SUPERNUS PHARMACEUTICALS INC
Form 10-Q
November 02, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 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, 2012

OR

o 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: 0-50440

SUPERNUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-2590184**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1550 East Gude Drive, Rockville, MD	**20850**
(Address of principal executive offices)	(Zip Code)

(301) 838-2500

(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. x Yes o No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, 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). x Yes o 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 large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

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

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

The number of outstanding shares of the registrant s common stock, par value $0.001 per share, as of the close of business on October 31, 2012 was 24,530,358.

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SUPERNUS PHARMACEUTICALS, INC.

FORM 10-Q QUARTERLY REPORT

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2012

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

Supernus Pharmaceuticals, Inc.

Consolidated Balance Sheet

(in thousands, except share amounts)

	December 31, 2011	September 30, 2012 (unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$ 48,544	$ 23,412
Marketable securities		37,256
Marketable securities - restricted	245	275
Accounts Receivable	128	500
Inventory		26
Prepaid expenses and other	338	1,276
Deferred financing costs, current	144	144
Total current assets	49,399	62,889
Property and equipment, net	1,310	1,384
Purchased patents, net	912	740
Long Term Investments		1,804
Other assets	55	55
Deferred financing costs, long-term	2,054	142
Total assets	$ 53,730	$ 67,014
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 10,078	$ 10,485
Accrued compensation	1,547	1,801
Deferred revenue	232	576
Interest payable	138	238
Secured notes payable, net	6,775	11,490
Total current liabilities	18,770	24,590
Deferred revenue, net of current portion	465	381
Secured notes payable, net of current portion and discount	22,711	14,116
Other non-current liabilities	1,399	1,558
Supplemental executive retirement plan	245	275
Warrant liability	697	1,463
Total liabilities	44,287	42,383
Stockholders equity:		

Series A convertible preferred stock, $0.001 par value - 49,625,000 shares and 65,000,000 shares authorized at December 31, 2011 and September 30, 2012, respectively; 49,000,000 shares issued and outstanding at December 31, 2011 and zero shares issued and outstanding as of September 30, 2012, respectively; aggregate liquidation preference of $69,520 and zero at December 31, 2011 and September 30, 2012, respectively		49		
Common stock, $0.001 par value - 62,625,000 shares and 130,000,000 shares authorized at December 31, 2011 and September 30, 2012, respectively; 1,662,321 and 24,466,049 shares issued and outstanding at December 31, 2011 and September 30, 2012, respectively		2		24
Additional paid-in capital		49,362		97,378
Accumulated other comprehensive income		1		(29)
Accumulated deficit		(39,971)		(72,742)
Total stockholders equity		9,443		24,631
Total liabilities and stockholders equity	$	53,730	$	67,014

See accompanying notes.

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Supernus Pharmaceuticals, Inc.

Consolidated Statements of Operations

(in thousands, except share and per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2011	2012	2011	2012
	(unaudited)		(unaudited)	
Revenues	$ 11	$ 91	$ 761	$ 391
Costs and Expenses				
Research and development	8,425	8,306	23,126	18,367
Selling, general and administrative	1,501	4,075	5,143	11,450
Total costs and expenses	9,926	12,381	28,269	29,817
Operating loss from continuing operations	(9,915)	(12,290)	(27,508)	(29,426)
Other income (expense):				
Interest income	3	39	29	91
Interest expense	(499)	(880)	(1,357)	(2,771)
Other income (expense)	260	(351)	30	(665)
Total other income (expense)	(236)	(1,192)	(1,298)	(3,345)
Loss from continuing operations	(10,151)	(13,482)	(28,806)	(32,771)
Discontinued operations:				
Income from discontinued operations	417		646	
Net loss	$ (9,734)	$ (13,482)	$ (28,160)	$ (32,771)
Cumulative dividends on Series A convertible preferred stock	$ (858)	$	$ (2,573)	$ (1,143)
Net loss attributable to common stockholders	$ (10,592)	$ (13,482)	$ (30,733)	$ (33,914)
Loss per common share:				
Basic and Diluted				
Continuing operations	$ (6.90)	$ (0.55)	$ (19.68)	$ (2.36)
Discontinued operations	0.26		0.40	
Net loss	(6.64)	(0.55)	(19.28)	(2.36)
Weighted-average number of common shares:				
Basic and Diluted	1,595,821	24,464,281	1,594,288	14,356,546

See accompanying notes.

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Supernus Pharmaceuticals, Inc.

Consolidated Statements of Comprehensive Loss

(in thousands)

	Three months ended September 30,		Nine months ended September 30,	
	2011	2012	2011	2012
	(unaudited)		(unaudited)	
Comprehensive loss:				
Net Loss	$ (9,734)	$ (13,482)	$ (28,160)	$ (32,771)
Unrealized (losses) gains on marketable securities	(1)	(35)	2	(29)
Total comprehensive loss	$ (9,735)	$ (13,517)	$ (28,158)	$ (32,800)

See accompanying notes.

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Supernus Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Nine Months Ended September 30,	
	2011	2012
	(unaudited)	
Cash flows from operating activities		
Net loss	$ (28,160)	$ (32,771)
Income from discontinued operations	(646)	
Loss from continuing operations	(28,806)	(32,771)
Adjustments to reconcile loss from continuing operations to net cash used in operating activities:		
Gain on sale of property and equipment	(25)	
Change in fair value of warrant liability	(10)	766
Unrealized loss (gain) on marketable securities	1	(29)
Depreciation and amortization	651	650
Amortization of deferred financing costs	159	248
Stock-based compensation expense	(44)	235
Changes in operating assets and liabilities:		
Accounts Receivable	(516)	(372)
Inventory		(26)
Prepaid expenses and other assets	(137)	(938)
Accounts payable and accrued expenses	(2,471)	660
Interest payable	138	101
Deferred revenue	439	259
Other non-current liabilities	553	158
Net cash used in operating activities from continuing operations	(30,068)	(31,059)
Net cash provided by operating activities from discontinued operations	2,141	
Net cash used in operating activities	(27,927)	(31,059)
Cash flows from investing activities		
Purchases of marketable securities	(17,890)	(56,476)
Sales and maturities of marketable securities	26,855	17,416
Purchases of property and equipment, net	(494)	(553)
Net cash provided by (used in) investing activities from continuing operations	8,471	(39,613)
Net cash provided by investing activities from discontinued operations		
Net cash provided by (used in) investing activities	8,471	(39,613)
Cash flows from financing activities		
Proceeds from issuance of common stock, net of underwriters discounts	1	52,447
Proceeds from issuance of (payments on) secured notes payable	15,000	(4,019)
Financing costs	(705)	(2,888)
Net cash provided by financing activities from continuing operations	14,296	45,540
Net cash used in financing activities from discontinued operations	(2,096)	
Net cash provided by financing activities	12,200	45,540
Net change in cash and cash equivalents	(7,256)	(25,132)
Cash and cash equivalents at beginning of period	23,740	48,544
Cash and cash equivalents at end of period	$ 16,484	$ 23,412

Supplemental cash flow information:				
Cash paid for interest-Continuing operations	$	990	$	2,257
Cash paid for interest-Discontinued operations	$	9,044	$	
Noncash conversion of preferred stock to common stock	$		$	49

See accompanying notes.

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Supernus Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements

For the Three and Nine Months Ended September 30, 2011 and 2012
(unaudited)

1. Organization and Business

Supernus Pharmaceuticals, Inc. (the Company) is a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system diseases, including neurological and psychiatric disorders. The Company has two proprietary products and several proprietary product candidates in clinical development that address large market opportunities in epilepsy and attention deficit hyperactivity disorder. Trokendi XR™ (formerly known as SPN-538) received tentative approval from the Food and Drug Administration (the FDA) on June 25, 2012, and Oxtellar XR™ was approved by the FDA on October 19, 2012 (See footnote 8).

2. Management s Plans as to Continuing as a Going Concern

The accompanying financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Since inception, the Company has incurred, and continues to incur, significant losses from operations.

The Company s current operating assumptions, which reflect management s best estimate of future revenue and operating expenses, indicate that current cash on hand, including the proceeds received from the sale of common stock in May 2012, should be sufficient to fund operations as currently planned into the second quarter of 2013. As a result, the Company envisions that it will need to raise additional capital prior to this time so as to be able to continue its business operations as currently conducted and fund deficits in operating cash flows.

Although the Company intends to raise additional capital, there can be no assurance that any financing will be available to the Company at any given time or available on favorable terms. The type, timing and terms of financing selected by the Company will be dependent upon the Company s cash needs, the availability of financing sources and the prevailing conditions in the financial markets.

3. Summary of Significant Accounting Policies

Basis of Presentation

The Company s consolidated financial statements include the accounts of Supernus Pharmaceuticals, Inc. and Supernus Europe Ltd., and include the accounts of its wholly-owned subsidiary, TCD Royalty Sub, LLC (TCD) through December 14, 2011, the date that the Company sold all of its equity interests in TCD. The assets, liabilities, and results of operations related to TCD are presented as discontinued operations for all periods in the accompanying consolidated financial statements. These companies are collectively referred to herein as Supernus or the Company. All intercompany transactions and balances have been eliminated in consolidation.

The Company s consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States (U.S. GAAP) for interim financial information. In the opinion of management, the consolidated financial statements reflect all adjustments necessary to fairly present the Company s financial position, results of operations and cash flows for the periods presented. These adjustments are of a normal recurring nature.

Certain notes and other information have been omitted from the interim consolidated financial statements presented in this Quarterly Report on Form 10-Q. Therefore, these financial statements should be read in conjunction with the Company s financial statements for the year ended December 31, 2011 filed as part of the Company s Registration Statement on Form S-1/A (File No. 333-171375) (the Registration Statement).

The results of operations for the three and nine months ended September 30, 2012 are not necessarily indicative of the Company s future financial results.

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Use of Estimates

The preparation of the financial statements in accordance with U.S. GAAP requires the Company to make estimates and judgments in certain circumstances that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. In preparing these consolidated financial statements, management has made its best estimates and judgments of certain amounts included in the financial statements, giving due consideration to materiality. On an ongoing basis, the Company evaluates its estimates, including those related to revenue recognition, fair value of assets and common stock, income taxes, preclinical study and clinical trial accruals and other contingencies. Management bases its estimates on historical experience or on various other assumptions, including information received from its service providers, which it believes to be reasonable under the circumstances. Actual results could differ from these estimates.

Cash and Cash Equivalents

The Company considers all investments in highly liquid financial instruments with an original maturity of three months or less to be cash equivalents.

Marketable Securities

Marketable securities consist of investments in U.S. Treasuries, various U.S. governmental agency debt securities, corporate bonds and other fixed income securities. Management classifies the Company s investments, both short-term and long-term, as available-for-sale. Long-term investments are those which have maturity dates greater than twelve months after the balance sheet date. Such securities are carried at estimated fair value, with any unrealized holding gains or losses reported, net of any tax effects reported, as accumulated other comprehensive income, which is a separate component of stockholders equity. Realized gains and losses, and declines in value judged to be other-than-temporary, if any, are included in consolidated results of operations. A decline in the market value of any available-for-sale security below cost that is deemed to be other-than-temporary results in a reduction in fair value, which is charged to earnings in that period, and a new cost basis for the security is established. Dividend and interest income is recognized as interest income when earned. The cost of securities sold is calculated using the specific identification method. The Company places all investments with highly rated financial institutions.

Marketable Securities Restricted

The Company has established the Supernus Supplemental Executive Retirement Plan (SERP) for the sole purpose of receiving funds for two executives from a previous SERP and providing a continuing deferral program under the Supernus SERP. As of December 31, 2011 and September 30, 2012, the estimated fair value of the mutual fund investment securities within the SERP of approximately $245,000 and $275,000 respectively, has been recorded as restricted marketable securities. A corresponding noncurrent liability is also included in the consolidated balance sheets to reflect the Company s obligation for the SERP. The Company has not made, and has no plans to make, contributions to the SERP. The securities can only be used for purposes of paying benefits under the SERP.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and marketable securities. The counterparties are various corporations and financial institutions of high credit standing.

Substantially all of the Company s cash and cash equivalents are maintained with well known, U.S. and Non U.S. financial institutions and corporations. Deposits held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, management believes they bear minimal risk. The Company has not experienced any other than temporary losses on its deposits of cash, cash equivalents, short-term investments and restricted investments.

Fair Value of Financial Instruments

The carrying amounts of financial instruments, including cash and cash equivalents, accounts receivable, and accounts payable and accrued expenses, approximate fair value due to their short-term maturities.

The fair value of an asset or liability should represent the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. Such transactions to sell an asset or transfer a liability are assumed to occur in the principal or most advantageous market for the asset or liability. Accordingly, fair value is determined based on a

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hypothetical transaction at the measurement date, considered from the perspective of a market participant rather than from a reporting entity s perspective.

The Company reports assets and liabilities that are measured at fair value using a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

• Level 1 Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

• Level 2 Inputs are quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (interest rates, yield curves, etc.) and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).

• Level 3 Unobservable inputs that reflect the Company s own assumptions, based on the best information available, including the Company s own data.

In accordance with the fair value hierarchy described above, the following tables show the fair value of the Company s financial assets and liabilities that are required to be measured at fair value (in thousands):

	Total Carrying Value at December 31, 2011	Fair Value Measurements at December 31, 2011 Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$ 48,544	$ 48,544	$	$
Marketable securities- restricted	245		245	
Total assets at fair value	$ 48,789	$ 48,544	$ 245	$
Liabilities:				
Warrant liability	$ 697	$	$	$ 697

	Total Carrying Value at September 30, 2012	Fair Value Measurements at September 30, 2012 (unaudited) Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)

Assets:								
Cash and cash equivalents	$	23,412	$	23,412	$		$	
Marketable securities		37,256				37,256		
Marketable securities- restricted		275				275		
Long Term Investments		1,804				1,804		
Total assets at fair value	$	62,747	$	23,412	$	39,335	$	
Liabilities:								
Warrant liability	$	1,463	$		$		$	1,463

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The Company s Level 1 assets include money market funds, and U.S. Treasuries and government agency debt securities with quoted prices in active markets. At December 31, 2011, Level 2 assets include mutual funds in which the SERP assets are invested. At September 30, 2012 such assets include mutual funds in which the SERP assets are invested, commercial paper and corporate bonds and other fixed income securities. Level 2 securities are valued using third-party pricing sources that apply applicable inputs and other relevant data into their models to estimate fair value.

Level 3 liabilities include the fair market value of outstanding warrants to purchase Common Stock recorded as a derivative liability. Prior to the IPO on May 1, 2012, these warrants provided the right to purchase Series A Preferred Stock that were converted to the right to purchase common stock upon the completion of the IPO. At December 31 , 2011, the fair value of the preferred stock warrant liability was calculated using a probability-weighted expected return model (PWERM). At September 30, 2012 the fair value of the common stock warrant liability was calculated using a Monte-Carlo simulation on a Black-Scholes lattice model with the following assumptions:

Exercise Price	$4 - $5 per share
Volatility	80%
Stock Price as of September 30, 2012	$11.55 per share
Term	8.3 - 9.3 years
Dividend Yield	0.0%
Risk-Free Rate	1.4% - 1.5%

Significant changes to these assumptions would result in increases/decreases to the fair value of the outstanding warrants.

Changes in the fair value of the warrants are recognized in Other Income (Expense) on the Consolidated Statement of Operations. The following table presents information about the Company s common stock warrant liability as of September 30, 2012:

		Nine Months Ended September 30, 2012 (in thousands) (unaudited)
Balance at December 31, 2011	$	697
Changes in fair value of warrants included in other income (expense)		766
Balance at September 30, 2012	$	1,463

Inventory

Inventories, which are recorded at the lower of cost or market, include materials, labor and other direct and indirect costs and are valued using the first-in, first-out method. The Company capitalizes inventories produced in preparation for commercial launches when the related product candidates are considered likely to receive regulatory approval and it is probable that the related costs will be recoverable through the commercial sale of the product.

Property and Equipment

Property and equipment is stated at cost. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to operations. Repairs and maintenance costs are expensed as incurred. Depreciation and amortization are computed using the straight-line method over the following average useful lives.

Computer equipment	3 years
Software	3 years
Lab and office equipment	5 years
Furniture	7 years
Leasehold Improvements	Shorter of lease term or useful life
Manufacturing equipment	5 - 10 years

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Intangible Assets

Intangible assets consist primarily of purchased patents. Patents are carried at cost less accumulated amortization, which is calculated on a straight-line basis over the estimated useful lives of the patents, generally estimated to be ten years. The carrying value of the patents is assessed for impairment annually during the fourth quarter of each year, or more frequently if impairment indicators exist.

Deferred Financing Costs

Deferred financing costs consist of financing syndication costs incurred by the Company in connection with the closing of the Company s notes payable as well as legal, accounting and other costs incurred in connection with preparing for the Company s IPO. The Company amortizes the deferred financing costs associated with its notes payable over the term of the related debt (i.e. 3.5-4.0 years) using the effective interest method. On May 1, 2012, concurrent with the closing of the IPO, the Company reclassified all previously deferred financing costs related to the IPO as a charge against the proceeds received.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of purchased patents and property and equipment. The Company assesses the recoverability of its long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If indications of impairment exist, projected future undiscounted cash flows associated with the asset are compared to the carrying amount to determine whether the asset s value is recoverable. Evaluating for impairment requires judgment, including the estimation of future cash flows, future growth rates and profitability and the expected life over which cash flows will occur. Changes in the Company s business strategy or adverse changes in market conditions could impact impairment analyses and require the recognition of an impairment charge equal to the excess of the carrying value of the long-lived assets over its estimated fair value.

Preclinical Study and Clinical Trial Accruals and Deferred Advance Payments

The Company estimates preclinical study and clinical trial expenses based on the services performed pursuant to contracts with research institutions, investigators, and clinical research organizations that conduct these activities on its behalf. In recording service fees, the Company estimates the time period over which the related services will be performed and compares the level of effort expended through the end of each period to the cumulative expenses recorded and payments made for such services and, as appropriate, accrues additional service fees or defers any non-refundable advance payments until the related services are performed. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust its accrual or deferred advance payment accordingly. If the Company later determines that it no longer expects the services associated with a nonrefundable advance payment to be rendered, the advance payment will be charged to expense in the period that such determination is made.

Income Taxes

The Company utilizes the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company accounts for uncertain tax positions in its consolidated financial statements when it is more-likely-than-not that the position will be sustained upon examination by the tax authorities. Such tax positions must initially and subsequently be measured as the largest amount of tax benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the tax authority assuming full knowledge of the position and relevant facts. The Company s policy is to recognize any interest and penalties related to income taxes in income tax expense.

Revenue Recognition

The Company s revenues have been generated through collaboration and research and development agreements. These agreements include fees for development services provided to customers, payments for achievement of specified development, regulatory and sales milestones, and, to a lesser extent, upfront license payments, which comprise the Company s development and milestone revenue. The Company records any amounts received in advance of services performed as deferred revenue and recognizes the amount ratably over the period it is earned.

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Multiple Element Arrangements

For arrangements entered into with multiple elements, the Company evaluates whether the components of each arrangement are separate elements based on certain criteria. Accordingly, revenues from collaboration agreements are recognized based on the performance requirements of the agreements. The Company recognizes revenue when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the fee is fixed and determinable, and collection is reasonably assured.

Non-refundable license fees are recognized as revenue when the Company has a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured, and the Company has no further significant performance obligations in exchange for the license.

As of January 1, 2011, the Company accounts for its multiple element arrangements pursuant to Accounting Standard Codification (ASC) 605-25, *Revenue Recognition Multiple-Element Arrangements*. ASC 605-25 establishes a selling-price hierarchy for determining the selling price of each element within a multiple-deliverable arrangement. Specifically, the selling price assigned to each deliverable is to be based on vendor-specific objective evidence (VSOE) if available; third-party evidence, if VSOE is unavailable; and estimated selling prices if neither VSOE or third-party evidence is available.

Milestone Payments

Milestone payments have been recognized as revenue when the collaborative partner acknowledges completion of the milestone and substantive effort was necessary to achieve the milestone. The Company accounts for milestone payments pursuant to the guidance in ASC 605-28, *Revenue Recognition Milestone Method.* Under this guidance, management may recognize revenue contingent upon the achievement of a milestone in its entirety in the period in which the milestone is achieved only if the milestone meets all the criteria within the guidance to be considered substantive. Substantive milestone payments are recognized upon achievement of the milestone only if all of the following conditions are met:

- the milestone payments are non-refundable;

- achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement;

- substantive effort on the Company s part is involved in achieving the milestone;

- the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone; and

• a reasonable amount of time passes between the up-front license payment and the first milestone payment as well as between each subsequent milestone payment.

Determination as to whether a payment meets the aforementioned conditions involves management s judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone, and therefore the resulting payment would be considered part of the overall consideration for the work being performed. Accordingly, revenue would be recognized over the anticipated life of the agreement.

The Company s milestone revenues were approximately $0 and $750,000 for the three and nine months ended September 30, 2011 and $0 and $150,000 for the three and nine months ended September 30, 2012, respectively.

Research and Development Costs

Research and development expenditures are expensed as incurred. Research and development costs primarily consist of employee-related expenses, including salaries and benefits; expenses incurred under agreements with contract research organizations, investigative sites, and consultants that conduct the Company s clinical trials; the cost of acquiring and manufacturing clinical trial materials; the cost of manufacturing materials used in process validation, to the extent that those materials are manufactured prior to receiving regulatory approval for those products, facilities costs that do not have an alternative future use; related depreciation and other allocated expenses; license fees for and milestone payments related to in-licensed products and technologies; stock-based compensation expense; and costs associated with non-clinical activities and regulatory approvals.

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Stock-Based Compensation

Employee stock-based compensation is measured based on the estimated fair value on the grant date. The grant date fair value is calculated using the Black-Scholes option-pricing model, which requires the use of subjective assumptions including volatility, expected term, risk-free rate, and the fair value of the underlying common stock. For awards that vest based on service conditions, the Company recognizes expense using the straight-line method less estimated forfeitures. The Company has awarded non-vested stock. Subsequent to its IPO, the fair value of the Company s common stock is based on observable market prices. The Company recognizes the estimated fair value of stock options on a straight-line basis over the requisite service period as the awards vest, and the estimated fair value of compensation expense associated with ESPP awards over the contribution period.

For stock option grants and non-vested stock subject to performance-based milestone vesting, the Company records the expense over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates when the achievement of a performance-based milestone is probable based on the relative satisfaction of the performance conditions as of the applicable reporting date.

The Company records the expense for stock option grants to non-employees based on the estimated fair value of the stock option using the Black-Scholes option-pricing model. The fair value of non-employee awards is remeasured at each reporting period. As a result, stock compensation expense for non-employee awards with vesting is affected by changes in the fair value of the Company s common stock.

Warrant Liability

In January 2011, the Company entered into a secured credit facility pursuant to a loan and security agreement with certain lenders, which was subsequently amended in December 2011, providing for term loans of up to an aggregate of $30.0 million. In connection with the drawdown of $15.0 million under the secured credit facility on January 26, 2011, the Company issued to its lenders warrants to purchase an aggregate of 375,000 shares of the Company s Series A Preferred Stock at an exercise price of $1.00 per share. The warrants became exercisable immediately and expire on January 26, 2021. Upon completion of the Company s initial public offering on May 1, 2012, the lender warrants converted into warrants to purchase 93,750 shares of common stock at an exercise price of $4.00 per share. These warrants are recorded as a derivative liability and, as such, the Company reflects the warrant liability at fair value in the consolidated balance sheets. The fair value of this derivative liability is remeasured at the end of every reporting period and the change in fair value is reported in the consolidated statements of operations as other income (expense). As of December 31, 2011 and September 30, 2012, the fair value was estimated to be approximately $460,000 and $937,000, respectively. The change in fair value of approximately $477,000 has been recorded in other income (expense) in the Company s consolidated statements of operations for the nine months ended September 30, 2012.

In connection with the drawdown of the second $15.0 million under the secured credit facility on December 30, 2011, the Company issued to its lenders warrants to purchase an aggregate of 200,000 shares of the Company s Series A Preferred Stock at an exercise price of $1.50 per share. The warrants became exercisable immediately and expire on December 30, 2021. Upon completion of the Company s initial public offering on May 1, 2012, the warrants converted into warrants to purchase 49,999 shares of common stock at an exercise price of $5.00 per share. These warrants are recorded as a derivative liability and, as such, the Company reflects the warrant liability at fair value in the consolidated balance sheets. The fair value of this derivative liability is remeasured at the end of every reporting period and the change in fair value is reported in the consolidated statements of operations as other income (expense). As of December 31, 2011 and September 30, 2012, the fair value was estimated to be approximately $237,000 and $526,000, respectively. The change in fair value of approximately $289,000 has been recorded in other income (expense) in the Company s consolidated statements of operations for the nine months ended September 30, 2012.

The terms of the warrant agreements provide for down-round anti-dilution adjustment for the warrants in certain situations whereby the Company sells or issues (a) shares at a price per share less than the exercise price of the warrants, or (b) equity-linked financial instruments with strike prices less than the exercise price of the warrants. As a result of this down round provision, the warrants continue to be classified as derivative liability.

Prior to completion of the Company s IPO, the fair value of the preferred stock warrants was estimated in accordance with the guidance outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (the Technical Practice Aid). Several objective and subjective factors were considered when valuing each equity security and related warrant at a valuation date. The Company utilized the probability weighted expected return method, PWERM , to estimate the fair value of the preferred stock warrants. Under the PWERM, the value of each equity security and warrant was estimated based upon an analysis of future values for the entire equity instrument assuming various future outcomes. Share value was based upon the probability-weighted present value of the expected outcomes, as well as the rights of each class of preferred and common stock. A probability was estimated for each possible event based on the facts and circumstances as of the valuation date.

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Subsequent to the completion of the Company s IPO, which occurred on May 1, 2012, the fair value of the common stock warrants is determined using a Black-Scholes model within a Monte-Carlo framework. The Monte-Carlo simulation is a generally accepted statistical method used to estimate fair value based on the application of subjective assumptions, consistently applied for each period, including the probability, timing and magnitude of our issuance of additional common stock in future financings. This valuation is computed at the end of each fiscal quarter to reflect conditions at each valuation date until the warrants are exercised or they expire. In addition to assumptions regarding future equity financings, consideration is also given to the current stock price, anticipated stock volatility going forward, and the anti-dilution provisions embedded in the warrant agreements. In October 2012, 101,667 of these warrants were exercised (See Footnote 8).

Loss Per Share

Basic loss per common share is determined by dividing loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted earnings per share is computed by dividing the earnings attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period. The treasury stock method is used to determine the dilutive effect of the Company s stock option grants, warrants and potential employee stock purchase plans (ESPP) and the if-converted method is used to determine the dilutive effect of the Company s Series A Preferred Stock. The weighted-average shares used to calculate both basic and diluted loss per share are the same. The following common stock equivalents were excluded in the calculation of diluted loss per share because their effect would be anti-dilutive:

	Three months ended September 30,		Nine months ended September 30,	
	2011	2012	2011	2012
Series A Preferred Stock	12,249,998		12,249,998	5,409,671
Warrants Outstanding	20,364	91,184	26,227	71,662
Stock Options, Non-vested Stock Options and ESPP awards	404,856	346,783	429,442	290,029

4. Property and Equipment

Property and equipment consists of the following (in thousands):

	December 31, 2011	September 30, 2012 (unaudited)
Computer equipment	$ 586	$ 604
Software	209	209
Lab equipment and furniture	3,465	3,707
Leasehold improvements	1,486	1,778
	5,746	6,298
Less accumulated depreciation and amortization	(4,436)	(4,914)
	$ 1,310	$ 1,384

Depreciation expense on property and equipment was $167,000 and $479,000 for the three and nine months ended September 30, 2011 and $154,000 and $478,000 for the three and nine months ended September 30, 2012, respectively.

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5. Purchased Patents

The Company acquired certain patents in 2005. The following sets forth the gross carrying amount and related accumulated amortization of the patents (in thousands):

		December 31, 2011		September 30, 2012 (unaudited)	
	Weighted-Average Life	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
		(in thousands)			
Purchased Patents	10.0	$ 2,292	$ 1,380	$ 2,292	1,552

Amortization expense was approximately $57,000 for the three months ended September 30, 2011 and 2012 and was approximately $172,000 for the nine months ended September 30, 2011 and 2012. The net book value of intangible assets as of December 31, 2011 and September 30, 2012 was approximately $0.9 million and $0.7 million, respectively.

6. Notes Payable