INFINITY PHARMACEUTICALS, INC.
Form 10-Q
May 06, 2015
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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 March 31, 2015

OR

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

For the transition period from to .

Commission file number 000-31141

INFINITY PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**33-0655706**
(State or other jurisdiction of	**(I.R.S. Employer**
incorporation or organization)	**Identification No.)**

784 Memorial Drive, Cambridge, Massachusetts 02139

(Address of principal executive offices) (zip code)

(617) 453-1000

(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 x 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 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 the definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer x	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 x

Number of shares of the registrant s Common Stock, $0.001 par value, outstanding on April 30, 2015: 49,042,486

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INFINITY PHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2015

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PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Financial Statements

INFINITY PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands, except share and per share amounts)

	March 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 223,045	$ 307,405
Available-for-sale securities	10,008	25,321
Loan commitment asset, net (note 9)		647
Prepaid expenses and other current assets	6,317	11,195
Total current assets	239,370	344,568
Property and equipment, net	22,720	18,970
Long-term available-for-sale securities	508	519
Restricted cash	1,680	1,680
Long-term receivable (note 11)	3,006	3,006
Other assets	358	401
Total assets	$ 267,642	$ 369,144
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 5,697	$ 5,947
Accrued expenses	12,564	17,768
Due to Takeda, current		6,667
Deferred revenue, current	26,060	24,495
Total current liabilities	44,321	54,877
Deferred revenue, less current portion	79,581	85,510
Deferred rent (note 11)	4,082	3,375
Construction liability (note 11)	18,082	15,456
Other liabilities	497	454
Total liabilities	146,563	159,672
Commitments and contingencies		
Stockholders equity:		

Preferred Stock, $0.001 par value; 1,000,000 shares authorized, no shares issued and outstanding at March 31, 2015 and December 31, 2014				
Common Stock, $0.001 par value; 100,000,000 shares authorized, and 49,028,780 and 48,878,828 shares issued and outstanding, at March 31, 2015 and December 31, 2014, respectively		49		49
Additional paid-in capital		681,434		676,521
Accumulated deficit		(560,514)		(467,212)
Accumulated other comprehensive income		110		114
Total stockholders equity		121,079		209,472
Total liabilities and stockholders equity	$	267,642	$	369,144

The accompanying notes are an integral part of these unaudited, condensed consolidated financial statements.

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INFINITY PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014
Collaboration revenue	$ 4,363	$
Operating expenses:		
Research and development	88,428	34,491
General and administrative	8,550	6,804
Total operating expenses	96,978	41,295
Loss from operations	(92,615)	(41,295)
Other income (expense):		
Interest expense	(647)	(1,139)
Investment and other income (loss)	(40)	168
Total other income (expense)	(687)	(971)
Net loss	$ (93,302)	$ (42,266)
Basic and diluted loss per common share	$ (1.91)	$ (0.87)
Basic and diluted weighted average number of common shares outstanding	48,939,383	48,348,767
Other comprehensive income (loss):		
Net unrealized holding losses on available-for-sale securities arising during the period	(4)	(1)
Comprehensive loss	$ (93,306)	$ (42,267)

The accompanying notes are an integral part of these unaudited, condensed consolidated financial statements.

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INFINITY PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows

(unaudited)

(in thousands)

	Three Months Ended March 31, 2015	2014
Operating activities		
Net loss	$ (93,302)	$ (42,266)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	354	468
Stock-based compensation including 401(k) match	3,751	3,744
Net amortization of premium/discount on available-for-sale securities	72	592
Non-cash interest expense on Due to Takeda amount		52
Amortization of loan commitment asset	647	1,139
Other, net	1	(30)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	4,921	(1,050)
Accounts payable, accrued expenses and other liabilities	(5,778)	463
Due to Takeda	(6,667)	(6,667)
Deferred revenue	(4,364)	
Deferred rent	707	
Net cash used in operating activities	(99,658)	(43,555)
Investing activities		
Purchases of property and equipment	(1,112)	(176)
Purchases of available-for-sale securities		(12,536)
Proceeds from maturities of available-for-sale securities	15,248	41,172
Net cash provided by investing activities	14,136	28,460
Financing activities		
Proceeds from issuances of common stock related to stock incentive plans	1,162	1,952
Net cash provided by financing activities	1,162	1,952
Net decrease in cash and cash equivalents	(84,360)	(13,143)
Cash and cash equivalents at beginning of period	307,405	68,114
Cash and cash equivalents at end of period	$ 223,045	$ 54,971
Supplemental schedule of noncash investing and financing activities		
Loan commitment asset	$	$ 11,350
Facility fee	$	$ 3,000

Fixed assets in accrued expenses	$	367	$	
Increase in construction liability and CIP for amount paid by landlord	$	2,626	$	
Warrants issued	$		$	8,350

The accompanying notes are an integral part of these unaudited, condensed consolidated financial statements.

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Infinity Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Organization

Infinity Pharmaceuticals, Inc. is an innovative biopharmaceutical company dedicated to discovering, developing and delivering best-in-class medicines to patients with difficult-to-treat diseases. As used throughout these unaudited, condensed consolidated financial statements, the terms Infinity, we, us, and our refer to the business of Infinity Pharmaceuticals, Inc. and its wholly-owned subsidiaries.

2. Basis of Presentation

These condensed consolidated financial statements include the accounts of Infinity and its wholly-owned subsidiaries. We have eliminated all significant intercompany accounts and transactions in consolidation.

The accompanying condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accruals and revisions of estimates, considered necessary for a fair presentation of the accompanying condensed consolidated financial statements have been included. Interim results for the three months ended March 31, 2015 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2015.

The information presented in the condensed consolidated financial statements and related footnotes at March 31, 2015, and for the three months ended March 31, 2015 and 2014, is unaudited, and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2014 have been derived from our audited financial statements. For further information, please refer to the consolidated financial statements and accompanying footnotes included in our annual report on Form 10-K for the fiscal year ended December 31, 2014, which was filed with the U.S. Securities and Exchange Commission on February 24, 2015.

3. Significant Accounting Policies

Cash Equivalents and Available-For-Sale Securities

Cash equivalents and available-for-sale securities primarily consist of money market funds, U.S. government-sponsored enterprise obligations, corporate obligations and mortgage-backed securities. Corporate obligations include obligations issued by corporations in countries other than the United States, including some obligations that have not been guaranteed by governments or government agencies. We consider all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents. Cash equivalents, which consist of money market funds and corporate obligations, are stated at fair value. They are also readily convertible to known amounts of cash and have such short-term maturities that each presents insignificant risk of change in value due to changes in interest rates. Our classification of cash equivalents is consistent with prior periods.

We determine the appropriate classification of marketable securities at the time of purchase and reevaluate such designation at each balance sheet date. We have classified all of our marketable securities at March 31, 2015 and December 31, 2014 as available-for-sale. We carry available-for-sale securities at fair value, with the unrealized gains and losses reported in accumulated other comprehensive income, which is a separate component of stockholders equity.

We adjust the cost of available-for-sale debt securities for amortization of premiums and accretion of discounts to maturity. We include such amortization and accretion in investment and other income. The cost of securities sold is based on the specific identification method. We include in investment and other income interest and dividends on securities classified as available-for-sale.

We conduct periodic reviews to identify and evaluate each investment that is in an unrealized loss position to determine whether an other-than-temporary impairment exists. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. Unrealized losses on available-for-sale debt securities that are determined to be temporary, and not related to credit loss, are recorded, net of tax, in accumulated other comprehensive income.

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For available-for-sale debt securities in an unrealized loss position, we perform an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security, or may be required to do so, the security s decline in fair value is deemed to be other-than-temporary, and the full amount of the unrealized loss is recorded within earnings as an impairment loss.

Regardless of our intent to sell a security, we perform additional analysis on all securities in an unrealized loss position to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where we do not expect to receive cash flows sufficient to recover the amortized cost basis of a security and are recorded within earnings as an impairment loss.

Segment Information

We operate in one business segment, which focuses on drug discovery and development. We make operating decisions based upon performance of the enterprise as a whole and utilize our consolidated financial statements for decision making.

All of our revenues to date have been generated under research collaboration agreements.

Basic and Diluted Net Loss per Common Share

Basic net loss per share is based upon the weighted average number of common shares outstanding during the period. Diluted net loss per share is based upon the weighted average number of common shares outstanding during the period plus the effect of additional weighted average common equivalent shares outstanding during the period when the effect of adding such shares is dilutive. Common equivalent shares result from the assumed exercise of outstanding stock options (the proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method) and the exercise of outstanding warrants (the proceeds of which have not been used for repurchases under the treasury stock method). In addition, the assumed proceeds under the treasury stock method include the average unrecognized compensation expense of stock options that are in-the-money. This results in the assumed buyback of additional shares, thereby reducing the dilutive impact of stock options. Common equivalent shares have not been included in the net loss per share calculations for the periods presented because the effect of including them would have been anti-dilutive. Total potential gross common equivalent shares consisted of the following:

	At March 31,	
	2015	**2014**
Stock options	8,039,498	6,772,555
Warrants	1,000,000	1,000,000

Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income (loss). Other comprehensive income (loss) is comprised of unrealized holding gains and losses arising during the period on available-for-sale securities that are not other-than-temporarily impaired. During the three months ended March 31, 2015, there were no reclassifications out of accumulated other comprehensive income (loss).

Stock-Based Compensation Expense

For awards granted to employees and directors, including awards under our Employee Stock Purchase Plan, or ESPP, we measure stock-based compensation cost at the grant date based on the estimated fair value of the award and recognize it as expense over the requisite service period on a straight-line basis. We record the expense of services rendered by non-employees based on the estimated fair value of the stock option as of the respective vesting date. We use the Black-Scholes valuation model in determining the fair value of all equity awards. For awards with performance conditions, we estimate the likelihood of satisfaction of the performance conditions, which affects the period over which the expense is recognized, and recognize the expense over the requisite service period on a straight-line basis. We have no awards with market conditions.

Revenue Recognition

To date, all of our revenue has been generated under research collaboration agreements. The terms of these research collaboration agreements may include payment to us of non-refundable, upfront license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. We evaluate all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. Based on this evaluation, the deliverables are separated into units of accounting. For each unit of accounting identified within an arrangement, we determine the period over which the performance obligation occurs. Revenue is then recognized using the proportional performance method. The proportional performance method is used when the level of effort to complete the performance obligations under an arrangement can be reasonably estimated. We recognize revenue based upon our best estimate of the selling price for each element when there is no other means to determine the fair value of that item and allocate the consideration based on the relative values. The process for determining the best estimate of the selling price involves significant judgment and estimates.

At the inception of each agreement that includes milestone payments, we evaluate whether each milestone is substantive on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether:

- the consideration is commensurate with either (1) our performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from our performance to achieve the milestone,
- the consideration relates solely to past performance, and
- the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

In making this assessment, we evaluate factors such as the clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required, and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement. We recognize revenues related to substantive milestones in full in the period in which the substantive milestone is achieved. If a milestone payment is not considered substantive, we recognize the applicable milestone over the remaining period of performance.

We will recognize royalty revenue, if any, based upon actual and estimated net sales by the licensee of licensed products in licensed territories, and in the period the sales occur. We have not recognized any royalty revenue to date.

Research and Development Expense

Research and development expense consists of expenses incurred in performing research and development activities, including salaries and benefits, overhead expenses including facilities expenses, materials and supplies, preclinical expenses, clinical trial and related clinical manufacturing expenses, comparator drug expenses, stock-based compensation expense, depreciation of equipment, contract services, and other outside expenses. We also include as research and development expense upfront license payments related to acquired technologies which have not yet reached technological feasibility and have no alternative use. We expense research and development costs as they are incurred. Prepaid comparator drug expenses are capitalized and then recognized as expense when title transfers to us. We have been a party to collaboration agreements in which we were reimbursed for work performed on behalf of the collaborator, as well as one in which we reimbursed the collaborator for work it had performed. We record all appropriate expenses under our collaborations as research and development expense. If the arrangement provides for reimbursement of research and development expenses incurred by us, we evaluate the terms of the arrangement to determine whether the reimbursement should be recorded as revenue or as an offset to research and development expense. If the arrangement provides for us to reimburse the collaborator for research and development expenses or for the achievement of a development milestone for which a payment is due, we record the reimbursement or the achievement of the development milestone as research and development expense.

Income Taxes

We use the liability method to account for income taxes. Deferred tax assets and liabilities are determined based on temporary differences between financial reporting and income tax basis of assets and liabilities, as well as net operating loss and tax credit carryforwards, and are measured using the enacted tax rates and laws that will be in effect when the differences reverse. Deferred tax assets are reduced by a valuation allowance to reflect the uncertainty associated with their ultimate realization. The effect of a change in tax rate on deferred taxes is recognized in income or loss in the period that includes the enactment date.

We use our judgment for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. We recognize any material interest and penalties related to unrecognized tax benefits in income tax expense.

Due to the uncertainty surrounding the realization of the net deferred tax assets in future periods, we have recorded a full valuation allowance against our otherwise recognizable net deferred tax assets as of March 31, 2015 and December 31, 2014.

Fair Value Measurements

We define fair value 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. We determine fair value based on the assumptions market participants use when pricing the asset or liability. We also use the fair value hierarchy that prioritizes the information used to develop these assumptions.

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We value our available-for-sale securities utilizing third party pricing services. The pricing services use many observable market inputs to determine value, including benchmark yields, reportable trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers, reference data, new issue data, monthly payment information and collateral performance. We validate the prices provided by our third party pricing services by understanding the models used, obtaining market values from other pricing sources, and confirming that those securities trade in active markets.

Property and Equipment

Property and equipment are stated at cost. Depreciation is recorded using the straight-line method over the estimated useful lives of the applicable assets. Assets included in construction-in-progress are not depreciated until placed into service. Application development costs incurred for computer software developed or obtained for internal use are capitalized. Upon sale or retirement, the cost and related accumulated depreciation are eliminated from the respective account, and the resulting gain or loss, if any, is included in current operations. Amortization of leasehold improvements and capital leases is recorded as depreciation expense and included in research and development and general and administrative expense, as applicable. Repairs and maintenance charges that do not increase the useful life of the assets are charged to operations as incurred. Property and equipment are depreciated over the following periods:

Laboratory equipment	5 years
Computer equipment and software	3 to 5 years
Leasehold improvements	Shorter of lease term or useful life of asset
Furniture and fixtures	7 years

4. Stock-Based Compensation

Total stock-based compensation expense related to all equity awards for the three months ended March 31, 2015 and 2014 comprised the following:

	Three Months Ended March 31, 2015	**Three Months Ended March 31, 2014**
	(in thousands)	
Effect of stock-based compensation on net loss by line item:		
Research and development	$ 2,235	$ 2,205
General and administrative	1,515	1,539

As of March 31, 2015, we had approximately $26.7 million of total unrecognized compensation cost, net of estimated forfeitures, related to unvested stock options and awards under our ESPP, which are expected to be recognized over a weighted-average period of 2.7 years.

During the three months ended March 31, 2014, two members of our board of directors retired and were granted the right to exercise their vested stock options for an additional six-month period. In addition, one employee whose employment terminated received an accelerated vesting of his unvested options. In connection with these modifications, we recognized an additional $0.4 million in stock-based compensation expense during the three months ended March 31, 2014.

Stock Options

During the three months ended March 31, 2015, we granted options to purchase 1,643,841 shares of our common stock at a weighted average fair value of $9.43 and a weighted average exercise price of $15.56. During the three months ended March 31, 2014, we granted options to purchase 1,152,884 shares of our common stock at a weighted average fair value of $7.79 and a weighted average exercise price of $13.13. For the three months ended March 31, 2015 and 2014, the fair values were estimated using the Black-Scholes valuation model using the following weighted-average assumptions:

	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014
Risk-free interest rate	1.4%	1.7%
Expected annual dividend yield		
Expected stock price volatility	71.5%	71.1%
Expected term of options	5.4 years	5.1 years

During the three months ended March 31, 2015, options to purchase 138,310 shares of common stock were exercised, with a weighted-average exercise price of $8.40.

Employee Stock Purchase Plan

The weighted-average fair value of each purchase right granted during the three months ended March 31, 2015 and 2014 was $7.62 and $6.33, respectively. For the three months ended March 31, 2015 and 2014, the fair values were estimated using the Black-Scholes valuation model using the following weighted-average assumptions:

	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014
Risk-free interest rate	0.4%	0.2%
Expected annual dividend yield		
Expected stock price volatility	70.3%	75.21%
Expected term of options	1.2 years	1.2 years

5. Cash, Cash Equivalents and Available-for-Sale Securities

The following is a summary of cash, cash equivalents and available-for-sale securities:

	March 31, 2015			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
Cash and cash equivalents due in 90 days or less	$ 223,045	$	$	$ 223,045
Available-for-sale securities:				
Corporate obligations due in one year or less	10,009		(1)	10,008
Mortgage-backed securities due after ten years	397	111		508
Total available-for-sale securities	10,406	111	(1)	10,516
Total cash, cash equivalents and available-for-sale securities	$ 233,451	$ 111	$ (1)	$ 233,561