commencement of patient enrollment in FDA trials for the Company's Cologuard pre-cancer and cancer screening test, and a \$500,000 payment upon FDA approval of the Company's Cologuard test. The upfront payment of \$80,000 was made in the third quarter of 2009 and expensed to research and development in the second quarter of 2009. The Company began enrollment in its FDA trial in June of 2011 and the milestone payment of \$250,000 was made in June of 2011 and expensed to research and development in the second quarter of 2011. It is uncertain as to when the FDA will approve the Company's pre-cancer and cancer screening test. Therefore, the \$500,000 milestone payment has not been recorded as a liability. The Company periodically evaluates the status of the FDA trial.

In addition, the Company is making payments to MAYO for research and development efforts. During the three and nine months ended September 2012, the Company made payments of \$0.3 million and \$0.6 million, respectively. At September 30, 2012 the Company recorded an estimated liability in the amount of \$0.2 million for research and development efforts. During the three and nine months ended September 2011, the Company made payments of \$0.3 million and \$1.0 million and at September 30, 2011 the Company recorded an estimated liability in the amount of \$0.3 million for research and development efforts.

**May 2012 Amendment**

In May 2012 the Company expanded its relationship with MAYO through an amendment to the License Agreement. As part of the amendment, the Company's license was expanded to include all gastrointestinal cancers and diseases, and new cancer screening applications of stool- and blood-based testing. As consideration, the Company granted MAYO 97,466 shares of restricted stock, one quarter of which vested immediately, with the remainder to vest in three equal annual installments. The Company recognized \$1.0 million in licensing expense during the nine months ended September 30, 2012 in connection with the restricted stock grant.

As part of the amendment, the Company is required to make additional restricted stock grants to MAYO as certain milestones are met with respect to the commercial launch of the Company's second and third licensed products. Additionally, the Company will make milestone payments once certain sales levels are reached on the second and third licensed products. It is uncertain as to when these milestones will be met; therefore, the milestone payments have not been recorded as liabilities. The Company periodically evaluates the status of the milestone payments.

#### **(4) STOCK-BASED COMPENSATION**

##### **Stock-Based Compensation Plans**

The Company maintains the 2010 Omnibus Long-Term Incentive Plan, the 2010 Employee Stock Purchase Plan, the 2000 Stock Option and Incentive Plan and the 2000 Employee Stock Purchase Plan (collectively, the "Stock Plans").

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**Stock-Based Compensation Expense**

The Company recorded \$1.5 million and \$4.0 million in stock-based compensation expense during the three and nine months ended September 30, 2012 in connection with the amortization of restricted stock and restricted stock unit awards, stock purchase rights granted under the Company's employee stock purchase plan and stock options granted to employees, non-employee consultants and non-employee directors. The Company recorded \$1.2 million and \$2.7 million in stock-based compensation expense during the three and nine months ended September 30, 2011 in connection with the amortization of restricted stock and restricted stock unit awards, stock purchase rights granted under the Company's employee stock purchase plan and stock options granted to employees and non-employee directors.

The estimated fair value of stock options and restricted stock and restricted stock unit awards is recognized to expense using the straight-line method over the vesting period.

**Determining Fair Value**

**Valuation and Recognition** - The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model based on the assumptions in the table below.

**Expected Term** - The Company uses the simplified calculation of expected life, described in the SEC's Staff Accounting Bulletins 107 and 110, as the Company does not currently have sufficient historical exercise data on which to base an estimate of expected life. Using this method, the expected life is determined using the average of the vesting period and the contractual life of the stock options granted.

**Expected Volatility** - Expected volatility is based on the Company's historical stock volatility data over the expected term of the awards.

**Risk-Free Interest Rate** - The Company bases the risk-free interest rate on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent expected term.

**Forfeitures** - The Company records stock-based compensation expense only for those awards that are expected to vest. A forfeiture rate is estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from initial estimates.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
<b>Option Plan Shares</b>				
Risk-free interest rates	0.81% - 0.89%	1.12% - 1.52%	0.81% - 0.89%	1.12% - 2.3%

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Expected term (in years)	6	6	6	6
Expected volatility	86%	91% - 92%	86% - 92%	91% - 92%
Dividend yield				